8 July 2022
EMA/285848/2020
Information Management

Product Management Service (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe

Chapter 2: Data elements for the electronic submission of information on medicinal products for human use

Version 2.1.1.

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Table of contents

Summary of changes

Following the publication of version 2.1 in June 2021, the content of this document was amended to contain the following changes:

- General updates to improve the quality of the user guidance;
- Reference newly created RMS lists and updated existing lists to support PMS data entry;
- Contain updated technical information on conformance, data type, value, conformance, ISO/FHIR elements name/paths and FHIR Complementary Information across the guidance, where applicable;
- Contain updated information in Annex II - Common/European Union (EU) and national data set to be in alignment with the contents of the relevant Chapter 2;
- Include new paragraph Submission of information on medicinal products with valid marketing authorisation in the territory of Northern Ireland
- The below listed sections now include updated information:
  - Identifiers and defining characteristics of a medicinal product entry in PMS
  - Product Management Service Identifier (PMS ID),
  - Medicinal Product Identifier (MPID)
  - Relationship between PMS ID and ISO IDMP standard 11615 Medicinal Product Identifier (MPID) and Packaged Medicinal Product Identifier (PCID)
  - User guidance
  - Reason
  - 1.2. Medicinal Product Identifier (MPID)
  - 1.3. Domain
  - 1.4. Type
  - 1.5. (Authorised) pharmaceutical form
  - 1.6. Combined pharmaceutical dose form
  - 1.7. Legal status of supply
  - 1.9.1. Regulatory authorisation type
  - 1.9.2. Orphan designation status
  - 1.9.3. Orphan designation number
  - 1.9.4. Orphan designation status date
  - 1.9.5. Market exclusivity start date
  - 1.10. Paediatric use indicator
  - 1.11.1. Language
  - 1.13. Product classification
  - 1.13.1. xEVMPD product type information

- 1.13.2. 1.10. Legal basis
- 1.13.3. ATC code(s)
- 1.13.4. Medicinal product category
- 1.13.5. Genetically Modified Organisms (GMOs)
- 1.14. Medicinal product name
- 1.14.2. Country/Language
- 1.14.2.1. Country
- 1.14.2.2. Language
- 1.14.3.1. Name part type
- 1.14.3.2. Name part text
- 1.15.1. File type
- 1.15.2. File code
- 1.16.2. Role
- 1.17.1. Email address
- 1.17.3. Role
- 1.18. Attached document
- 1.18.1. Master (Attached document) Identifier
- 1.18.1.1. Identifier value
- 1.18.1.2. Identifier system
- 1.18.2.1. Identifier value
- 1.18.2.2. Identifier system
- 1.18.3. (Attached document) Type
- 1.18.4. (Attached document) Effective Date
- 1.18.5. (Attached document) Language
- 1.19.1. Product cross-reference type
- 1.19.2. Product cross-reference resource identifier
- 1.20.1. Manufacturer
- 1.20.2. Operation type
- 1.20.3. Manufacturing operation start date
- 1.20.4. Manufacturing operation end date
- 1.20.5. Confidentiality indicator
- 1.20.6. Manufacturing authorisation reference number
- 1.20.7. Effective date

- 1.20.8. (Manufacturing business operation) Medicines Regulatory Agency Organisation
- 2.1. Regulatory authorisation type
- 2.3. Country
- 2.4. Authorisation status
- 2.9. (Marketing authorisation) Regulator
- 2.10.2. Procedure type – Medicines approval system
- 2.10.5.2. Regulatory application type
- 3.1. Indication as "Disease/Symptom/Procedure"
- 3.2. Co-morbidity
- 3.3. Intended effect
- 4.2.1. Language
- 4.4. Pack size
- 4.5. Legal status of supply
- 4.6.1. Country
- 4.6.2. Marketing status
- 4.6.5. Risk of supply shortage
- 4.6.7.1. Reason
- 4.7.1. Regulatory authorisation type
- 4.7.3. Country
- 4.7.4. Authorisation status
- 4.8. Package item (container)
- 4.8.1. Package item (container) type
- 4.8.5. Package item (container) quantity
- 4.8.6. Data carrier identifier
- 4.8.7. Material
- 4.9. Package (component)
- 4.9.1. Component type
- 4.9.2. Component material
- 4.10. Medical device
- 4.10.1. Type of medical device used in combination with medicinal product
- 4.10.2. Medical device type
- 4.10.3. Medical device identification
- 4.10.4. Medical device trade name

- 4.10.5. Medical device quantity
- 4.11.1. Unit of presentation
- 4.11.2. Manufactured item quantity
- 4.11.3. Manufactured dose form
- 4.11.5. Manufactured item description
- 4.11.5.1. Language
- 4.12. Shelf life / Storage
- 4.12.1. Shelf life type
- 4.12.2. Shelf life time period and units
- 4.12.3. Special precautions for storage
- 5.1. Ingredient role
- 5.2. Origin of the substance
- 5.4. Manufacturer
- 5.5. Substance
- 5.5.1. Substance
- 5.5.2. Substance strength (quantitative composition)
- 5.5.2.2. Strength (presentation)
- 5.5.2.2.1. Quantity operator
- 5.5.2.2.2. Strength (presentation single value or low limit)
- 5.5.2.2.3. Strength (presentation high limit)
- 5.5.2.3. Strength (concentration)
- 5.5.2.3.1. Quantity operator
- 5.5.2.3.2. Strength (concentration single value or low limit)
- 5.5.2.3.3. Strength (concentration high limit)
- 5.5.3. Substance reference strength (quantitative composition)
- 5.5.3.1. Reference substance
- 5.5.3.2. Quantity operator
- 5.5.3.3. Reference strength (Presentation)
- 5.5.3.3.1. Quantity operator
- 5.5.3.3.2. Reference strength (Presentation single value or low limit)
- 5.5.3.3.3. Reference strength (Presentation high limit)
- 5.5.3.4. Reference strength (Concentration)
- 5.5.3.4.1. Quantity operator

  - 5.5.3.4.2. Reference strength (Concentration single value or low limit)
  - 5.5.4.1. File type
  - 5.5.4.2.1. File identifier type
  - 5.5.4.2.2. File Identifier
  - 5.5.4.3. Submission date
  - 5.5.4.4. Date of last update
  - 5.5.4.5. Manufacturer
  - 6.1. Pharmaceutical product description
  - 6.1.1. Language
  - 6.2. Administrable dose form
  - 6.3. Unit of presentation
  - 6.5. Device
  - 6.6. Route of administration
  - 8. Annex II - Common/European Union (EU) and national data set
- The below listed sections were inserted as new:
  - 1.18.6. URL value (New)
  - 1.18.7. (Attached document) Status (New)
  - 4.3. Manufacturer (New)
  - 4.8.5.1. Quantity operator (New)
  - 4.8.6.1. Identifier value (New)
  - 4.8.6.2. Identifier system (New)
  - 4.10.5.1. Quantity operator (New)
  - 4.10.6. Medical device description (New)
  - 4.10.6.1. Language (New)
  - 4.10.7. Medical device description of intended purpose (New)
  - 4.10.7.1. Language (New)
  - 4.10.8. Medical device classification (New)
  - 4.10.9. Medical device manufacturer (New)
  - 4.11.2.1. Quantity operator (New)

Glossary

ASMF: Active Substance Master File

ATC code: Anatomical Therapeutic Chemical code

ATMP: Advanced therapy medicinal product

CAPs: Centralised Authorised Products.

CE: Certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA)

CEP: Certificate of Suitability

DCP: Decentralised procedure

eAF: electronic Application Form

EC: European Commission

EEA: European Economic Area

EMA: European Medicines Agency

EMEA: European Medicines Evaluation Agency

EMVS: European Medicines Verification System

EU: European Union

EUDAMED: European database on medical devices

EURD: The European Union reference dates (EURD)

FHIR: Fast Healthcare Interoperability Resources

GMO: genetically modified organism

GMP: Good distribution-practice certificates

HMA: Heads of Medicines Agencies

IBD: International birth date

ID: Identifier

IDMP: Identification of Medicinal Products

IG: Implementation guide

IS/LI/NO: Iceland, Liechtenstein, Norway

ISO: International Organization for Standardization

LOC ID: Location Identity

MA: Marketing Authorisation

MAA: Marketing Authorisation Application

MAH: Marketing Authorisation Holder

MFL EV: Master File Location EudraVigilance

MPID: Medicinal Product Identifier

MRP: Mutual recognition procedure

NAPs: Nationally Authorised Products

NCA: National competent authority

OMS: Organisations Management Service

ORG ID: Organisation identity

PCID: Packaged Medicinal Product Identifier

PL: Package leaflet

PMF: Plasma Master File

PMS: Product Management Service

PSMF: Pharmacovigilance system master file

PSURs: Periodic Safety Update reports.

PSUSA Periodic Safety Update Report (PSUR) single assessment (PSUSA)

RMS: Referentials Management Service

SMS: Substance Management Service (SMS)

SPOR: Substances Products Organisations Referentials

TSEs: transmissible Spongiform Encephalopathies

VAMF: Vaccine Antigen Master File

XEVMPD: eXtended EudraVigilance medicinal product dictionary (XEVMPD)

XEVPRM: Extended EudraVigilance Medicinal Product Report Message

Scope of this guidance

This document provides detailed guidance on the data elements and associated business rules applicable to:

- the **submission of information of authorised medicinal products** for **human use**;[1]
- the **maintenance of authorised medicinal product data** previously submitted.

to the Product Management Service (PMS) only in accordance with the International Organisation for Standardisation (ISO), Identification of Medicinal Products (IDMP).

ISO IDMP standards specify the use of standardised definitions for the identification and description of medicinal products for human use.

ISO IDMP distinguishes between Authorised Medicinal Product and Investigational Medicinal Product. This guidance covers only aspects relevant to the Authorised medicinal product parts of the standard. The use of ISO IDMP is required in accordance with Articles 25 and 26 of Commission Implementing Regulation (EU) No 520/2012. These provisions mandate Member States, marketing authorisation holders and the European Medicines Agency (EMA) to use ISO IDMP standards for the exchange and communication of information on medicinal products.

Medicinal products in scope

This guidance applies to all authorised products that fall under the scope of Article 57(2) of Regulation (EC) No 726/2004, as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012, which mandates marketing authorisation holders to submit and maintain product information electronically on all authorised medicinal products for human use.

Medicinal products falling out of scope of Article 57(2) of Regulation (EC) No 726/2004 legal obligations include:

- investigational medicinal products;
- products for which the marketing authorisation is not valid;
- traditional use registration for herbal medicinal products (Article 16a of Directive 2001/83/EC);
- simplified registration for homeopathic medicinal products (Article 14 of Directive 2001/83/EC);
- medicinal products within the scope of Article 5 of Directive 2001/83/EC i.e., 'Named patient use' falling under Article 5(1) and 'EU Distribution Procedure' under Article 5(2);
- parallel distribution/parallel import of medicinal products (Article 76(3) and (4) of Directive 2001/83/EC);
- medicinal products authorised outside the European Economic Area (EEA) or following a non-EU procedure;
- extemporaneous Medicinal products (e.g., medicinal products prepared in a pharmacy based on a medical prescription such as pharmacy preparations);
- intermediate products intended for subsequent processing by an authorised manufacturer.

[1] The term "Authorised" refers to concept of authorized and registered medicinal products as defined in ISO IDMP.

Medicinal products falling out of scope of Article 57(2) of Regulation (EC) No 726/2004 legal obligation may be submitted on a voluntary basis in line with the requirements and business processes described in this guidance (as applicable).

Note: EU IG V2.0 focuses primarily on the authorised products that fall under the scope of Article 57(2) of Regulation (EC) No 726/2004. While investigational medicinal products will not be addressed in PMS iteration 1, it is expected that EU IG V3 will further elaborate the specifications and business rules for the Medicinal products falling out of scope of Article 57(2) of Regulation (EC) No 726/2004 as needed.

Submission of medicinal products authorised in EEA countries outside the EU

In general, Iceland, Liechtenstein and Norway have, through the EEA agreement, adopted the complete Union acquis on medicinal products and are consequently applying the EU rules governing marketing authorisation procedures (i.e., national, centralised, decentralised and mutual recognition procedures). However, the Commission's decisions (including decisions granting marketing authorisations) do not directly confer rights and obligations to holders of a marketing authorisation in these countries. The marketing authorisations granted by the European Commission must be transposed by the competent authorities of Iceland, Liechtenstein and Norway through corresponding decisions based on relevant national laws. In such cases marketing authorisations granted in Iceland, Liechtenstein and Norway are legally separate from the Commission's decision when granting an MA.

Therefore, separate entries for the marketing authorisations granted in Iceland, Liechtenstein and Norway should be submitted in PMS under Article 57(2) requirements of Regulation (EC) No. 726/2004.

For medicinal products authorised in Liechtenstein, Norway and Iceland through the centralised procedure the applicable country code (i.e., LI/NO/IS) shall be specified.

Submission of information on medicinal products with valid marketing authorisation in the territory of Northern Ireland

Medicinal products authorised nationally in the UK (e.g., via the national, MRP or DCP procedure) with valid marketing authorisation in the territory of Norther Ireland, and that are to be sold in Northern Ireland under the Northern Ireland protocol, must be registered in PMS as they were in the XEVMPD. Such products are in scope of Article 57(2) legal obligations.

- The country of authorisation of such medicinal product must reference 'United Kingdom (Northern Ireland) (XI)' as the country of authorisation.
- EU authorisation procedure value must be referenced (e.g., national, decentralised, MRP etc.).

In accordance with the Protocol on Ireland/Northern Ireland, marketing authorisations granted via the **centralised procedure** will continue to be valid in the territory of Northern Ireland. Therefore, no separate AMP entry needs to be created for a medicinal product with a marketing authorisation granted via the centralised procedure and valid in the territory of Northern Ireland.

Submission of medicinal products authorised under mutual recognition or decentralised procedure in Liechtenstein

It is clarified in the Notice to Applicants (Volume 2A, Chapter 1) that on the basis of a bilateral agreement between **Liechtenstein** and **Austria** automatic recognition of the Marketing Authorisations granted in Mutual Recognition Procedure (MRP) or Decentralised Procedure (DCP) is operational. This

allows Liechtenstein to use Marketing Authorisations granted by Austria if the applicants have identified Liechtenstein as CMS in the application form submitted with MRP or DCP applications. At the end of the procedures, Austria grants authorisations that are recognised by Liechtenstein. This marketing authorisation can be considered as a marketing authorisation granted in accordance with the pharmaceutical acquis for the purpose of EU legislation.

Therefore, the marketing authorisation of these products must fulfil requirements provided for in, inter alia, Regulation (EU) 726/2004 and Directive 2001/83/EC.

- The attachment to be used for reference in a medicinal product entity is an Austrian SmPC.
- The information shall however be provided in German.

Marketing authorisations granted by the Swiss authorities and recognised by Liechtenstein

In the Notice to Applicants (Volume 2A, Chapter 1) it is also clarified that based on a bilateral agreement between **Liechtenstein** and **Switzerland**, a Swiss marketing authorisation is effective in Liechtenstein. This recognition has no effect outside the customs union between Switzerland and Liechtenstein. Consequently, a marketing authorisation granted by the Swiss authorities and recognised by Liechtenstein, while Switzerland does not apply the EU pharmaceutical *acquis*, cannot be considered as a marketing authorisation granted in accordance with the pharmaceutical *acquis* for the purpose of EU legislation and therefore falls outside the scope of, *inter alia*, Regulation (EU) 726/2004 and Directive 2001/83/EC.

Therefore, marketing authorisations granted by the Swiss authorities and recognised by Liechtenstein fall out of scope of Article 57(2) requirements and do not therefore need to be submitted to PMS.

Submission of medicinal product data using FHIR

Medicinal product data shall be submitted to the Product Management System (PMS) using the FHIR message format. The data elements for medicinal products presented in this guidance are based on the following reference information:

- Summary of Product Characteristics (SmPC);
- Module 1.2 – Electronic Application form (eAF);
- relevant sections in Module 3 – Quality;
- medicinal product authorisation information (as referred to in the Legal Notice on the Implementation of Article 57(2) of Regulation (EC) No. 726/2004 published by the Agency);
- pharmacovigilance information (as referred to in the Legal Notice on the Implementation of Article 57(2) of Regulation (EC) No. 726/2004 published by the Agency).

Additional information on the process for submission can be found in *EU IG Chapter 3 - Process for the electronic submission of medicinal product information*.

The contents of each document [i.e., Module 1.2 – Electronic Application form (eAF), relevant sections in Module 3 – Quality, Summary of Product Characteristics (SmPC)] supporting the regulatory process shall be aligned, where applicable, to ensure the discrepancies between the documents are minimized. The content should enhance the quality of the product data reported in PMS. This requirement applies to new medicinal products single entry in PMS.

Based on the above principle, the SmPC as authorized/to be authorized is the main referring document for data entry purposes.

However, for medicinal product entry already available in PMS (existing product data), following the data load according to **Chapter 7 - Migration guide**, whenever the common contents of each of the above supporting documentation are not aligned, the information available in the relevant sections in Module 3 can be used to harmonize the values in PMS. This requirement applies provided data confidentiality is ensured and if no additional complexity is added to the data entry in PMS. For additional information, refer to section 1.3.1 of EU IG Chapter 8 – Practical example.

Note: Further information referring to existing product data will be made available in the ***EU IG Chapter 9 - Process for submitting existing data on medicinal products authorised for human use***. This chapter is under development, and it will be made available at later stage.

Identifiers and defining characteristics of a medicinal product entry in PMS

A medicinal product single entry in Product Management Service (PMS) is determined by the first regulatory application to the relevant competent authority. This is further defined by a set of characteristics that defines a medicinal product as a single unique entry in the PMS database.

Upon successful submission of product data to PMS, the system generates a set of unique identifiers:

- Product Management Service Identifier (PMS ID);
- Medicinal Product Identifier (MPID);
- Packaged Medicinal Product Identifier (PCID).

First submission means the first time the product data is introduced in PMS.

Following a successful submission of new medicinal product data, the applicable identifiers are assigned to each PMS entity.

Each unique identifier is assigned based on a specific set of defining elements reported in the below sections.

While only one PMS ID and MPID can be generated per medicinal product single entry at the time of the first regulatory application, multiple PCIDs can be generated based on the number of authorized packaged medicinal products.

Once the relevant unique identifiers are generated by the system, these can be used throughout the medicinal product lifecycle, during the regulatory procedures (i.e., variation to the terms of the marketing authorisations, renewal of the marketing authorisations etc.).

The medicinal product single entry is subject to versioning in PMS. The versioning is based on the changes occurring during the medicinal product lifecycle. The subsequent versions may lead to the assignment of new MPID and/or PCIDs.

Note: This version of the guidance does not report information on additional identifiers such as the Pharmaceutical Product Identifier (PhPID). Further details on the related definitions and defining elements will be available at later stage as it requires further discussions prior the implementation.

For further information related to the generation of the identifiers during the regulatory procedure, refer to *EU IG Chapter 3 - Process for the electronic submission of medicinal product information*.

Product Management Service Identifier (PMS ID)

In PMS, each individual medicinal product entry is assigned a single and unique PMS identifier (PMS ID) that remains unchanged through the lifecycle of the medicinal product. The PMS ID is a supplementary stable ID to any existing authorisation number or equivalent identifier as assigned by an authorising body.

The PMS ID is automatically generated by the PMS system based on the first submission of the authorised medicinal product data to PMS.

The PMS ID is only composed by digits. The value is maintained by a database sequence.

Example of PMS IDs would be: *00005005; 00001234; 00000567; 00000174*.

Note: While the format of the identifier is confirmed, the number of digits may vary based on the amount of medicinal product entries performed in PMS. These examples are illustrative only.

The defining characteristics for the creation of each single medicinal product entry in PMS (associated to each PMS ID) includes:

- initial regulatory submission/application number;
- country (note: EU in the case of centrally authorised products);
- active substance[1] (or group of active substances contained in the same medicinal product);
- pharmaceutical form(s)[2] [*intended authorised pharmaceutical form(s)];
- medicinal product strength[3] [4] (as intended for authorisation);
- Full (medicinal product) name as mentioned in *Section 1: Name of the Medicinal Product* of the corresponding SmPC or other regulatory document and corresponding to the data element "Full name" in Medicinal Product Name section;
- national identifier [marketing authorisation number(s)].

The following considerations apply to the concept of medicinal product entry in PMS and its associated PMS ID:

- The defining elements are only used to generate the unique PMS ID at the time of the first submission to PMS. Whenever one of the defining elements described above is different at the time of the first submission of the relevant medicinal product to PMS, this constitutes a different product entry in the PMS database and hence a different PMS ID is assigned.
- Once the PMS ID is assigned and linked to a medicinal product entry using the above-mentioned defining characteristics, the **PMS ID remains unchanged during the entire lifecycle of the product.**

[1] A group of active substances contained in the same medicinal product includes fixed dose combinations or medicinal products with more than one pharmaceutical product e.g., contraceptive pill and pessary containing different active substances.
2 This definition applies to the authorised pharmaceutical form that may include one or more routes of administration in certain term names available in the used RMS lists, e.g., concentrate and solvent for solution for injection/infusion; solution for injection/infusion; emulsion for injection/infusion; solution for injection/infusion in pre-filled syringe. For the complete list of RMS lists used refer to 1.5. (Authorised) pharmaceutical form.
3 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 PMS ID.
4 Includes products with more than one pharmaceutical product in the same medicinal product (e.g., starting packs with different strengths)

- For nationally authorised products (NAPs), the PMS ID is aimed to be aligned with the concept of individual medicinal products in regulatory application procedures (e.g., electronic application forms).
- Whenever two medicinal products have the same attributes described above but are considered two different regulatory procedures by the competent authority (e.g., duplicate medicinal products due to duplicate regulatory applications submitted), these should be considered two different medicinal products in PMS with two different PMS IDs and product lifecycles.

In addition, the ISO standard ISO11615 identifies a number of general conditions for both the Medicinal Product Identifier (MPID) (see ISO11615, Section 8.2) and the Packaged Medicinal Product Identifier (PCID) (see ISO11615, Section 8.3).

Medicinal Product Identifier (MPID)[5]

A Medicinal Product Identifier (MPID) is a supplementary ID governed by the elements defined in ISO standard ISO11615 and is assigned in addition to the PMS ID as well as any existing authorisation number or equivalent identifier as assigned by the relevant competent authority. The MPID is automatically generated by the PMS system following the successful submission of the medicinal product data in PMS.

MPIDs are composed of the following elements:

- country code segment (ISO 3166-1 alpha-2 code elements);
- marketing authorisation holder (i.e., organisation ID) code segment;
- medicinal product code segment (i.e., a unique system generated medicinal product ID).

Any change of the initially submitted values related to these three code segments during the life cycle of the medicinal product should result in the assignment of a new MPID generated by the system.

The **country code segment** of the MPID reflects the country where the medicinal product is authorised and should be assigned in line with the ISO 3166-1 alpha-2 code elements.

- In case of a centralised product, the value "EU" is used for European Union.
- For Greece, the ISO code "GR" should be used instead of "EL" as the officially assigned country code.
- For United Kingdom (Northern Ireland), the code "XI" should be used, as this is the standard that the EU has decided upon to reference Northern Ireland.

The **marketing authorisation holder code** segment of the MPID is the MAH ID assigned by Organisations Management Service (OMS) following a successful submission of an organisation's information in OMS. An organisation will be identified by the OMS LOC ID as this will be unique for an organisation at its location.

Based on the LOC ID of the MAH the system will query OMS data to find the relevant ORG ID relevant for the assignment of the MPID in the system. The ORG ID is therefore the defining element which is part of the MPID structure.

If the required organisation and/or related location are not available, the addition of the unlisted organisation and/or related location should be requested from OMS. Please refer to the process described in the OMS Web User Manual available in the 'Documents' section of the Organisations

[5] Concept of MPID - © CEN, reproduced with permission

Management Service (OMS) on how to submit and maintain organisation data in OMS. A **unique medicinal product ID code segment** is the unique part of the MPID assigned to the medicinal product according to the following defining attributes:

- Medicinal Product name: only the following name parts are considered for the generation of the MPID: 1.14.3.3.1. , 1.14.3.3.2. Scientific name part, 1.14.3.3.10. Trademark or company name part;
  - The translations of the medicinal product name for medicinal products covered by the same marketing authorisation (MA) number are considered to be the same in terms of medicinal product name. Therefore, for countries such as Belgium and Luxembourg where there is more than one official language, the names in French, Dutch and German are considered to be part of the same medicinal product, hence are part of the same MPID and will not result in the assignment of separate MPIDs. Refer to table 1b in section 1.18. Attached document.
  - Likewise, the name of medicinal products authorised via the centralised procedure and covered by the same MA number is also considered to be the same in terms of medicinal product name, hence are part of the same MPID and will not result in the assignment of separate MPIDs. Refer to table 1b in section 1.18. Attached document.
- the [authorised] pharmaceutical dose form(s) [refer to section 1.5. (Authorised) pharmaceutical form];
- the active substance (s)/active moieties and their corresponding strength;
- device(s) where a medicinal product is combined with a medical device and where the pharmacological, immunological or metabolic action is the principal mode of action; the medical device is presented as part of the medicinal product.
- therapeutic indication(s) as authorised;
  - Any changes to the listed therapeutic indications of the Medicinal Product as authorised **may result in the assignment of a new MPID.**
  - Where a change to the listed therapeutic indication(s) of the Medicinal Product as authorised is introduced with the aim to modify an existing indication(s) (i.e., reword of the indication), a new MPID **will not** be assigned.
  - Where a change to the listed therapeutic indication(s) of the Medicinal Product as authorised is introduced with the aim to extend or introduced in a completely new indication/target disease, a new MPID **will** be assigned.
  - Therapeutic indications will not be considered at the time of migration but only at a later point in time.
- marketing authorisation number;
  - This attribute is associated to the definition of MPIDs hence **it may be a defining characteristic of MPID,** in accordance with the rules defined in the section 'Marketing authorisation information, therefore **not all the changes** to the Marketing Authorisation number of the Medicinal Product as authorised **may** result in the assignment of a new MPID.

    Example: The addition of a new pack without a change of the marketing authorisation number at the medicinal product level will not result in the assignment of a new MPID. However, in this instance a new PCID will be assigned. For further information refer to the examples in Annex I.
- legal status of supply (refer to section 1.7. Legal status of supply)

- The legal status of supply will not be considered at the time of migration but only at a later point in time.

The unique medicinal product ID code segment is created with a successful data submission and updated with a successful change to the above-mentioned attributes. The value of this segment is meant to guarantee the uniqueness of the MPID in the system.

Example of MPIDs would be: *EU-100000396-00180000 or IT-100030306-00000001*.

Note 1: While the format of the identifier is confirmed, the number of digits may vary based on the amount of medicinal product entries performed in PMS. These examples are illustrative only.

Changes to any of the elements listed above generated by data quality improvements should not trigger the generation of a new MPID. Data quality assurance activities may involve corrections of typographical errors, omissions or spelling errors which may not be linked to a regulatory submission. For further information on how to manage the different types of changes in PMS, refer to section 3. Maintenance submission of an authorised medicinal product (AMP) of EU IG Chapter 3 and section *Provenance* in this Chapter.

Note 2: Some defining characteristics are not available at the time of migration and will be considered only later. The MPID product ID code segment will be initially generated without considering these values. At a later point in time, the same MPID product ID code segment will be assigned to the extended set of characteristics. Therefore, in most cases, the MPID will not change when the additional defining characteristic is added. For some records sharing the same MPID product ID code segment but having different values for the newly added characteristic, a new MPID product ID code segment will be generated. Thereafter, any change of this newly added characteristic will trigger a change of the MPID product ID code segment according to the rules laid out above.

Packaged Medicinal Product Identifier (PCID)[6]

For each Packaged Medicinal Product, a unique PCID shall be assigned by the system at the time of the successful submission of the medicinal product data in PMS. This is supplementary to any identifier/existing authorisation/approval number at package level assigned by the relevant competent authority.

There are two components of a PCID:

- MPID for the Medicinal Product;
- package description code segment, which refers to a unique identifier for each package in the context of the MPID e.g., 0001, 0002 etc.

  Note: For authorisations which cover only one pack (authorisation number or equivalent identifier is located at the level of the package medicinal product), one PCID will be assigned, with 0001 as the package description code segment. For authorisations which cover more than one pack (authorisation number or equivalent identifier is located at the level of medicinal product), a PCID will be assigned to each pack. For further information on how to report the marketing authorisation number(s), refer to sections 2.2. and 4.7.2. of this Chapter.

Example of PCIDs would be: *EU-100000396-00020080-0001 or SE-100001745-00040001-0001*.

[6] Concept of PCID - © CEN, reproduced with permission

Note: While the format of the identifier is confirmed, the number of digits may vary based on the amount of medicinal product entries performed in PMS. These examples are illustrative only.

Any change of the MPID component during the lifecycle of the medicinal product should result in the update of the relevant PCID(s), generated by the system.

Package description code segment is assigned according to the following defining attributes:

- package item (container)(s) — the type, quantity (items per package), material(s);
- package component(s) — type, material(s);
- manufactured item(s) — manufactured dose form, unit of presentation, quantity (items per package).

When the above defining attributes (MPID and/or attributes related to Package description code segment) differ in any way a new PCID is assigned automatically by the system.

Relationship between PMS ID and ISO IDMP standard 11615 Medicinal Product Identifier (MPID) and Packaged Medicinal Product Identifier (PCID)

In accordance with the above sections, the following principles apply to the relationships between PMS Medicinal Product identifier (PMS ID) and ISO standard ISO 11615 Medicinal Product Identifier (MPID) and Packaged Medicinal Product Identifier (PCID)**:**

- PMS ID remains stable from the first submission to PMS and throughout the lifecycle of the product including all post-authorisation activities. PMS ID is linked to regulatory procedure numbers.
- MPIDs and PCIDs consist of a few defining elements (e.g., marketing authorisation holder for MPIDs or package item container for PCIDs) that may change during the lifecycle of the product resulting in an updated MPID or PCID as applicable linked to regulatory activities during the lifecycle of the medicinal product. The result of changes to the MPID/PCID defining elements occurring during the lifecycle of the product, superseded MPIDs/PCIDs become non-current.
- PMS ID, MPIDs and PCIDs share few defining elements (i.e., medicinal product name, authorised pharmaceutical form). The above listed PMS ID defining elements support the assignment of the relevant identifier based on the values entered only at the first submission of the authorised medicinal product to PMS. Once generated the PMS ID remains stable during the entire lifecycle of the medicinal product. If any change occurs to the initially submitted values of the shared PMS ID, MPID and PCID defining elements, this will result only in the assignment of the updated MPIDs and PCIDs, while the PMS ID will remain unchanged. PMS ID will be associated to the MPID concept but will also be associated (within the PMS system) with all previous inactive MPIDs where MPIDs changed during the lifecycle of the medicinal product.
- PMS ID has only one medicinal product associated which is identified by the MPID and is linked to historical identifiers created during the medicinal product lifecycle. PMS ID may have one or multiple packaged medicinal product (presentations) associated which are identified by the PCID.

This concept is further illustrated in the following example. Additionally, detailed fictional examples on how IDs behave over the lifecycle of a medicinal product are presented as part of Annex I of this document.

Example(s):

Imatinib Company A 25 mg tablets and Imatinib Company A 50 mg tablets are registered through initial marketing authorisation application centralised procedure EMEA/H/C/000XXX/000.

Since this application includes one single pharmaceutical form and two strengths, two different unique entries should be submitted for (one for the 25 mg tablets and then another for the 50 mg tablets) then two unique PMS ID are set in accordance with the rules to set a unique PMS medicinal product.

Since this is the first submission, MPIDs and PCIDs are also set. MPIDs and PCIDs are subject to change throughout the lifecycle of the medicinal product when any post-authorisation activities affect any of their defining elements (e.g., MAH, legal status, package container).

The examples below provide a description on the evolution of the identifiers over the lifecycle of a product. Additional examples are included in Annex I.

Note: Examples below are fictitious and for illustration purpose only.

Imatinib Company A 25 mg tablets

Submission	Procedure/application number	PMS ID	MPID	Packs	PCIDs
Initial MAA	EMEA/H/C/000XXX/000	00005005	EU-100000396-00000001	Blister (alu) 1 tablet Blister (alu) 5 tablets	EU-100000396-00000001-0001 EU-100000396-00000001-0002
Addition of new manufacturer	EMEA/H/C/000XXX/IB/001	00005005	EU-100000396-00000001	Blister (alu) 1 tablet Blister (alu) 5 tablets	EU-100000396-00000001-0001 EU-100000396-0001-0002
Transfer of MA	EMEA/H/C/000XXX/T/002	00005005	EU-100000497-00000001	Blister (alu) 1 tablet Blister (alu) 5 tablets	EU-100000497-00000001-0001 EU-100000497-0001-0002
Change of primary packaging	EMEA/H/C/000XXX/IB/003	00005005	EU-100000497-00000001	Blister (PVC) 1 tablet Blister (PVC 5 tablets	EU-100000497-00000001-0003 EU-100000497-00000001-0004
Change in legal status	EMEA/H/C/000XXX/II/004	00005005	EU-100000497-00000002	Blister (PVC) 1 tablet Blister (PVC) 5 tablets	EU-100000497-00000002-0003 EU-100000497-00000002-0004

Imatinib company A 50 mg tablets

Submission	Procedure/application number	PMS ID	MPID	Packs	PCIDs
Initial MAA	EMEA/H/C/000XXX/000	00005006	EU-100000396-00180000	Blister (alu) 1 tablet Blister (alu) 5 tablets	EU-100000396-00180000-0001 EU-100000396-00180000-0002
Addition of new manufacturer	EMEA/H/C/000XXX/IB/001	00005006	EU-100000396-00180000	Blister (alu) 1 tablet Blister (alu) 5 tablets	EU-100000396-00180000-0001 EU-100000396-00180000-0002
Transfer of MA	EMEA/H/C/000XXX/T/002	00005006	EU-100000497-00180000	Blister (alu) 1 tablet Blister (alu) 5 tablets	EU-100000497-00180000-0001 EU-100000497-00180000-0002
Change of primary packaging	EMEA/H/C/000XXX/IB/003	00005006	EU-100000497-00180000	Blister (PVC) 1 tablet Blister (PVC) 5 tablets	EU-100000497-00180000-0003 EU-100000497-00180000-0004
Change in legal status	EMEA/H/C/000XXX/II/004	00005006	EU-100000497-00180001	Blister (PVC) 1 tablet Blister (PVC) 5 tablets	EU-100000497-00180001-0003 EU-100000497-00180001-0004

Access to identifiers

The unique identifiers listed in this guidance are generated by the PMS system upon successful submission of the medicinal product single entry to Product Management Service (PMS).

Following the relevant submission of the medicinal product entry to PMS, the system will provide a response which should allow the submitter to retrieve the medicinal product entry as is stored in PMS including the generated unique identifiers.

For further information related to the generation of the identifiers during the process of product data submission, refer to section 2. Initial submission of authorised medicinal product of EU IG Chapter 3 - Process for the electronic submission of medicinal product information.

User guidance

This section defines the attributes and provides business guidance and conventions for the electronic submission of medicinal product data and document to be provided into PMS.

The medicinal product data to be completed in PMS are in the scope of **Iteration 1** which is a sub-set of the full data model defined in the ISO 11615 standard (Annex A).

The elements marked with [EXT] in Figure 1 below are extensions to the ISO model added in the context of PMS Iteration 1 implementation.

To allow the reporting of multiple values some of the data elements available in this guidance are repeatable fields. This information is reported in the table of the relevant data element(s). A clear distinction on the possibility to repeat the entire class versus the different attributes of the class is also reported in this chapter.

In line with the SPOR program, PMS is supported with referentials, organisation and substance master data managed in RMS, OMS and SMS services respectively.

RMS, OMS and SMS terms are associated with unique identifiers assigned by the system at the time of the creation of the master data. Further information is available on the SPOR Portal.

Regarding the Referentials Management Service (RMS) operating model, RMS contains:

- Internally-managed lists (e.g., Marketing Authorisation Application Legal Basis, Special Precautions for Storage). These lists are displayed with the record "EMA" under the "List Owner" column in the RMS portal.
- lists owned by external maintenance organisations such as EDQM (pharmaceutical dose forms, routes of administration, units of presentation, etc.); WHO (ATC Human, ATC Vet); MSSO (MedDRA); ISO (Language). These lists are displayed with a record other than "EMA" under the "List Owner" column in the RMS portal (i.e., EDQM, WHO CC, ISO, etc.)

Each RMS term is associated with a unique RMS identifier and can be mapped to other systems, when applicable. Terms within RMS lists owned by external organisations (e.g., EDQM, WHO, MSSO) have an RMS ID as well as the ID from the relevant source system. The latter is marked in RMS as the main source for that term with the extended attribute "Is main source = Y" to ensure that the ID from the external list owner is displayed as the source ID (e.g., EDQM ID, ATC code from WHO, MedDRA code, etc.) and that this ID is displayed in the "Source ID" column in the RMS web portal.

As a general principle, PMS consume referentials from the RMS lists, hence the relevant RMS identifiers referring to the applicable RMS term are required to be submitted into PMS.

The user shall select the most suitable RMS term to reflect the structuring of the product data by applying standardized master data. The user should consider that not every available RMS term even if technically selectable to PMS is applicable from a regulatory point of view.

There are cases where the RMS terms contain the RMS ID which are mapped to the identifier of the external source (i.e., the source ID). When submitting product information into PMS, the RMS ID is the identifier to be used (therefore the source ID, if existing, should not be used). This principle applies to both internally-managed lists and externally-managed lists.

However, there are two externally-managed lists where the above reported principle does not apply. These exceptions are:

- **Medical Dictionary For Regulatory Activities – MedDRA** (RMS ID 100000000006). managed by MSSO.
- **Anatomical Therapeutic Chemical classification system – Human** (RMS ID 100000093533), managed by WHO CC.

In these two cases, the external ID from the relevant source system (source ID) can also be used to submit the relevant product information into PMS, as an alternative to using the RMS term IDs. Upon selection of the external source ID, the PMS system will automatically retrieve and show the appropriate RMS term as result of the mapping mechanisms explained above. In this case, the version of the external identifier shall correspond to the latest updated version available in RMS.

References to referentials, organisation and substance data either through FHIR Identifiers or CodeableConcept data types shall specify a "system" and "value" pair as per FHIR specification of these data types. For referentials and substance data a FHIR extension will be used to specify the version number of the data. The current document offers guidance on the "value". The "system" is a constant which differs per type of data and is per convention the SPOR API URL of the resource referred to. Details on how to form the FHIR data for these types of references can be found in Chapter VI – SPOR API Technical Specification.

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 medicinal product data for human use into PMS. This applies in the context of the regulatory submission (initial submission and maintenance of the product information) as well as notification, data enrichment and nullification of product data.
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. • Mandatory: the provision of the product data is compulsory; therefore, the field(s) shall be populated with the available information. • Conditional: the provision of the product data is compulsory only if the information is available. Therefore, the field(s) shall be populated accordingly. • Optional: the provision of the product data is not mandatory; however, the field(s) can be populated if the information is available.

Tag	Description
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 Element Name	Any mapping to ISO IDMP standards, when applicable.
ISO Path	The mapping of the ISO IDMP technical specifications, when applicable.
FHIR Element Name	The name of the FHIR element as presented in the FHIR resource list.
FHIR Path	The FHIR data model path as presented in the FHIR resource list.
FHIR Complementary Information	Additional information on expected values for FHIR data elements expected in addition to the value provided, for example the system to use for an identifier or which type of date is specified.

Additional information on the technical aspects such us reference systems, cardinality, data types, extensions, examples, etc. refer to Chapter VI – SPOR API Technical Specification and the latest version of the HL7 FHIR Specification is accessible through this link.

Note: This current version 2.1 of the Implementation Guide is based on HL7 FHIR Specification version 4.4.0 (FHIR R5 Preview 3) while the created FHIR messages examples are based either on 4.2.0 (FHIR R5 Preview 2) (source: http://hl7.org/fhir/2020Feb/) or 4.4.0 (FHIR R5 Preview 3) (source: http://hl7.org/fhir/2020May/).The HL7 FHIR Specification version mentioned in this guidance is a *preview* version, therefore it is not expected to be the version used at the time of the go-live of PMS. The go-live is intended to implement a major version of the FHIR specification such as FHIR R5. The guidance will be updated in due course to reflect the latest version used at the time of the go-live of PMS.

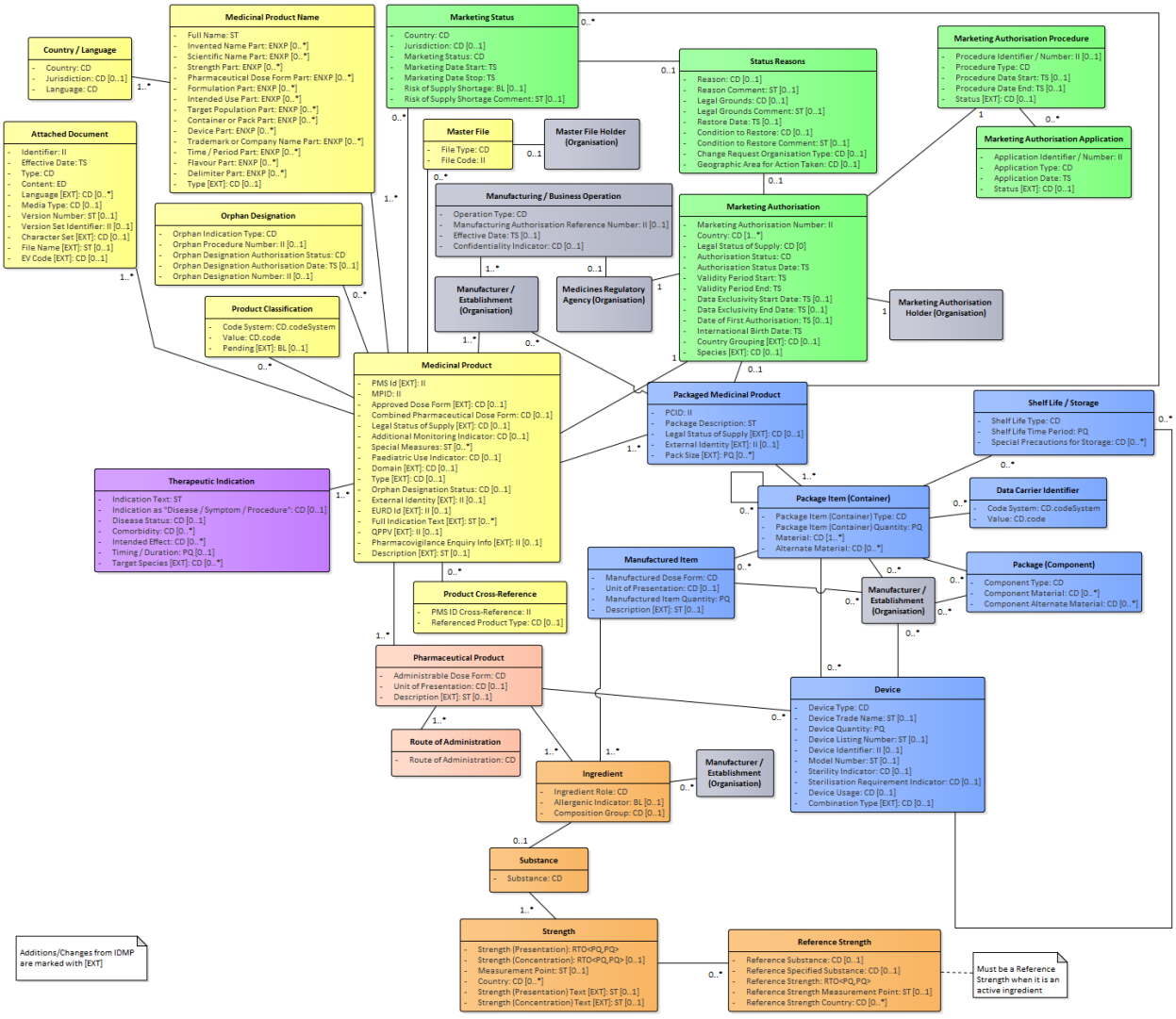


Figure 1: Iteration 1 ISO IDMP information model for authorised medicinal products with PMS extensions.[7] [8]

Note that not all the data elements showed in Figure 1 are implemented in the PMS data model. Therefore, these are not listed in the current version of the EU IG Chapter 2.

[7] In Figure 1 not all the data fields shown are part of the Iteration 1
[8] Figure of data model - © CEN, reproduced with permission

Provenance

The full information concerning the general overview of the submission of medicinal product data shall be specified in *Provenance*.

This data element is used to track information about the activity performed in PMS in the context of a creation or update of a version of a medicinal product dataset submission message, describing the target and agent involved. This information is used to convey a description of the action performed by specifying what the action is, why it is occurring and by who it is performed.

Provenance resources are prepared by the application that initiates the create/update etc. of the resource.

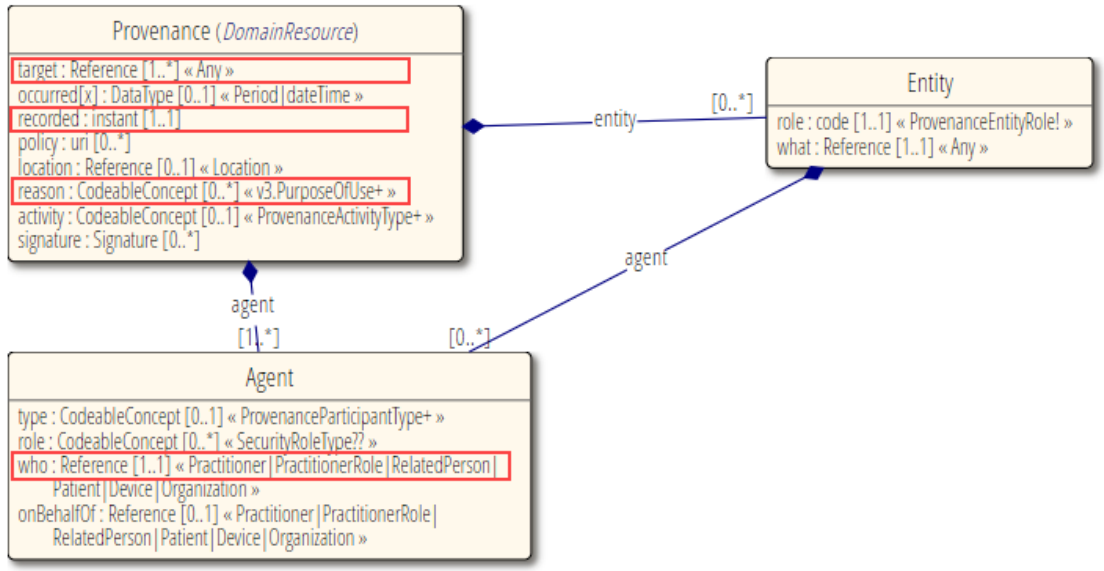


Figure 2 : FHIR *Resource Provenance* (source : http://www.hl7.org/fhir/)

The Provenance class and the individual attributes of this class are mandatory and not repeatable.

Provenance Class	Description
Repeatable	No
Conformance	Mandatory

Provenance class contain the flowing data elements.

Reason

Tag	Description
User Guidance	The reason for the submission of the medicinal product dataset in PMS shall be specified. The applicable value from the RMS list shall be selected to indicate the context in which the creation or change of/to the medicinal product data occurs. The dataset submission should be marked as:

Tag	Description
	• Regulatory Submission - Initial: this is applicable to data submission linked to initial regulatory procedures/applications submissions such as initial Marketing Application or Line Extension; • Regulatory Submission – Maintenance: this is applicable to report any change to the terms of the marketing authorisation requiring regulatory assessment (e.g., variations, renewals, transfer of marketing authorisation). • Notification: applicable if any change to the terms of the marketing authorization without Regulatory assessment is submitted. This term is to be used for data submission **not** linked to regulatory procedures/applications. The following situations apply: – Changes of (Pharmacovigilance) master file – Section 1.15 – Changes of QPPV Contact (QPPV) – Section 1.16 – Changes on contact information for pharmacovigilance enquiries – Section 1.17 – Change to the Authorisation Status changes triggered by Competent Authorities – Section 2.4 – Changes to the marketing status – Section 4.6 – Changes to the Data Carrier Identifier – Section 4.8.6. • Enrichment - Full: This reason should be used when the full FHIR dataset is provided to complete the full record following IDMP rules and compliance. • Enrichment – Partial: This reason should be used when specific resources are provided to partially enrich migrated data or correct erroneous migrated data. • Nullification: used to flag as "**nullified**" medicinal product entities created by mistake or entities provided erroneously.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	The applicable value as listed from the RMS list [list will be created in v2.2]
Value(s)	As listed in the RMS list. This list is to be created.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Reason
FHIR Path	Provenance.reason

For further information related to the process of submission, refer to sections 2 and 3 of EU IG Chapter 3 - Process for the electronic submission of medicinal product information.

Note: Further RMS terms may be created in due course if additional path related to the reason of submission are deemed necessary.

Target

Tag	Description
User Guidance	The reference to the Medicinal Product PMS ID which is impacted by the activity shall be specified.
Repeatable	No
Conformance	Mandatory
Data Type	Reference
RMS URI/URL	Not applicable
Value(s)	Reference to Medicinal Product.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Target
FHIR Path	Provenance.target

Recorded

Tag	Description
User Guidance	Timestamp of when the activity took place shall be specified.
Repeatable	No
Conformance	Mandatory
Data Type	Timestamp
RMS URI/URL	Not applicable
Value(s)	The timestamp format is YYYY-MM-DDThh:mm:ss.sss+zz:zz (e.g., 2020-02-07T14:53:33.134+02:00 or 2021-01-01T00:00:00Z). The time should be specified at least to the second and should include a time zone.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Recorded
FHIR Path	Provenance.recorded

Sender

Tag	Description
User Guidance	The Organisation identifier of the entity performing the activity shall be specified using the location identifier (LOC ID) linked to the organization as listed in the Organisation Management System (OMS) following a successful registration of the organisation's details. If the required organisation and/or related location are not available, the addition of the unlisted organisation and/or related location should be requested from OMS using the process described in the OMS Web User Manual in the 'Documents' section of the Organisation Management System (OMS).

Tag	Description
	When the LOC ID is specified, the system would give the information to which ORG ID the selected location is linked in the back end. This information will be shown through the PMS User Interface.
Repeatable	No
Conformance	Mandatory
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	As listed in SPOR OMS service (LOC ID)
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Who
FHIR Path	Provenance.agent.who

1. Medicinal product

The full information on Medicinal Product as presented in the FHIR *Resource MedicinalProductDefinition* is presented in the figure 3 below. In the context of the Iteration 1 of the PMS implementation, only the information highlighted in red is in scope and should be provided according to the rules and guidance as described in this section.

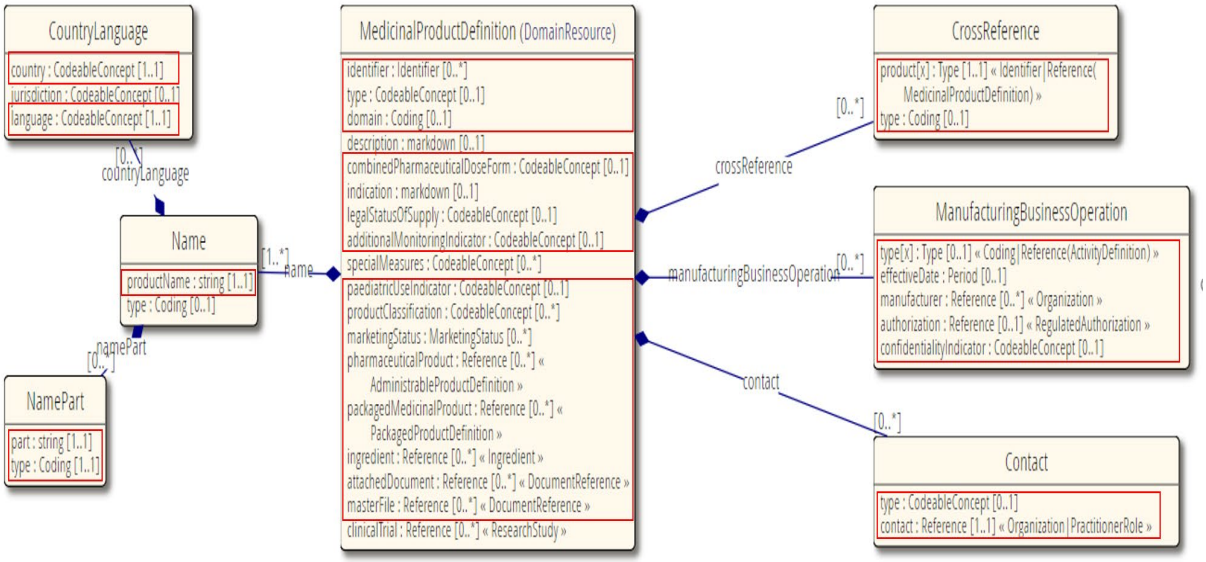


Figure 3: FHIR *Resource MedicinalProductDefinition* (source: http://www.hl7.org/fhir/)

The Medicinal Product Definition class and its attributes is mandatory and not repeatable. The individual attributes of this class shall be populated as applicable.

Medicinal Product Definition Class	Description
Repeatable	No
Conformance	Mandatory

1.1. Product Management Service Identifier (PMS ID)

PMS ID will be assigned to each medicinal product single entry following the first submission of the authorised medicinal product data to PMS. It is a unique, stable and permanent ID supplementary to any existing authorisation number or equivalent identifier as assigned by an authorising body.

The PMS ID is composed only by digits.

This attribute is automatically generated by the PMS system and remains unchanged through the lifecycle of the medicinal product.

The PMS ID shall be specified when performing any maintenance related activity of the medicinal product data.

Tag	Description
User Guidance	The PMS ID will be assigned following a successful **initial submission** of the medicinal product information in PMS.
Repeatable	No
Conformance	• For first data submission: Not applicable – ID generated by the system • For data maintenance: Mandatory
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	ID generated by the system
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Identifier
FHIR Path	MedicinalProductDefinition.id

1.2. Medicinal Product Identifier (MPID)[9]

MPID shall be assigned to each authorised medicinal product; it is a supplementary ID to any existing authorisation number or equivalent identifier as assigned by an authorising body in a region.

The MPID is defined by the following segments:

- country code segment (ISO 3166-1 alpha-2 code elements);
- marketing authorisation holder (i.e., organisation ID) code segment;
- medicinal product code segment (i.e., unique medicinal product ID).

Any change of the values related to these three code segments (as described in the Introductory section) should result in the assignment of a new MPID.

This attribute is automatically generated and maintained by the PMS system.

Tag	Description
User Guidance	The MPID will be assigned following a successful **first submission** of the medicinal product information in PMS.
Repeatable	No
Conformance	For first data submission and data maintenance: Not applicable – ID generated by the system

[9] Concept of MPID - © CEN, reproduced with permission

Tag	Description
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	ID generated by the system
ISO Element Name	MPID
ISO Path	/MedicinalProduct/MPID
FHIR Element Name	Identifier
FHIR Path	MedicinalProductDefinition.identifier
FHIR Complementary Information	MedicinalProductDefinition.identifier.system value is "http://ema.europa.eu/fhir/mpId"

1.3. Domain

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

Tag	Description
User Guidance	The domain shall be provided as a term ID. • The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. In the context of the implementation of PMS iteration 1 only medicinal product for human use shall be provided and therefore the value "human use" applies.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000004
Value(s)	Listed in the Domain RMS List
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Domain
FHIR Path	MedicinalProductDefinition.domain

Example(s):

Human use (100000000012)

1.4. Type

ISO IDMP distinguishes between Authorised Medicinal Product and Investigational Medicinal Product.

In the context of the implementation of PMS iteration 1, only Authorised Medicinal product is supported.

"Authorised Medicinal Product" covers Medicinal products for which a marketing authorisation in EU/EEA was requested or granted, including those for which the marketing authorisation is no longer valid. The product itself does not need to be authorised/approved and this information should be reflected in 2.4 Authorisation status (medicinal product level) and in 4.6.4. Authorisation status (package level), when applicable.

"Authorised Medicinal Product" also covers:

- traditional use registration for herbal medicinal products (Article 16a of Directive 2001/83/EC);
- simplified registration for homeopathic medicinal products (Article 14 of Directive 2001/83/EC);
- medicinal products within the scope of Article 5 of Directive 2001/83/EC i.e., 'Named patient use' falling under Article 5(1) and 'EU Distribution Procedure' under Article 5(2);
- parallel distribution/parallel import of medicinal products (Article 76(3) and (4) of Directive 2001/83/EC);
- medicinal products authorised outside the European Economic Area (EEA) or following a non-EU procedure;

- extemporaneous Medicinal products (e.g., medicinal products prepared in a pharmacy based on a medical prescription such as pharmacy preparations);
- intermediate products intended for subsequent processing by an authorised manufacturer.

Investigational medicinal products as defined in the Directive 2001/20/EC Article 2(d) are not covered in PMS iteration 1.

Tag	Description
User Guidance	The type shall be provided as a term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. In the context of the implementation of PMS iteration 1, only Authorised Medicinal product shall be provided.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000025915
Value(s)	As listed in the Medicinal Product Type RMS list.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Type
FHIR Path	MedicinalProductDefinition.type

Example(s):

Authorised Medicinal Product (200000025916)

Investigational Medicinal Product (200000025917)

1.5. (Authorised) pharmaceutical form

The pharmaceutical form as submitted for authorisations or as authorised by regulatory authorities and as reflected in regulatory documents shall be provided.

Pharmaceutical form might be authorised or submitted for authorisation as follows:

- Combined pharmaceutical form: when two or more manufactured dose forms that are intended to be combined to create a single administrable dose form. In this case the RMS list "Combined pharmaceutical form" shall be used.

  Example*:* powder and solvent for solution for injection

- Pharmaceutical dose form: when the authorised dose form involves a single standard term dose form which does not fall into one of the other categories and which may or may not undergo transformation prior to administration to the patient. In this case the RMS list "Pharmaceutical dose form" shall be used.

  Example*:* tablet, capsule, solution for injection

- Combined terms: 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" shall be used.

Example*:* solution for injection in pre-filled syringe

- Combination Package: 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 patient. In this case the RMS list "Combination Package" shall be used.

  Example*:* Cream + vaginal tablet

Tag	Description
User Guidance	The authorised pharmaceutical dose form(s) or the dose form submit shall be provided as an RMS term ID.
Repeatable	Yes
Conformance	Mandatory
Data Type	Codable Concept
RMS URI/URLs	• https://spor.ema.europa.eu/v1/lists/200000000006 • https://spor.ema.europa.eu/v1/lists/200000000004 • https://spor.ema.europa.eu/v1/lists/200000000007 • https://spor.ema.europa.eu/v1/lists/200000000008
Value(s)	As applicable in one of the SPOR RMS lists: • Combined pharmaceutical dose form • Pharmaceutical dose form • Combined term • Combination Package
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	authorisedDoseForm
FHIR Path	MedicinalProductDefinition.extension.authorisedDoseForm Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

1.6. Combined pharmaceutical dose form

'Combined pharmaceutical dose form' is a single term to describe two or more manufactured dose forms that are intended to be combined to create a single administrable dose form. If there is no combining needed in order to prepare the administrable dose form (e.g., medicinal product is composed of a single manufactured item that equals the administrable dose form) then the 'Combined pharmaceutical dose form' is left blank.

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 patient**. In these cases, the **field should be left blank.**

To illustrate this concept, additional examples are reflected below:

Example(s):

- 'Powder' and 'solvent' are two manufactured items that shall be combined to create a single pharmaceutical product. The administrable dose form that will be created using these two manufactured items and administered to the patient will be 'solution for injection'. The combined

pharmaceutical dose form to be used in this case is the standard term 'Powder and solvent for solution for injection'.

- "Film-coated tablet" involves a single manufactured item. This manufactured item corresponds with the administrable dose form (no previous preparation/combination with other manufactured item is needed). Therefore, this field should be left blank.
- "Oral Capsule" & "External Cream" correspond with two different administrable dose forms which do not need combining for administering to the patient. Therefore, this field should be left blank.

Tag	Description
User Guidance	The combined pharmaceutical dose form(s) shall be provided as an RMS term ID.
Repeatable	No
Conformance	Conditional
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000000006
Value(s)	As applicable in SPOR RMS Combined pharmaceutical dose form list
ISO Element Name	Combined Pharmaceutical Dose Form
ISO Path	/MedicinalProduct/CombinedPharmaceuticalDoseForm
FHIR Element Name	combinedPharmaceuticalDoseForm
FHIR Path	MedicinalProductDefinition.combinedPharmaceuticalDoseForm

1.7. Legal status of supply

Legal status of supply of the medicinal product as authorised by the relevant competent authority shall be specified.

In the scenario that legal status of supply differs at package level (different legal status for different package sizes of the same medicinal product), this information at medicinal product level is to be populated with the RMS term "*Medicinal product subject to medical prescription exempt for some pack sizes*". For those cases, the legal status of supply shall be entered at package level only refer to section 4.5. - Legal Status of Supply at Package Medicinal Product Level. In these cases, the field on product level will show the information that the "*Medicinal product subject to medical prescription exempt for some pack sizes*".

Tag	Description
User Guidance	The legal status of the medicinal product's supply, as authorised by the competent authority and applicable in the region, shall be specified using a term ID. • The applicable value shall be selected from the term ID as available in the applicable Referentials Management Service (RMS) list. • For Centralised Authorised Products (CAPs), this information is retrieved from Annex II.B - CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE and from section 4.2 – Posology of the Product information. • For Nationally Authorised Products (NAPs), this information may be retrieved from different sources that includes from the Product information the Summary of Product Characteristics (SmPC), Package

Tag	Description
	Leaflet (PL) or other annexes) to National Register of Medicinal Products. • The legal status for the supply is usually defined at medicinal product level and should be specified as Medicinal product subject to medical prescription or Medicinal product not subject to medical prescription; • In the scenario that legal status for the supply is defined at package level only (different legal status for different package sizes of the same medicinal product), the term *Medicinal product subject to medical prescription exempt for some pack sizes* can be specified. For those cases, the legal status for the supply must be entered at package level (see section 4.5. - Legal Status for the Supply at Package Level).
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072051
Value(s)	As listed in the Legal Status for the Supply RMS list.
ISO Element Name	Legal Status of Supply
ISO Path	/MedicinalProduct/MarketingAuthorisation/LegalStatusOfSupply
FHIR Element Name	legalStatusOfSupply
FHIR Path	MedicinalProductDefinition.legalStatusOfSupply

Example(s):

Medicinal product subject to medical prescription (100000072084)

Medicinal product not subject to medical prescription (100000072076)

Medicinal product subject to medical prescription exempt for some pack sizes(example of term to be created)

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

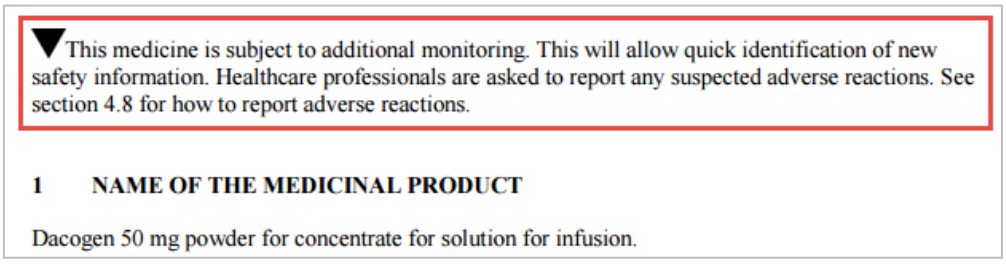
1.8. Additional monitoring indicator

Indication whether the medicinal product is subject to additional monitoring (black triangle/symbol) in accordance with Art. 23 of Regulation (EC) No 726/2004.

Tag	Description
User Guidance	The value indicating whether the medicinal product is subject to additional monitoring should be specified if the medicinal product is subject to additional monitoring.
Repeatable	No
Conformance	Mandatory
Data Type	Boolean

Tag	Description
RMS URI/URL	Not applicable
Value(s)	True / False
ISO Element Name	Additional Monitoring Indicator
ISO Path	/MedicinalProduct/AdditionalMonitoringIndicator
FHIR Element Name	additionalMonitoringIndicator
FHIR Path	MedicinalProductDefinition.additionalMonitoringIndicator

Example(s):



In this case as the medicinal product is subject to additional monitoring, the Boolean concept "True" shall be selected.

1.9. Orphan designation

Orphan designation is a status assigned to a medicine intended to treat a rare condition as defined in Regulation (EC) No 141/2000.

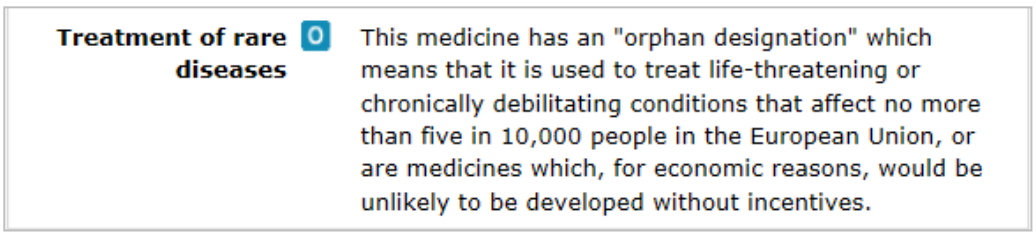
Medicinal products designated as Orphan Medicinal Products are listed in the Register of designated Orphan Medicinal Products published by the European Commission accessible through the following link.

This section shall be completed when an authorised medicinal product is designated as an orphan medicinal product bearing one or more orphan indications. If the authorised medicinal product is not designated as an orphan medicinal product this section shall be left blank.

The authorised medicinal product can be associated to more than one orphan drug designation (ODD).

Example(s):

Medicinal product with orphan designation



In FHIR resources, Orphan Designation is captured as a special type of RegulatedAuthorization (refer to Figure 4), which illustrates how the resource is used in the context of an Orphan Designation:

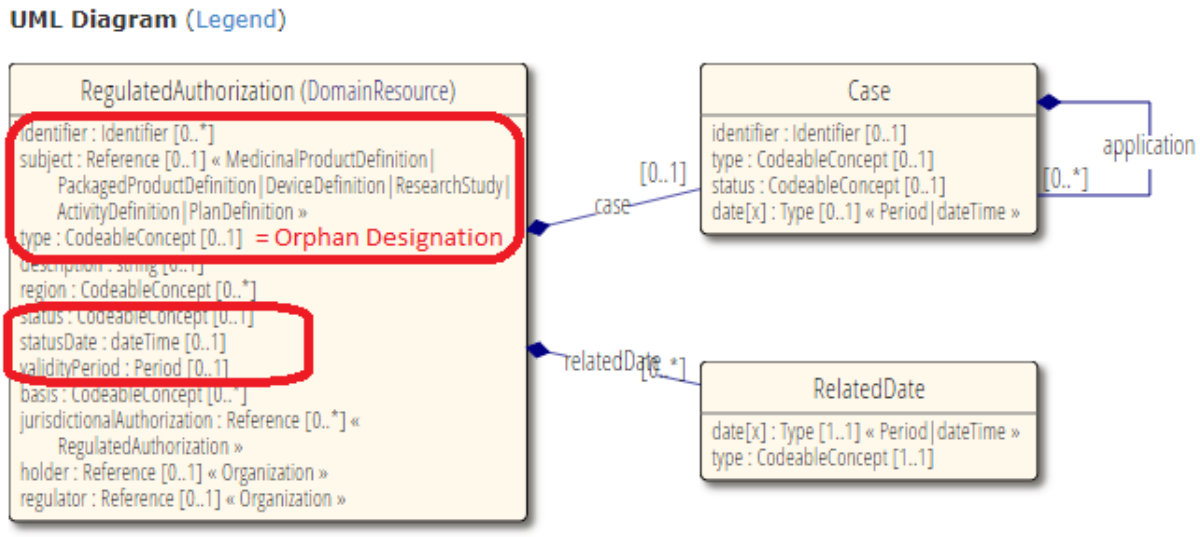


Figure 4: Orphan Designation Status as captured by the RegulatedAuthorization class in FHIR (Source: http://www.hl7.org/fhir/)

The Orphan Designation class is conditional and repeatable while the individual attributes of this class are not repeatable and shall be populated as applicable.

Orphan Designation Class	Description
Repeatable	Yes
Conformance	Conditional

1.9.1. Regulatory authorisation type

Regulatory applications may be submitted to obtain different type of authorisations or regulatory entitlements such as orphan designations, Advanced therapy medicinal product (ATMP) classification, marketing authorisations etc. in accordance with the current European regulatory framework for medicinal products. The regulatory authorisation type "Orphan Designation" shall be specified in this section.

Tag	Description
User Guidance	The type of regulatory authorisation shall be specified, when applicable. Please note that the RegulatedAuthorization type shall be set as Orphan Designation. The applicable value shall be selected from the term ID as available in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/220000000060
Value(s)	• As listed in the Regulatory Entitlement Type RMS list. • The value "Orphan Designation" shall be selected.
ISO Element Name	Not Applicable
ISO Path	Not Applicable
FHIR Element Name	Type
FHIR Path	RegulatedAuthorization.type

1.9.2. Orphan designation status

Tag	Description
User Guidance	The following Orphan designation regulatory status shall be specified where applicable: • Valid: starting from the date of the EC decision of the initial Marketing Authorisation Application OR variation, granting an indication covered by an orphan designation. • Expired: when the ME period for that orphan designation has expired, at the end of the 6, 10 or 12-year period of ME. • Withdrawn: when the Orphan Designation of the medicinal product is withdrawn by the MAH (via a specific procedure). • The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. The Orphan Designation status of the medicinal product (where applicable) can be found in the individual product entry at the EC Register of medicinal product accessible via this link.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072049
Value(s)	As listed in the Regulatory Entitlement Status RMS list.
ISO Element Name	Orphan Designation Status
ISO Path	/MedicinalProduct/OrphanDesignationStatus
FHIR Element Name	status
FHIR Path	RegulatedAuthorization.status

Example(s):

Valid, Expired, Withdrawn

1.9.3. Orphan designation number

Tag	Description
User Guidance	The Orphan designation number granted by the European Commission as listed in the Register of designated Orphan Medicinal Products shall be specified. This is a repeatable field.
Repeatable	No
Conformance	Mandatory
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	As assigned by the European Commission decision in Orphan Designation register.
ISO Element Name	OrphanDesignationNumber
ISO Path	/MedicinalProduct/OrphanDesignation/OrphanDesignationNumber
FHIR Element Name	Identifier

Tag	Description
FHIR Path	RegulatedAuthorization.identifier
FHIR Complementary Information	RegulatedAuthorization.identifier.system value is "http://ema.europa.eu/fhir/marketingAuthorizationNumber"

Example(s):

EU/3/XXXX/53

1.9.4. Orphan designation status date

Tag	Description
User Guidance	The date when the orphan designation status of the medicinal product was assigned shall be specified where applicable. The following dates are applicable per status: • Valid: date of the EC decision of the initial Marketing Authorisation Application that designates the medicinal product as orphan. • Expired: date of expiration of the market exclusivity period for the medicinal product. • Withdrawn: date of withdrawal of the Orphan Designation of the medicinal product by the MAH. The date when the orphan designation status of the medicinal product was assigned can be found in the individual product entry in the EC Register of medicinal product accessible via this link.
Repeatable	No
Conformance	Mandatory
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	OrphanDesignationAuthorisationDate
ISO Path	/MedicinalProduct/OrphanDesignation/OrphanDesignationAuthorisationDate
FHIR Element Name	statusDate
FHIR Path	RegulatedAuthorization.statusDate

Example(s):

2017-10-23

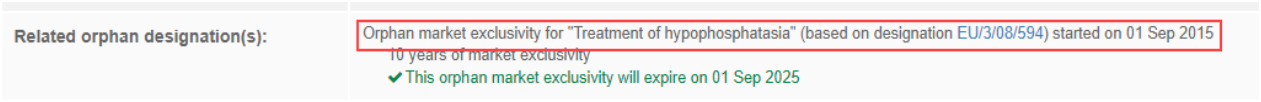
1.9.5. Market exclusivity start date

Tag	Description
User Guidance	The date when the **market exclusivity** of the orphan medicinal product starts shall be specified where applicable and shall reflect the date of the authorisation of the first indication. The date of start of the market

Tag	Description
	exclusivity of the orphan medicinal product can be found in the individual product entry at the EC Register of medicinal product accessible via this link.
Repeatable	No
Conformance	Mandatory
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	validityPeriod
FHIR Path	RegulatedAuthorization.validityPeriod.start

Example(s):

2015-09-01



1.10. Paediatric use indicator

The value indicating whether the medicinal product is authorised and explicitly indicated for paediatric use shall be specified.

As per Regulation (EC) No 1901/2006:

- Article 1 - 'paediatric population' means that part of the population aged between birth and 18 years;
- Article 3 - 'medicinal product authorised for a paediatric indication' means a medicinal product which is authorised for use in part or all of the paediatric population and in respect of which the details of the authorised indication are specified in the summary of the product characteristics drawn up in accordance with Article 11 of Directive 2001/83/EC.

The above-mentioned definitions can be used with the authorised indications of a medicinal product when completing this section. This information is to be inferred from section *4.1-Therapeutic indications* of the SmPC. In certain cases, the target adult/paediatric population is not referred in section *4.1 of the SmPC*; this information can also be inferred from section *4.2 – Posology and method of administration* of the SmPC.

Example(s):

Example 1: information of paediatric use included in section 4.1 of the SmPC

Section 4.1 Therapeutic indications of the SmPC states: Levetiracetam ProductXYZ is indicated as monotherapy in the treatment of partial onset seizures in adults and adolescents from 16 years of age with newly diagnosed epilepsy.

Example 2: information of paediatric use not reflected in section 4.1 of the SmPC but included in section 4.2 of the SmPC

Section 4.2 Posology and method of administration of the SmPC states:

Posology

Monotherapy for adults and adolescents from 16 years of age.

Therefore, in both cases, the value 'Yes' shall be specified.

Tag	Description
User Guidance	Paediatric use indicator shall be completed to indicate whether a medicinal product is authorised for a paediatric indication with the following values: • Yes: shall be selected if an indication for paediatric population (children under the age of 18) is stated in Section 4.1 Therapeutic indications of the SmPC and/or a posology is stated for any subset of the paediatric population in Section 4.2. Posology and method of administration of the SmPC. • No: shall be selected if the medicinal product does not meet any of the above condition.
Repeatable	No
Conformance	Mandatory
Data Type	Boolean
RMS URI/URL	Not applicable
Value(s)	True / False
ISO Element Name	Paediatric Use Indicator
ISO Path	/MedicinalProduct/PaediatricUseIndicator
FHIR Element Name	paediatricUseIndicator
FHIR Path	MedicinalProductDefinition.paediatricUseIndicator

1.11. Full indication text

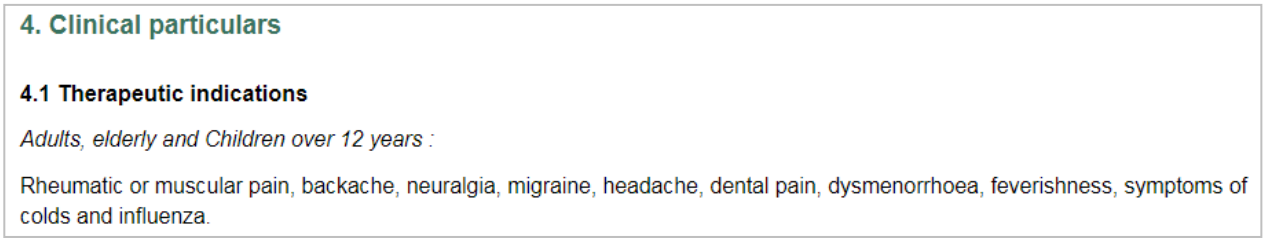
The description of the authorised full therapeutic indication(s) shall be described in text as reflected in Section *4.1 Therapeutic Indications* of the corresponding SmPC or another regulatory document (e.g., Package leaflet) if no SmPC is available.

- centrally authorised products (CAPs): only the English version of the full indication text is mandatory to be submitted;
- for nationally authorised products (NAPs) including products registered through the mutual recognition procedure (MRP), decentralised procedure(DCP) and national procedure (NP):
  - the text shall be provided in the national language, as authorised by the competent authority and as stated in section *4.1 Therapeutic Indications* of the corresponding SmPC. Provision of additional translation in English is on optional basis,
  - in countries with multiple languages (e.g., Belgium) the full therapeutic indication of at least one local language is mandatory,

Additional examples can be found below.

Tag	Description
User Guidance	The description of the authorised full therapeutic indication(s) shall be described in text as reflected in Section *4.1 Therapeutic Indications* of the corresponding SmPC or other regulatory document (identical copy and paste). This is a repeatable field where full indication text is included in more than a single language. Only in cases where rich text shall be provided, Markdown language can be used, and the content of this field shall adhere to Markdown format.
Repeatable	Yes
Conformance	Mandatory (at least one language) Optional (for additional languages in countries with multiple languages)
Data Type	Markdown
RMS URI/URL	Not applicable
Value(s)	Free text or markdown text for rich content
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Indication
FHIR Path	MedicinalProductDefinition.indication
FHIR Complementary Information	The data element is repeatable by using a FHIR extension. Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

Example(s):



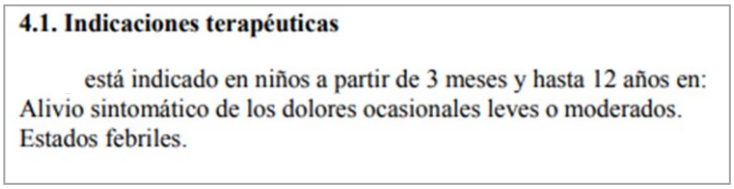
4. Clinical particulars

4.1 Therapeutic indications

Adults, elderly and Children over 12 years :

Rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza.

Indication text: Adults, elderly and Children over 12 years: Rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza.



4.1. Indicaciones terapéuticas

está indicado en niños a partir de 3 meses y hasta 12 años en:
Alivio sintomático de los dolores ocasionales leves o moderados.
Estados febriles.

Indication text: Medicinal Product XX esta indicado en niños a partir de 3 meses y hasta 12 anos en: Alivio sintomático de los dolores ocasionales leves o moderados. Estados febriles.

1.11.1. Language

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

Tag	Description
User Guidance	The language of the medicinal product indication, as approved by the regulatory authority and indicated in the corresponding regulatory document(s) shall be specified as a term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072057
Value(s)	As indicated in the Language RMS list
ISO Element Name	Not Applicable
ISO Path	Not Applicable
FHIR Element Name	valueCode
FHIR Path	MedicinalProductDefinition.indication.extension.language Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

1.12. EURD ID

The legal requirements for submission of Periodic Safety Update Reports (PSURs) are established in Regulation (EU) No 1235/2010, Directive 2010/84/EU and in Commission Implementing Regulation (EU) No 520/2012.

The 2010 legislation introduced the principle of EU single assessment where a substance is authorised in more than one Member State. The aim is to harmonise and strengthen the safety and benefit-risk review of medicines across the European Economic Area.

The Agency maintains a list of EU reference dates and frequency of submission of PSURs (EURD list) for active substances contained in medicines in the EU. This list is updated on an ongoing basis.

MAHs are required to submit PSURs to national competent authorities and the Agency according to the dates published in this list.

Tag	Description
User Guidance	When the medicinal product is part of a PSUR single assessment procedure in accordance with the European Union reference date dates and frequency of submission of periodic safety reports list (EURD list), the EURD ID shall be provided. The EURD ID shall be derived from the procedure number of the PSUR single assessment, which is published in the EURD list Excel file available on the 'Periodic safety update reports' webpage. In case of medicinal product with no active ingredient, the EURD ID can be left blank.
Repeatable	No
Conformance	Conditional

Tag	Description
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	The EURD ID should be included without any leading zeros and as listed in the Excel file "List of European Union reference dates and frequency of submission of periodic safety update reports"
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Identifier
FHIR Path	MedicinalProductDefinition.identifier
FHIR Complementary Information	MedicinalProductDefinition.identifier.system value is "http://ema.europa.eu/fhir/eurdId"

Example(s):

For procedure number PSUSA/00000009/202103, the EURD ID is 9. This value will be used for all medicinal products containing '5-aminolevulinic acid'.

List of Union reference dates and frequency of submission of periodic safety update reports (PSURs)

Related Information:
Introductory cover note to the List of European Union reference dates and frequency
Requests for amendments of the EU reference dates list
The PSUR assessment procedure will start according to the Timetables published
Single Assessment Reports of PSURs are shared among all Marketing Authorisation Holders involved in the concerned procedure.

ID	Active substances and combinations of active substances	Procedure number of the PSUR single assessment (DLP)	Procedure number of the PSUR single assessment procedure (Next DLP)
9	5-aminolevulinic acid (glioma)	PSUSA/00000009/202103	

1.13. Product classification

The medicinal product can be classified according to various classification systems. In the context of PMS iteration 1, the product classification describes the following product information:

- XEVMPD Medicinal product types;
- Legal basis;
- ATC Code(s);
- Medicinal product category
- Genetically modified organisms

The Product Classification class is mandatory and not repeatable while the individual attributes of this class are repeatable and shall be populated as applicable.

Product Classification Class	Description
Repeatable	No

Product Classification Class	Description
Conformance	Mandatory

1.13.1. xEVMPD product type information

The type of medicinal products shall be completed. Product type is for the purpose of pharmacovigilance fees in accordance with the current XEVMPD controlled list.

Tag	Description
User Guidance	The medicinal product type shall be provided as applicable as a term ID. • The applicable value(s) shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. • The value "Other" should be specified only if none of the other available values is applicable.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000000324
Value(s)	The System and Code should be specified as listed in the XEVMPD Medicinal Product Type RMS list
ISO Element Name	Product Classification
ISO Path	/MedicinalProduct/ProductClassification/
FHIR Element Name	productClassification
FHIR Path	MedicinalProductDefinition.productClassification

Example(s):

Medicinal product that is parallel distributed shall reference the value 'Parallel/Imported medicinal product (Article 76(3) and (4) of Directive No 2001/83/EC)'.

1.13.2. Legal basis

The legal basis for the marketing authorisation shall be provided.

- For medicinal products where the legal basis of the marketing authorisation predates Directive 2001/83/EC, (taking into account that the pharmaceutical Acquis Communautaire has been amended over time), the legal basis applicable under the current Union legal framework which corresponds to the legal basis in the legislation that was **applicable at time of submission of your application** shall be specified. This statement is in line with the xEVMPD requirement stated in Note 5 of Chapter 3.II: XEVPRM User Guidance.
- Where the authorisation procedure is specified as "EU Registration Procedures - Traditional use registration for herbal medicinal product the legal basis should also be selected as "Traditional use registration application for an herbal medicinal product (Article 16a of Directive No 2001/83/EC)".
- Where the authorisation procedure is specified as "EU Registration Procedures - Simplified registration procedure for homeopathic medicinal products" the legal basis should also be selected as "Simplified registration application for a homeopathic medicinal product (Article 14 of Directive No 2001/83/EC)".

Tag	Description
User Guidance	The legal basis for the marketing authorisation shall be provided as applicable as a term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. NOTE: The relevant RMS list contains terms which can be used for medicinal products that can be submitted into PMS on a voluntary bases.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000116045
Value(s)	The System and Code should be specified as listed in the Marketing Authorisation Application Legal Basis RMS list.
ISO Element Name	Product Classification
ISO Path	/MedicinalProduct/ProductClassification/
FHIR Element Name	productClassification
FHIR Path	MedicinalProductDefinition.productClassification

1.13.3. ATC code(s)

Tag	Description
User Guidance	• The ATC code as indicated in section *5.1 Pharmacodynamic properties* of the corresponding SmPC or other regulatory document shall be provided (if available) as an RMS term ID. If multiple values apply to the same medicinal product then multiple values shall be selected by repeating the field. • Deprecated (i.e., non-current) ATC Codes may be referenced. • All five levels of an ATC Code can technically be used; however, the most granular level of information is expected wherever available. • The applicable value(s) shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. • If ATC code is not available or is not yet defined this field shall be populated with the RMS ID referring to the substance group of the last available level of the ATC Codes and information in 1.13.3.1 - ATC Code flag completed.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000093533
Value(s)	Listed in the Anatomical Therapeutic Chemical classification system – Human RMS list
ISO Element Name	Product Classification
ISO Path	/MedicinalProduct/ProductClassification
FHIR Element Name	productClassification
FHIR Path	MedicinalProductDefinition.productClassification

Example(s):

Section 5.1 of the SmPC states:

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-epileptics, other anti-epileptics, ATC code: N03AX16.

ATC code N03AX16 should therefore be selected from the RMS list; in RMS this will be uniquely identified by a specific RMS ID (e.g., 100000093537).

1.13.3.1. ATC code(s) – Flag

Tag	Description
User Guidance	ATC Code - Flag shall be completed whenever ATC code is not available or is not yet defined with the following values: • True: Applicant or Marketing Authorisation holder applied for an ATC code, but it has not yet been assigned. • False: Applicant or Marketing Authorisation holder has not applied for ATC code or ATC code is not applicable.
Repeatable	No
Conformance	Conditional
Data Type	Boolean
RMS URI/URL	Not applicable
Value(s)	True / False
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	atcPending
FHIR Path	MedicinalProductDefinition.productClassification.extension.atcPending Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

1.13.4. Medicinal product category

The medicinal product category based on the nature of the active substance or combination of substances and based on how it exerts a pharmacological, immunological or metabolic action or whether it has a special classification (e.g., advanced therapy medicinal product, vaccine, etc.) shall be provided.

If multiple values apply to the same medicinal product, then multiple values shall be selected by repeating the field (e.g., A vaccine consisting of a recombinant protein will be classified as immunological and biological medicinal product).

Tag	Description
User Guidance	Indication on the type of medicinal product should be included to indicate on whether the medicinal product is biological, vaccine, ATMP, chemical or other product types based on the nature of active substance or combination of substances. The applicable value(s) shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	Yes
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000155526
Value(s)	Listed in the Product Category RMS list
ISO Element Name	Product Classification
ISO Path	/MedicinalProduct/ProductClassification
FHIR Element Name	productClassification

Tag	Description
FHIR Path	MedicinalProductDefinition.productClassification

Example(s):

Biological Medicinal Product, Immunological Medicinal Product, Advanced Therapy Medicinal Product, Chemical Medicinal Product

1.13.5. Genetically Modified Organisms (GMOs)

In accordance with the definition provided in Article 2(2) of Directive 2001/18/EC:

"'genetically modified organism (GMO)' means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."

Therefore, the Genetically Modified Organisms (GMOs) data element is required to be specified with the applicable value indicated in the below table.

Tag	Description
User Guidance	Genetically Modified Organisms attribute shall be completed to indicate whether a medicinal product contain or consists of Genetically Modified Organisms (GMOs) with the following values, based on the Directive 2001/18/EC: • Yes: shall be selected if the medicinal product does contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC • No: shall be selected if the medicinal product does not contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC
Repeatable	No
Conformance	Mandatory
Data Type	Boolean
RMS URI/URL	Not applicable
Value(s)	True / False
ISO Element Name	Product Classification
ISO Path	/MedicinalProduct/ProductClassification
FHIR Element Name	characteristic
FHIR Path	MedicinalProductDefinition.characteristic

1.14. Medicinal product name

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

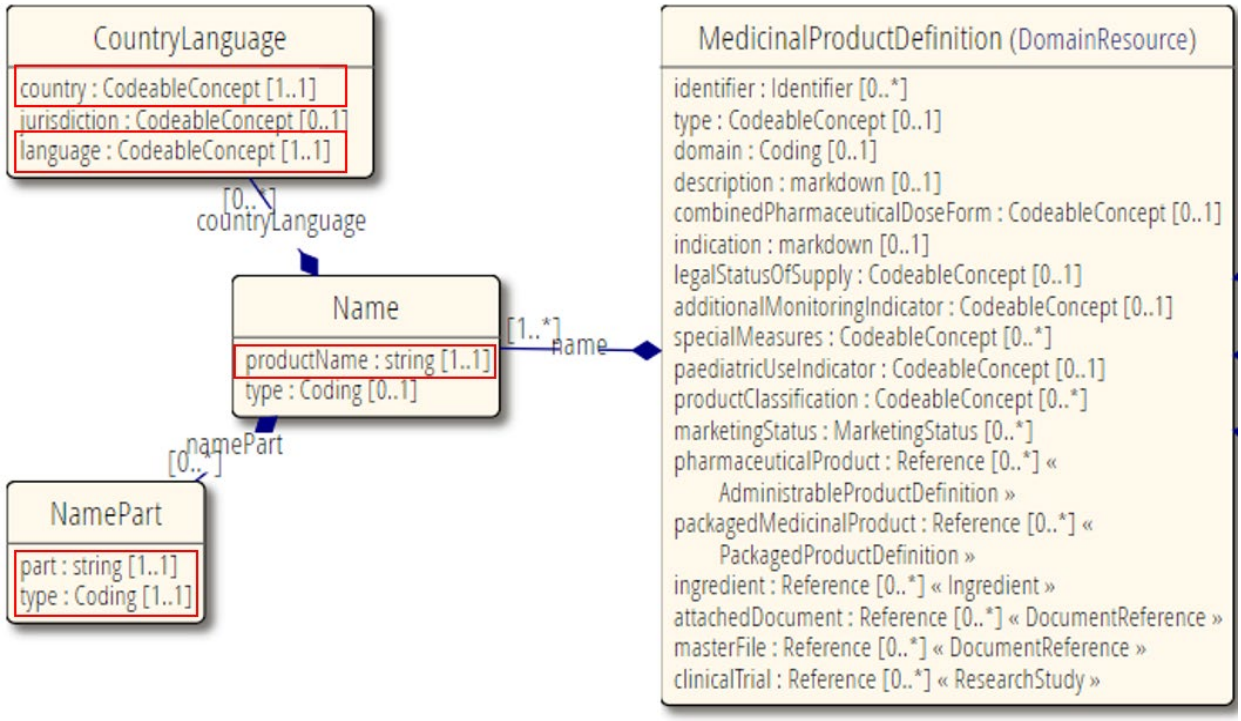


Figure 5: Extract of the Resource MedicinalProductDefinition (source: http://www.hl7.org/fhir)

The class is capturing the full medicinal product name in line with the country/language where the name applies. The class NamePart is capturing fragments (coding words or phrases) of the medicinal product name and is mandatory.

Note that the structure described above is implemented in a manner that does not allow the submission of various name parts independently in various languages; once it is deemed necessary to provide the name parts in a particular language, a minimum of mandatory fields (described below) shall be provided. For example, it is not possible to enter only the 'Intended use name part' in German and only the 'Invented name part' in French; the system will mandate for each language chosen a minimum set of fields.

Product name and name parts should be provided using the capitalisation as stated in the SmPC.

The Medicinal product name class is mandatory and repeatable while the individual attributes of this class are mandatory (with the exception of some name part data elements) and not repeatable (with the exception of the delimiter part name data element).

Medicinal product name Class	Description
Repeatable	Yes
Conformance	Mandatory

1.14.1. Full name

Tag	Description
User Guidance	The full medicinal product name as indicated in *Section 1: Name of the Medicinal Product* of the corresponding SmPC or other regulatory document shall be specified, in line with the local language of the country where the product is authorised.

Tag	Description
	• Full name, country and splitting of the name in parts shall be repeated as per applicable languages in multi-language countries (e.g., Belgium) • Based on the authorisation procedure, marketing authorisation holder may submit translations of the name in English on an optional basis (Refer to table 1a).
Repeatable	Yes
Conformance	Mandatory
Data Type	String
RMS URI/URL	Not applicable
Value(s)	The full medicinal product name as free text.
ISO Element Name	FullName
ISO Path	/MedicinalProduct/MedicinalProductName/FullName
FHIR Element Name	productName
FHIR Path	MedicinalProductDefinition.name.productName

Example(s):

Helia 200 mg compresse rivestite

BeatCold® Orange paracetamol easy-to-swallow tablets

Ibuprofen capsules

Diclofenac PharmaABC 32 Filmtabletten

DrugABC 2013/2014 suspension for injection (influenza vaccine, surface antigen, inactivated)

1.14.2. Country/Language

This section describes how to populate information on the language used for the product name, where the medicinal product name shall be provided in additional official languages used in a country. The class Country/Language is mandatory in the PMS implementation.

As a rule, it is mandatory when an SmPC/PL is available in a given language, the name and name parts in that language shall be provided; this is captured in the table below under the phrasing 'when applicable'.

For the centrally authorised products, conventionally, the authorisation country should be filled in as 'EU'.

The following table summarises the requirement:

Table 1a – Medicinal product – language requirements

Authorisation Procedure	Country of authorisation	Translations of medicinal product name and source documentation: Summary of Product Characteristics (SmPC)
Centralised Procedure (CAP)	EU Member states	English + All other languages as applicable in EU
	Iceland, Liechtenstein and Norway (IS/LI/NO)	English + National language(s) of the country of authorisation when applicable

Authorisation Procedure	Country of authorisation	Translations of medicinal product name and source documentation: Summary of Product Characteristics (SmPC)
Mutual Recognition Procedure (MRP)	EU Member state, (IS/LI/NO)	National language(s) of the country of authorisation Any other language when applicable English translation – optional submission
Decentralised Procedure (DCP)	EU Member state, (IS/LI/NO)	National language(s) of the country of authorisation Any other language when applicable English translation – optional submission
National Procedure (NAP)	EU Member state, (IS/LI/NO)	National language(s) of the country of authorisation Any other language when applicable English translation – optional submission

English SmPC is acceptable where the local SmPC has not yet been issued; once the SmPC in the national language becomes available it shall be provided in the context of the data maintenance; i.e., when the variation leads to changes.

List of official languages per country can be found on the EMA corporate website.

The Country/Language class and its attributes are mandatory and not repeatable.

Medicinal product name Class	Description
Repeatable	No
Conformance	Mandatory

1.14.2.1. Country

Tag	Description
User Guidance	The country where the medicinal product name has been authorised, as approved by the regulatory authority and indicated in the corresponding regulatory document(s), shall be specified as a term ID. • For products authorised through the **MRP/DCP** routes, the country of the marketing authorisation shall be selected (products introduced through this route are entered as individual product entities for each national authorisation). • For products authorised through purely **national procedure**, the country where the marketing authorisation was granted shall be selected) • For products authorised through **Centralised Procedure** the value EU shall be selected. Alternatively, Norway/Iceland/Liechtenstein shall be selected as Norway/Iceland/ Liechtenstein are entered as individual product entities. At least one country shall be specified per Medicinal Product name.

Tag	Description
	The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000002
Value(s)	As listed in the Country RMS list.
ISO Element Name	Country
ISO Path	/MedicinalProduct/MedicinalProductName/Country-Language/Country
FHIR Element Name	Country
FHIR Path	MedicinalProductDefinition.name.countryLanguage.country

Example(s):

France, Czech Republic, Ireland

1.14.2.2. Language

Tag	Description
User Guidance	The language of the medicinal product name for the specified country, as approved by the regulatory authority and indicated in the corresponding regulatory document(s) shall be specified as a term ID. • The applicable value shall be selected from the term and term ID as listed in the Referentials Management Service (RMS) list. • For products authorised through MRP/DCP/National Procedure the English translation of the name may be selected on a voluntary basis (Refer to table 1a). • For products authorised through MRP/DCP/National Procedure, in case of countries with multiple languages (e.g., Belgium) the medicinal product name in all official languages shall be specified (Refer to table 1b).
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072057
Value(s)	Listed in the Language RMS list
ISO Element Name	Language
ISO Path	/MedicinalProduct/MedicinalProductName/Country-Language/Language
FHIR Element Name	Language
FHIR Path	MedicinalProductDefinition.name.countryLanguage.language

Example(s):

French, English, Dutch

1.14.3. (Medicinal product name) name part(s)

The medicinal product name parts (*MedicinalProductDefinition.name.namePart*) shall be specified along with the language of the country as shown in section *1.14.2. Country/Language* and as the marketing authorisation applies in accordance with the referenced SmPC.

List of official languages per country can be found on the EMA corporate website.

For additional related information please refer also to:

- Table 1a - Medicinal Product – language requirements (refer to section 1.14.2. Country/Language);
- Table 1b - Requirements for Medicinal Product records and attachments for countries with more than one national language (refer to section 1.18. Attached document)

(Medicinal product name) name part(s) Class	Description
Repeatable	Yes – Delimiter part type No – All other name part types
Conformance	Mandatory

The parts of the medicinal product name should be specified as follows:

1.14.3.1. Name part type

Tag	Description
User Guidance	The applicable value(s) shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list Medicinal Product Name Part Type. In accordance with the definition provided in Article 1(20) of Directive 2001/83/EC, the name of the medicinal product may be an invented name or may be either the INN/common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder. Therefore, the following is required as minimum medicinal product name: • Either Type = *Invented name part* or/and Type = *Scientific name part* shall be specified as applicable in the product name part; • If Type = *Scientific name part* has been specified and the Type = *Invented name part* has NOT been specified, the Type = *Trademark or company name* part shall be specified as applicable When the full presentation name along with its corresponding information on 'Country' and 'Language' has been provided, it is expected that the 'Invented Name Part' is populated as minimum information. Where the 'Invented name part' is not applicable, both 'Scientific Name part' and 'Trademark or company name part' shall be populated as a minimum requirement. The system will reject the provision of name parts that do not comply with these minimal requirements in order to ensure that the information

Tag	Description
	provided as regard to the medicinal product name is meaningful (e.g.,: it is not accepted to provide only 'Name' and 'Intended use part' or only 'Device part' and 'Flavour part').
Repeatable	No
Conformance	Mandatory
Data Type	Coding
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/220000000000
Value(s)	The applicable name part type of the *Full name* as term listed in the Referentials Management Service (RMS) list Medicinal Product Name Part Type. A dedicated RMS list is available with the following values: • Invented name part • Scientific name part • Strength part • Pharmaceutical dose form part • Formulation part • Intended use part • Target population part • Container or pack part • Device part • Trademark or company name part • Time/period part • Flavour part • Delimiter part
ISO Element Name	(The types of the name parts from Medicinal Product Name)
ISO Path	/MedicinalProduct/Medicinal Product Name/{various}
FHIR Element Name	Type
FHIR Path	MedicinalProductDefinition.name.namePart.type

1.14.3.2. Name part text

Tag	Description
User Guidance	The fragment of a product name (as selected in 1.14.3.1) shall be specified as applicable.
Repeatable	No
Conformance	Mandatory
Data Type	String
RMS URI/URL	Not applicable
Value(s)	The applicable name fragment of the *Full name* as free text
ISO Element Name	(The name parts from Medicinal Product Name)
ISO Path	/MedicinalProduct/MedicinalProductName/{various}
FHIR Element Name	Part
FHIR Path	MedicinalProductDefinition.name.namePart.part

1.14.3.3. Name part convention and guidance

1.14.3.3.1. Invented name part

Invented name part	Description
Repeatable	No
Conformance	Conditional

The invented (i.e., trade) name part text, if contained within the *Full name*, shall be specified.

- If no invented name is included in the *Full name,* then no information needs to be provided in this data element.
- If a trademark symbol (e.g., ®, ™) is included in the full name, it shall not be provided in this data element. This information should be reported as trademark or company name part as indicated in section.1.14.3.3.10. Trademark or company name part of this Chapter.
- With the scope to facilitate the precise identification of the product concerned for pharmacovigilance purposes, if any qualifier [i.e., Plus, Zydis] is included in the full name, it shall be provided in this data element.

This does not apply in case of any other characteristics included in the Full name (i.e., target population, pharmaceutical dose form etc) to be reported in the designated name part(s) in the below reported additional data elements.

Example(s):

Full name: Helia™ 200 mg compresse rivestite

Invented part: Helia

Full name: BeatCold® Orange paracetamol slow release tablets

Invented part: BeatCold

Full name: Ibuprofen capsules

Invented part: *<this data element should not contain any information>*

Full name: Diclofenac PharmaABC 32 Filmtabletten

Invented part: *<this data element should not contain any information>*

Full name: DrugABC 2013/2014 suspension for injection (influenza vaccine, surface antigen, inactivated)

Invented part: DrugABC

Full name: XYZ Plus 20 Film-coated tablets

Invented part: XYZ Plus

Note: the examples above focus on the name part described and do not give a complete picture of all the name parts applicable to each example

1.14.3.3.2. Scientific name part

Scientific name part	Description
Repeatable	No
Conformance	Conditional

The scientific or common (i.e., generic) name part text, if contained within the Full name, shall be specified. If no common (i.e., generic) name is included in the Full name, then no information shall be specified in this data element.

With the scope to facilitate the precise identification of the product concerned for pharmacovigilance purposes, if any qualifier [i.e., Plus, Zydis] is included in the full name, it shall be provided in this data element. This does not apply in case of any other characteristics included in the Full name (i.e., target population, pharmaceutical dose form etc) to be reported in the designated name part(s) in the below reported additional data elements.

Example(s):

Full name: BeatCold® Orange paracetamol slow release tablets

Scientific part: paracetamol

Full name: Helia™ 200 mg compresse rivestite

Scientific part: *<this data element should not contain any information>*

Full name: Ibuprofen capsules

Scientific part: Ibuprofen

Full name: Diclofenac PharmaABC 32 Filmtabletten

Scientific part: Diclofenac

Full name: DrugABC 2013/2014 suspension for injection

Scientific part: *<this data element should not contain any information>*

Full name: Ibuprofen Zydis 40 Film-coated tablets

Scientific part: Ibuprofen Zydis

Note: the examples above focus on the name part described and do not give a complete picture of all name parts applicable to each example.

1.14.3.3.3. Strength part

Strength part	Description
Repeatable	No
Conformance	Conditional

The strength name part text, if contained within the Full name, shall be specified.

If no strength is included in the Full name, then no information shall be specified in this data element.

Note: The strength included in this field may be different from the strength of the active ingredient of the pharmaceutical product.

Example(s):

Full name:	Helia™ 200 mg compresse rivestite
Strength part:	200 mg
Full name:	Ibuprofen 400 mg Liquid Capsules
Strength part:	400 mg
Full name:	BeatCold® Orange paracetamol slow release tablets
Strength part:	*<this data element should not contain any information>*
Full name:	Diclofenac PharmaABC 32 Filmtabletten
Strength part:	*<this data element should not contain any information>*
Full name:	DrugABC 2013/2014 suspension for injection (influenza vaccine, surface antigen, inactivated)
Strength part:	*<this data element should not contain any information>*

Note: the examples above focus on the name part described and do not give a complete picture of all name parts applicable to each example.

1.14.3.3.4. Pharmaceutical dose form part

Pharmaceutical dose form part	Description
Repeatable	No
Conformance	Conditional

The pharmaceutical dose form name part text, if contained within the Full name, shall be specified. If no pharmaceutical dose form name is included in the Full name, then no information shall be specified in this data element.

Note: The pharmaceutical dose form name included in this data element may be different from the manufactured and/or administrable dose form.

Example(s):

Full name:	Helia™ 200 mg compresse rivestite
Pharmaceutical dose form part:	compresse rivestite
Full name:	BeatCold® Orange paracetamol slow release tablets
Pharmaceutical dose form part:	slow release tablets
Full name:	Ibuprofen capsules
Pharmaceutical dose form part:	capsules
Full name:	Diclofenac PharmaABC 32 Filmtabletten
Pharmaceutical dose form part:	Filmtabletten
Full name:	DrugABC 2013/2014 (influenza vaccine, surface antigen, inactivated)
Pharmaceutical dose form part:	*<this data element should not contain any information>*
Full name:	Superdrug Shower Gel
Pharmaceutical dose form part:	Shower Gel

Note: the examples above focus on the name part described and do not give a complete picture of the entire name parts applicable to each example.

1.14.3.3.5. Formulation part

Formulation part	Description
Repeatable	No

Formulation part	Description
Conformance	Conditional

The formulation name part text, if contained within the Full name, shall be specified. If no formulation name is included in the Full Name, then no information shall be specified in this data element.

Example(s):

Full name: XYZ Strawberry 120 mg/5 ml sugar free oral suspension for children

Formulation part: sugar free

Full name: BeatCold® Orange paracetamol slow release tablets

Formulation part: *<this data element should not contain any information>*

Full name: DrugABC 2013/2014 suspension for injection (influenza vaccine, surface antigen, inactivated)

Formulation part: *<this data element should not contain any information>*

Note: the examples above focus on the name part described and do not give a complete picture of all the name parts applicable to each example.

1.14.3.3.6. Intended use part

Intended use part	Description
Repeatable	No
Conformance	Conditional

The intended use name part text, if contained within the Full name, shall be specified.

If no intended use name is included in the Full name, then no information shall be specified in this data element.

Example(s):

Full name: DrugABC 200mg migraine relief tablet

Intended use part: migraine relief

Full name: XYZ Strawberry 120 mg/5 ml oral suspension for children

Intended use part: *<this data element should not contain any information>*

Full name:	ProductX Max Strength Heartburn Relief Oral Suspension
Intended use part:	heartburn relief

Full name:	Mivera contraceptive tablets
Intended use part:	contraceptive

Note: the examples above focus on the name part described and do not give a complete picture of all the name parts applicable to each example.

1.14.3.3.7. Target population part

Traget population part	Description
Repeatable	No
Conformance	Conditional

The target population name part text, if contained within the Full name, shall be specified.

If no target population name is included in the Full name, then no information shall be specified in this data element.

Example(s):

Full name:	XYZ Strawberry 120 mg/5 ml oral suspension for children
Target population part:	for children

Full name:	ProductX Infant Suspension
Target population name:	infant

Full name:	ABC Adult Vaccine, suspension for injection
Target population part:	adult

Full name:	BeatCold® Orange paracetamol slow release tablets
Target population part:	*<this data element should not contain any information>*

Note: the examples above focus on the name part described and do not give a complete picture of all the name parts applicable to each example.

1.14.3.3.8. Container or pack part

Container or pack part	Description
Repeatable	No
Conformance	Conditional

The container or pack name part text, if contained within the Full name, shall be specified.

If no container or pack name is included in the Full name, then no information shall be specified in this data element.

Example(s):

Full name: XYZ 50 mg/ml solution for injection in a vial

Container or pack part: in a vial

Full name: DrugABC 200mg migraine relief tablet

Container or pack part: *<this data element should not contain any information>*

Note: the examples above focus on the name part described and do not give a complete picture of all the name parts applicable to each example.

1.14.3.3.9. Device part

Device part	Description
Repeatable	No
Conformance	Conditional

The device name part text, if contained within the Full Name, shall be specified.

If no device name is included in the Full name, then no information shall be provided in this data element.

Example(s):

Full name: ProductX 100 units/ml solution for injection in pre-filled pen

Device part: in pre-filled pen

Full name: DruxY 160 Inhaler

Device part: inhaler

Full name: XYZ Strawberry 120 mg/5 ml oral suspension for children

Device part: *<this data element should not contain any information>*

Note: the examples above focus on the name part described and do not give a complete picture of all the name parts applicable to each example.

1.14.3.3.10. Trademark or company name part

Trademark or company name part	Description
Repeatable	No
Conformance	Conditional

The trademark or company name part text, if contained within the Full name, shall be specified.

If no trademark or company name is included in the Full name, then no information shall be specified in this data element except for cases where an invented name part is not mentioned in the full name. In these exceptional cases the organisation name (MAH name) should be entered in order to give the product name a minimum of identifiable product information.

Example(s):

Full name: Insulin PharmaX Comb 30/70 100 I.E.,/ml Zylinderampullen mit Injektionssuspension

Trademark or company name part: PharmaX

Full name: XYZ® Express 200 mg Liquid Capsules

Trademark or company name part: ®

Full name: Ibuprofen liquid capsules

Trademark or company name part: PharmaABC

Note that Company name was not included in the name. In this exceptional case, the name of the marketing authorisation holder shall be included (e.g., PharmaABC).

Full name: PharmaY Ibuprofen capsules

Trademark or company name part: PharmaY

Note: the examples above focus on the name part described and do not give a complete picture of all the name parts applicable to each example.

1.14.3.3.11. Time/period part

Time/period part	Description
Repeatable	No

Time/period part	Description
Conformance	Conditional

The time/period name of the medicinal product part text, if contained within the Full name, shall be specified.

If no time/period name is included in the Full name, then no information shall be specified in this data element.

Example(s):

Full name:	DrugABC 2013/2014 suspension for injection (influenza vaccine, surface antigen, inactivated)
Time/period part:	2013/2014

Full name:	Benny Allergy One A Day 20mg Tablets
Time/period part:	One A Day

Note: the examples above focus on the name part described and do not give a complete picture of all the name parts applicable to each example. Capitalisation/Format should be exactly as per the attached regulated document (e.g., SmPC). Requirements for attached regulated documents can be found in section 1.18. Attached document.

1.14.3.3.12. Flavour part

Flavour part	Description
Repeatable	No
Conformance	Conditional

The flavour name part text, if contained within the Full name, shall be specified.

If no flavour name is included in the Full name, then no information shall be specified in this data element.

Example(s):

Full name:	BeatCold paracetamol Orange syrup
Flavour part:	Orange

Full name:	PharmaABC sore throat relief lozenges lemon flavour
Flavour part:	lemon flavour

Note: the examples above focus on the name part described and do not give a complete picture of all the name parts applicable to each example.

1.14.3.3.13. Delimiter part

Delimiter part	Description
Repeatable	Yes
Conformance	Conditional

The delimiter name part text (including character such as /-(), and words including "and"), if contained within the Full name, shall be specified. The delimiter is used to separate one composite in a segment from another or separate one sub-composite from another.

Example(s):

Full name: Magraprime 5 mg / 15 mg tablets

Delimiter part: /

Full name: AmoAll (Amoxicillin 500 mg and Clavulanic acid 125 mg) tablets

Delimiter part: "And" ,"(" , ")"

1.15. (Pharmacovigilance) master file

The Pharmacovigilance master file location related to the authorised medicinal product shall be specified. Other type of master files (active substance master file, vaccine master file, plasma master file) are not currently in scope for this version of the EU IG.

The Pharmacovigilance system master file (PSMF) definition is provided in Article 1(28e) of Directive 2001/83/EC and the minimum requirements for its content and maintenance are set out in the Commission Implementing Regulation (EU) No 520/2012 on the Performance of Pharmacovigilance Activities Provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC (the Implementing Regulation is referenced as IR).

The detailed requirements provided by the Commission Implementing Regulation are further supported by the guidance in Module II – Pharmacovigilance system master file of the Good Vigilance Practice(s).

- The PSMF shall be located either:
  - at the site in the EU where the main pharmacovigilance activities of the marketing authorisation holder are performed; or
  - at the site in the EU where the qualified person responsible for pharmacovigilance operates [IR Art 7(1)].

As initial temporary process, registration of the PSMF location will need the use of two systems XEVMPD and PMS and will be performed in two steps:

- (1) At the time of the marketing authorisation application, the applicant should submit electronically the PSMF location information using the agreed format as referred to in chapter IV, Article 26 of the Commission Implementing Regulation (EU) No 520/2012 using the XEVMPD

database and XEVPRM format. This will generate a unique PSMF location reference number/identifier, which is the unique code assigned by the EMA to the master file.

- (2) Subsequently the PSMF location reference number/identifier generated in XEVMPD database should be linked to the medicinal product during the submission of product data in PMS.

This process will be revised in future versions of the EU IG to make use of a central repository for Master File information using SPOR capabilities.

The Pharmacovigilance system master file (PSMF) class and the individual attributes of this class are mandatory and not repeatable.

Pharmacovigilance system master file (PSMF) Class	Description
Repeatable	No
Conformance	Mandatory

1.15.1. File type

Tag	Description
User Guidance	The type of master file shall be specified. • The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. • For iteration 1 implementation, the value "PharmacoVigilance System Master File" shall always be specified.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/220000000070
Value(s)	Pharmacovigilance Master File to be selected from Master File Type RMS list.
ISO Element Name	File Type
ISO Path	/MedicinalProduct/MasterFile/FileType
FHIR Element Name	Type
FHIR Path	DocumentReference.type (referenced from MedicinalProductDefinition.masterFile)

Example(s):

Pharmacovigilance System Master File

1.15.2. File code

Tag	Description
User Guidance	The Pharmacovigilance System Master File Location (PSMFL) reference number/identifier generated by XEVMPD following successful registration in XEVMPD database shall be specified in PMS

Tag	Description
	• The MFL EV Code is the unique code assigned by the XEVMPD to a specific PSMF and to the location of the PSMF and it shall be specified accordingly. – If the Master File Location information was previously successfully submitted in the XEVMPD and a PSMFL EV Code had been assigned, the PSMFL shall be specified as available in the XEVMPD and as received in the XEVPRM Acknowledgement. – If the required Master File Location does not exist in the XEVMPD, the Master File Location information can be added using the 'Master File Location' section of the XEVPRM and submitted in the XEVMPD. • Further information on what triggers the request of PSMFL EV Code and how to submit MFL information in the XEVMPD are available in section *1.11. Initial submission of a Pharmacovigilance System Master File (PSMF) information* of the *Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2) of Regulation (EC) No. 726/2004* - Chapter 3.II: XEVPRM User Guidance. • Information on how the PSMFL entity should be maintained is described in section *2.3. Maintenance of a Pharmacovigilance System Master File Location (PSMFL) entity* of the *Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2) of Regulation (EC) No. 726/2004* - Chapter 3.II: XEVPRM User Guidance. This process will be revised in future versions of the EU IG to make use of the Organisation Management System and PMS as repository for Master File information.
Repeatable	No
Conformance	Mandatory
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	PSMFL as available in the XEVPMD/Article 57 database.
ISO Element Name	File Code
ISO Path	/MedicinalProduct/MasterFile/FileCode
FHIR Element Name	identifier
FHIR Path	DocumentReference.identifier (referenced from MedicinalProductDefinition.masterFile)
FHIR Complementary Information	DocumentReference.identifier.system value is "https://spor.ema.europa.eu/v1/lists/100000000009/terms/100000075665"

Example(s):

EV Code assigned to the PSMFL entity in the Article 57 database: *MFL1234*

1.16. Contact (QPPV)

MAHs are legally required to have a qualified person for pharmacovigilance (QPPV) based in the European Union (EU) in place at all times, in line with the Directive 2001/83/EC Article 104(3)(a).

Detailed information on how to register a QPPV can be obtained on the EudraVigilance registration webpage or in the EMA EudraVigilance Registration Manual.

The current registration of the QPPV is performed in two steps:

(1) QPPVs are required to self-register in the EMA Account Management Platform. Following the self-registration of the QPPV in the EMA Account Management Platform the QPPVs submit an EMA Service Desk request requesting their role to be certified by the EMA. Once the role is approved by the EMA, the QPPV retrieves the QPPV Code assigned.

(2) The QPPV is required to complete the registration information in the EudraVigilance restricted area.

Upon completion of the registration is, the **QPPV code from EudraVigilance shall be referenced in PMS**.

The details of the QPPV are pre-registered externally to PMS, therefore it is not necessary to provide full details of the QPPV again in the submission of the product. A reference to the identifier of the QPPV code of the pre-registered QPPV shall be used instead.

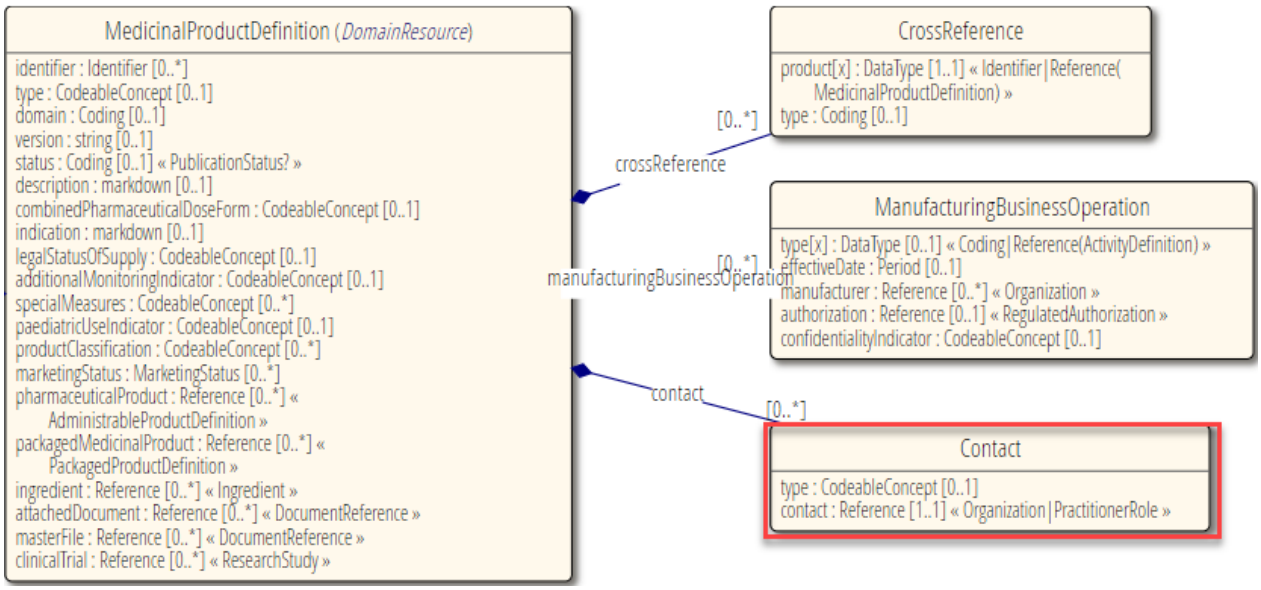


Figure 6: Extract of the Contact (QPPV) resource (source: http://www.hl7.org/fhir)

Contact (QPPV) class and its individual attributes are mandatory and not repeatable.

Contact (QPPV) Class	Description
Repeatable	No
Conformance	Mandatory

1.16.1. Identifier

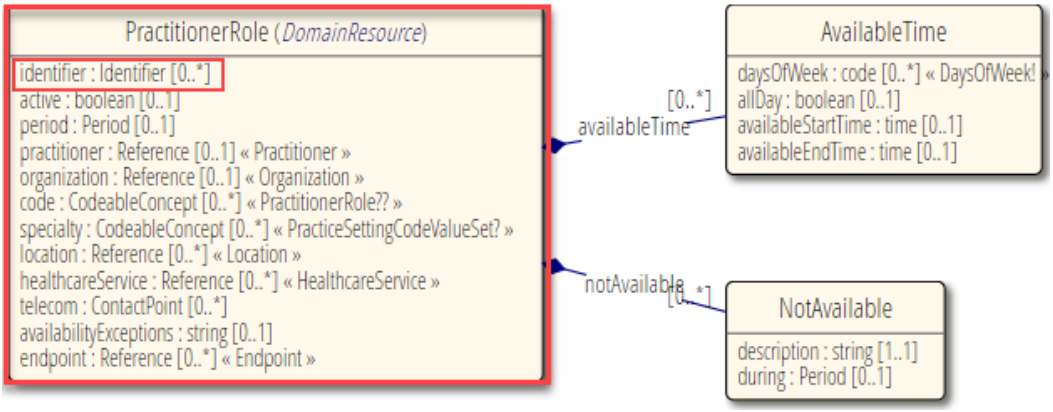


Figure 7: Extract of the Contact (Practitioner Role) resource (source: http://www.hl7.org/fhir)

Tag	Description
User Guidance	The identifier of the QPPV code as received after self-registration in the EMA Account Management Platform and completing the registration in EudraVigilance shall be specified. Please refer to the information available on the EudraVigilance: how to register webpage, section '*Registering individual users*'.
Repeatable	No
Conformance	Mandatory
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	The unique identifier of the QPPV shall be provided along with the reference to the system that issues it (EMA Account Management Platform)
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Identifier
FHIR Path	MedicinalProductDefinition.contact.contact(PractitionerRole).identifier
FHIR Complementary Information	MedicinalProductDefinition.contact.contact(PractitionerRole).identifier.system value to be defined based on RMS term entry for Source of Information RMS list.

Example(s):

1234

1.16.2. Role

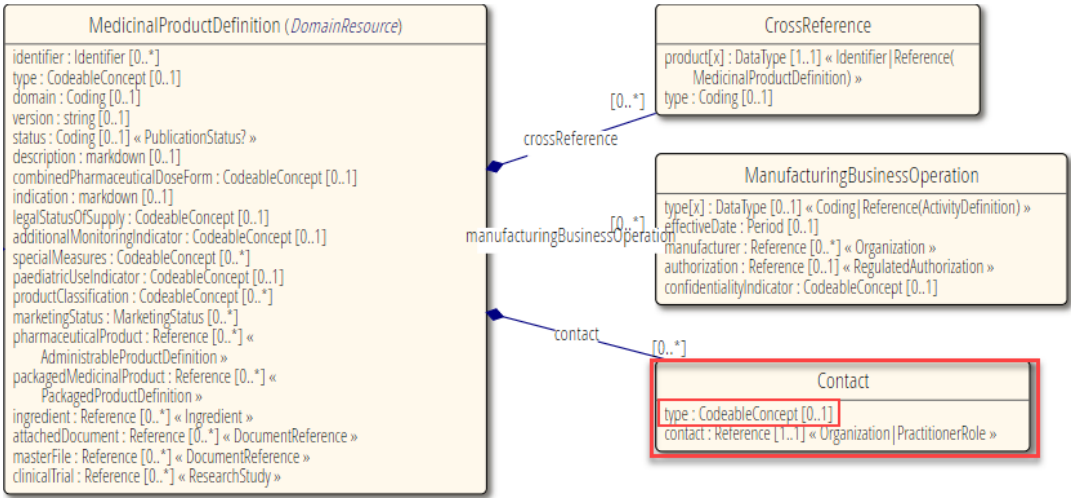


Figure 8: Extract of the Contact resource (source: http://www.hl7.org/fhir)

Tag	Description
User Guidance	The type of the contact in the context of the Medicinal Product shall be specified. For each medicinal product the type QPPV shall be specified. Only one QPPV can be specified per each medicinal product.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000154441
Value(s)	The value "Qualified Person in the EEA for Pharmacovigilance" shall be selected from the Contact Party Role RMS list.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Type
FHIR Path	MedicinalProductDefinition.contact.type

Example(s):

Qualified Person in the EEA for Pharmacovigilance (100000155057)

1.17. Pharmacovigilance enquiry information

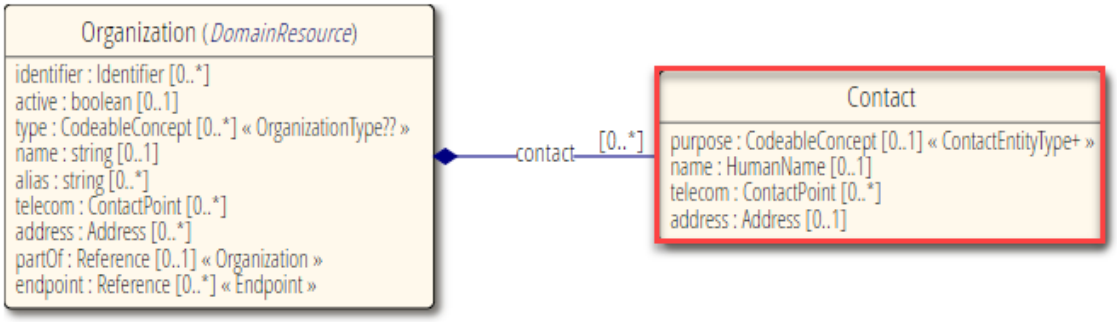


Figure 9: Extract of the Contact (Organization) resource (source: http://www.hl7.org/fhir)

The Pharmacovigilance enquiry information and its individual attributes are mandatory and repeatable, however one set of information is recommended to be specified.

Pharmacovigilance enquiry information Class	Description
Repeatable	Yes
Conformance	Mandatory

1.17.1. Email address

The information on Pharmacovigilance enquiry contacts is mandatory and shall be provided by means of the *Contact* Resource using the same representation described in section 1.16. Contact (QPPV).

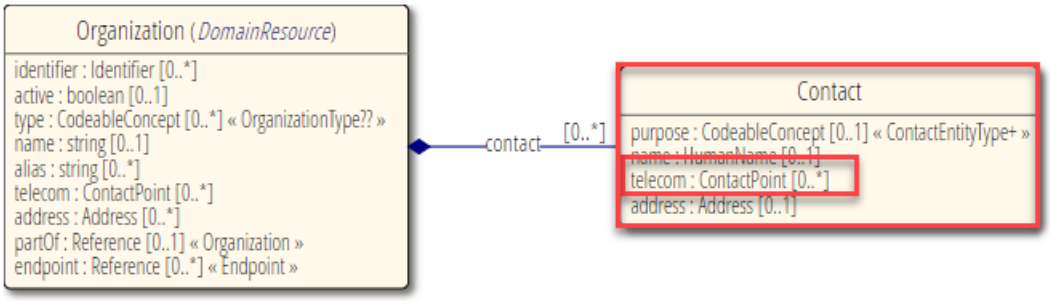


Figure 10: Extract of the detailed Contact (Organization) resource (source: http://www.hl7.org/fhir)

Tag	Description
User Guidance	The contact information for Pharmacovigilance enquires (functional e-mail and phone where enquiries related to Pharmacovigilance for each medicinal product shall be specified) will be made public by the Agency. This field carries the functional email address.
Repeatable	No
Conformance	Mandatory
Data Type	ContactPoint
RMS URI/URL	Not applicable
Value(s)	A valid email address.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Telecom

Tag	Description
FHIR Path	MedicinalProductDefinition.contact.contact(Organization).contact.telecom

Example(s):

system=email, value=pharmacovigilance@acme.com

1.17.2. Phone number

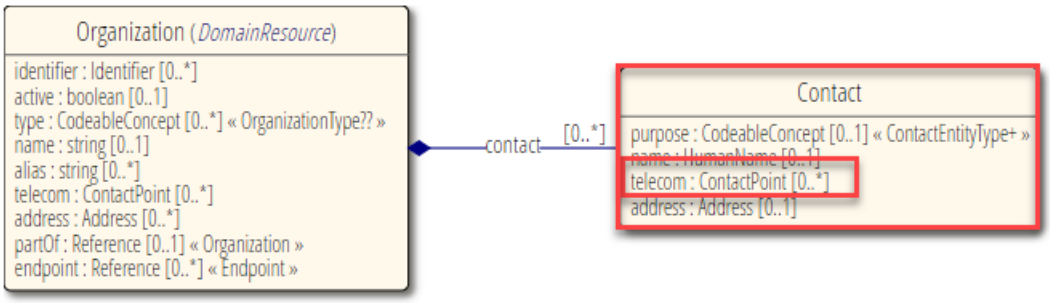


Figure 11: Extract of the detailed Contact (Organization) resource (source: http://www.hl7.org/fhir)

Tag	Description
User Guidance	The contact information for Pharmacovigilance enquiry (functional e-mail and phone where enquiries related to Pharmacovigilance for each medicinal product shall be specified) will be made public by the Agency. This field carries the phone number.
Repeatable	No
Conformance	Mandatory
Data Type	ContactPoint
RMS URI/URL	Not applicable
Value(s)	A valid phone number with international prefix.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Telecom
FHIR Path	MedicinalProductDefinition.contact.contact(Organization).contact.telecom

Example(s):

system=phone, value=+311234567890

1.17.3. Role

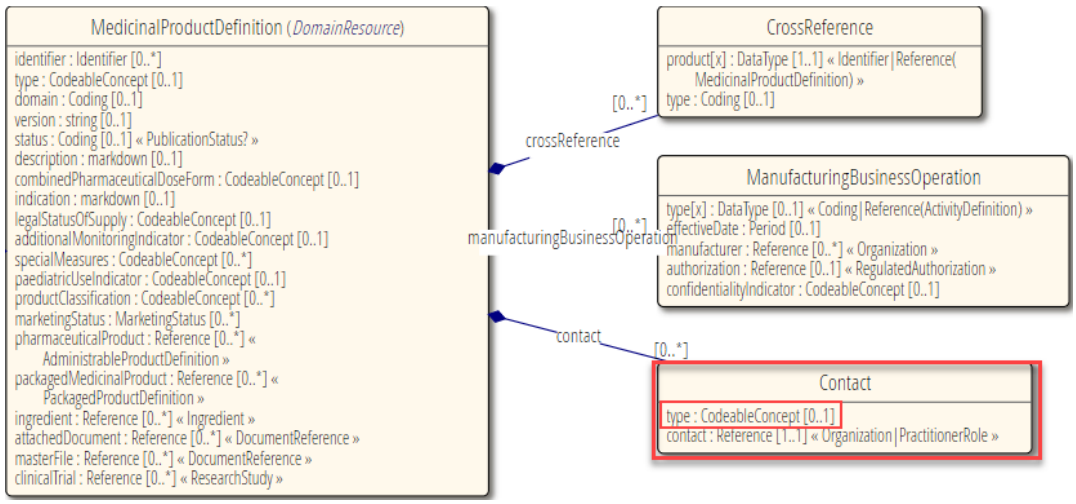


Figure 12: Extract of the Contact resource (source: http://www.hl7.org/fhir)

Tag	Description
User Guidance	The type of the contact in the context of the Medicinal Product shall be specified, indicating that this contact is of type pharmacovigilance enquiry information.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000154441
Value(s)	The value "Pharmacovigilance Enquiry Information" shall be selected from the Contact Party Role RMS list
ISO Element Name	Role
ISO Path	/MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationHolder/Contact/Role
FHIR Element Name	Type
FHIR Path	MedicinalProductDefinition.contact.type

1.18. Attached document

The medicinal product shall reference at least one document(s) supporting the regulatory process (e.g., initial marketing authorisation, variation, renewal, transfer of marketing authorisation etc.).

A copy of the SmPC document as authorised by the authorising body shall be provided. If this is not available, another equivalent document such as a package leaflet shall be provided.

i.e.,Note 1: The common contents of each document [i.e., Module 1.2 – Electronic Application form (eAF), Relevant sections in Module 3 – Quality, Summary of Product Characteristics (SmPC)] supporting the regulatory process shall be aligned where applicable to ensure the discrepancies across the documents are minimized. The content should enhance the quality of the product data reported in Product Management Service (PMS). This requirement applies to new medicinal products single entry in PMS. Refer to Submission of medicinal product data using FHIR.

Table 1b - Requirements for medicinal product records and attachments for countries with more than one national language

Country	National language(s)	Different MPID assigned?	Attachment to be used for reference	Comment	Language to be used when specifying medicinal product name and its applicable name part(s)
Belgium	Dutch	No	SmPC		Dutch
	French	No	SmPC		French
	German	No	PL	Since there is no SmPC in German, the PL is to be used The document granting authorisation/renewal should also be provided if the authorisation number or equivalent identifier is not stated in the referenced PL	German
Finland	Finnish	No	SmPC		Finnish
	Swedish	No	SmPC or PL	In cases where there is no SmPC in Swedish, the PL is to be used The document granting authorisation/renewal should also be provided if the authorisation number or equivalent identifier is not stated in the referenced PL	Swedish
Ireland	English	No	SmPC		English
	Irish	No	n/a	Authorisations are not issued in Irish and no SmPC/PL exists in this language	n/a
Luxembourg*	French	No	SmPC or an equivalent document (e.g., PL or similar text as authorised	French or Belgian SmPC/PL in French can be used The document granting authorisation/renewal should also be provided if the authorisation number	French

Country	National language(s)	Different MPID assigned?	Attachment to be used for reference	Comment	Language to be used when specifying medicinal product name and its applicable name part(s)
			by the Authorising Body)	or equivalent identifier is not stated in the referenced SmPC/PL	
	German	No	SmPC or an equivalent document (e.g., PIL or similar text as authorised by the Authorising Body)	German, Austrian or Belgian SmPC/PL in German can be used The document granting authorisation/renewal should also be provided if the authorisation number or equivalent identifier is not stated in the referenced SmPC/PL	German
	Luxembourgish	No	n/a	Authorisations are not issued in Luxembourgish and no SmPC/PL exists in this language	n/a
Malta	English	No	SmPC	The document granting authorisation/renewal should also be provided if the authorisation number or equivalent identifier is not stated in the referenced SmPC	English
	Maltese	No	n/a	Authorisations are not issued in Maltese and no SmPC/PL exists in this language	n/a

* Table 1b covers the scenario when the French as well as the German SmPC/PL are provided to the Luxembourgish Authority. If the MAH decided to provide only the French SmPC/PL or only the German SmPC/PL to the Luxembourgish Authority, then only one applicable document should be submitted in PMS.

Where, in exceptional circumstances, the national SmPC for **non-centrally authorised products** (MRPs/DCPs/NAPs) is not available, a similar text (i.e., the English common text, package leaflet or other similar text as authorised by the Authorising Body) can be used as an attachment for the submission in PMS. The medicinal product name and its applicable name part(s) shall however be provided in the language of the country where the marketing authorisation applies.

In addition, the following documents from module 1 and module 3 of the Common Technical Dossier (CTD) dossier shall be included where available (e.g., first submissions, changes in the composition of the medicinal product, changes/introductions of manufacturers of the finished product or active substance):

- Module 1.2 – Electronic Application form (eAF) (The eAF is the only document in Module 1.2 required, to be provided where relevant);
- Module 3.2.S.2.1 Manufacturer(s) (name, dosage form);
- Module 3.2.P.1 Description and Composition of the Drug Product (name, dosage form);
- Module 3.2.P.3.1 Manufacturer(s) (name, dosage form);

For Centrally Authorised products only the English version is required.

Document File type and format

The allowed file types for printed product information (i.e., SmPC/PL/marketing authorisation decision) and module 3 of the CTD dossier are: .PDF (1) [format: PDF v.1.4 and above, preferable PDF/A], .DOC (2), .DOCX (3).

Note: Scanned documents uploaded in PDF format should be avoided.

The FHIR DocumentReference (Figure 6) resource is used to describe documents. In the context of Iteration 1 of the PMS implementation, the information in figure 6 highlighted in red is within the scope and should be provided according to the rules and guidance described in this section:

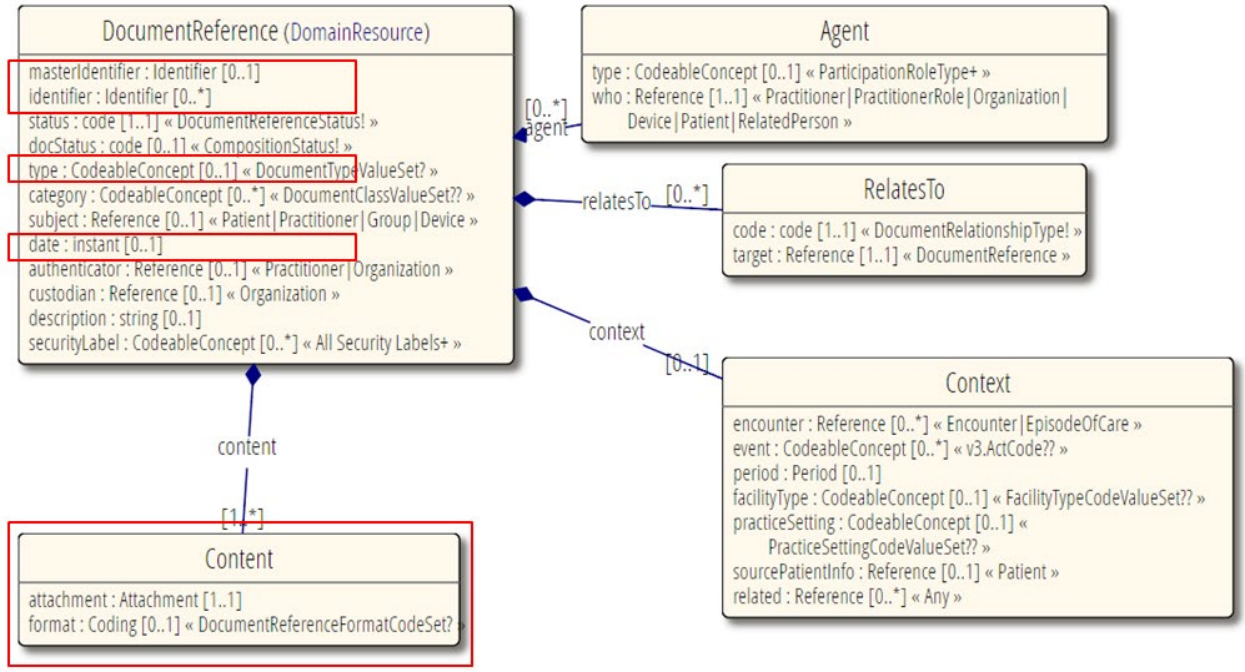


Figure 13: Resource DocumentReference (source : http://www.hl7.org/fhir)

The Attachment document class is mandatory and repeatable while the individual attributes of this class are not repeatable (except for the alternative (Attached document) Identifier data element) and shall be populated as applicable.

Attachment document Class	Description
Repeatable	Yes

Attachment document Class	Description
Conformance	Mandatory

1.18.1. Master (Attached document) Identifier

This section allows the MAH to indicate the identifier generated by the PMS system once the applicable attached document is uploaded into PMS.

The Attached document Identifier Section is completed in two steps:

(1) The intended document is directly uploaded into PMS. Once uploaded, PMS assigns a document identifier automatically and this information is available for the user (Refer to API Specification (Chapter VI) for further information).

(2) The user should record the PMS Attached Document Identifier during the submission on Medicinal Product Data.

The use of this data elements is based on the established processes of document submission discussed in EU IG Chapter 3 - Process for the electronic submission of medicinal product information (Stepwise approach for PMS Implementation).

The Master (Attachment document) Identifier attributes are conditional and not repeatable.

Attachment document Class	Description
Repeatable	No
Conformance	Conditional

1.18.1.1. Identifier value

Tag	Description
User Guidance	The ID assigned to the document once it is uploaded to the **PMS system**, which refers to the medicinal product, shall be specified. This identifier is specific to this version of the document. This unique identifier may be used elsewhere to identify this version of the document. Refer to Annex 9.1.1 of SPOR API technical specifications v2 Not applicable in the case of Nationally Authorised Products during Step 1 of implementation of the TOM, unless the medicinal product data is chosen to be submitted via API.
Repeatable	No
Conformance	Mandatory
Data Type	String
RMS URI/URL	Not applicable
Value(s)	Relevant identifier assigned by PMS once document is uploaded
ISO Element Name	Identifier
ISO Path	/MedicinalProduct/AttachedDocument/Identifier
FHIR Element Name	value
FHIR Path	DocumentReference.identifier.value (referenced from MedicinalProductDefinition.attachedDocument)

1.18.1.2. Identifier system

Tag	Description
User Guidance	The source system relevant to the attached documentation can be specified. The term "Product Management Service" shall be provided as a term ID from the Source of Information RMS list.
Repeatable	No
Conformance	Mandatory
Data Type	URI
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000009
Value(s)	URI referencing to the applicable RMS term from the Source of Information RMS list (i.e., https://spor.ema.europa.eu/v1/lists/100000000009/terms/100000075665).
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	System
FHIR Path	DocumentReference.identifier.system (referenced from MedicinalProductDefinition.attachedDocument)

Example(s):

- Product Management Service (PMS) [200000024893]

1.18.2. Alternative (Attached document) Identifier

This section allows the MAH to indicate whether the attached document has any other identifier in XEVMPD or any other external identifier that is used to identify the attached document, in addition to the referring source system.

This data elements can be used either to complete the information in addition to the 1.19.1. Master (Attached document) identifier or alternatively when information on 1.19.1. is not available.

The use of this data elements is based on the established processes of document submission discussed in EU IG Chapter 3 - Process for the electronic submission of medicinal product information (Stepwise approach for PMS Implementation). The Alternative (Attachment document) Identifier attribute is optional and repeatable.

Attachment document Class	Description
Repeatable	Yes
Conformance	Optional

1.18.2.1. Identifier value

Tag	Description
User Guidance	The ID assigned to the document by another source system. The EV Code of the attachment referring to the authorised medicinal product may be specified if applicable.

Tag	Description
	• If the attachment to be referenced was already submitted in the XEVMPD and an attachment EV Code has been assigned, • If the corresponding attachment is not available in the XEVMPD, the attachment identifier of another external system can be provided (i.e., applicant's document identifier in case the attachment is available in the industry's database and an identifier is assigned to it). • If the corresponding attachment is provided via the eCTD link, the link path to the attachment can be provided in this data element
Repeatable	No
Conformance	Mandatory
Data Type	String
RMS URI/URL	Not applicable
Value(s)	The pattern of the EV Code is 'ATT' followed by a number or alternatively the eCTD path. In the context of the migration of the Article 57 data from the XEVMPD into PMS, this information will be automatically provided in PMS as described in Chapter 7 of this Guidance.
ISO Element Name	Identifier
ISO Path	/MedicinalProduct/AttachedDocument/Identifier
FHIR Element Name	value
FHIR Path	DocumentReference.identifier.value (referenced from MedicinalProductDefinition.attachedDocument)

Example(s):

ATT12345

1.18.2.2. Identifier system

Tag	Description
User Guidance	The source system relevant to the attached documentation identifier can be specified. For each specified value can correspond only one source system. • If the attachment identifier is the EV Code assigned in xEVMPD, the "Extended EudraVigilance Medicinal Product Dictionary" is to be selected, • If the attachment identifier is referring to another external system such as the internal industry database, the term "Applicant's document" is to be selected • If the attachment is provided via the eCTD link and the link path to the attachment can be provided in this data element, the term "electronic Common Technical Document" is to be selected
Repeatable	No
Conformance	Mandatory
Data Type	URI

Tag	Description
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000009
Value(s)	URI referencing to the applicable RMS term from the Source of Information RMS list (i.e., https://spor.ema.europa.eu/v1/lists/100000000009 /terms/100000075665)
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	System
FHIR Path	DocumentReference.identifier.system (referenced from MedicinalProductDefinition.attachedDocument)

Example(s):

- Extended EudraVigilance Medicinal Product Dictionary (100000075665);

- electronic Common Technical Document (100000153730)

- Applicant's document (200000025171)

1.18.3. (Attached document) Type

Tag	Description
User Guidance	The value indicating the type of document shall be specified as a term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. In case where the approved SmPC does not state an authorisation number, a date of authorisation/renewal or the MAH, a copy of the document granting or renewing marketing authorisation (i.e., Letter of authorisation) should also be provided as an additional attachment. This list is to be updated with additional required values.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	• https://spor.ema.europa.eu/v1/lists/100000155531 • https://spor.ema.europa.eu/v1/lists/100000155719 • https://spor.ema.europa.eu/v1/lists/100000155552
Value(s)	As applicable in one the following RMS lists: • Product Information Document Type: Summary of Product Characteristics; Package leaflet eCTD EU Context of Use: M1.2 Application Form; M3.2.P.1 Description and Composition of the Drug Product (name, dosage form); M3.2.P.3.1 Manufacturer(s) (name, dosage form); M3.2.S.2.1 Manufacturer(s) (name, manufacturer) • Regulating Authority Submission Unit Type: Authorisation letter • Notification from a Competent Authority of the end/approval of regulatory procedure
ISO Element Name	Type
ISO Path	/MedicinalProduct/AttachedDocument/Type
FHIR Element Name	Type

Tag	Description
FHIR Path	DocumentReference.type (referenced from MedicinalProductDefinition.attachedDocument)

1.18.4. (Attached document) Effective Date

Tag	Description
User Guidance	The date, by which the corresponding updates become effective, as specified in the attached reference document shall be specified once available. • Where the version date is reflected in the SmPC (i.e., the physical document), it should be reflected as presented in section *10. Date of revision of text* of the SmPC. • When the date is not stated in the physical document, the date when the SmPC/module 1/module 3 documents have been approved by the NCA can be provided. • For quality changes not requiring regulatory approval to be included in the terms of the marketing authorisation (e.g., Type IA variations), the date of the implementation of this change should be provided.
Repeatable	No
Conformance	Conditional
Data Type	Period
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month, should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Effective Date
ISO Path	/MedicinalProduct/AttachedDocument/EffectiveDate
FHIR Element Name	Date
FHIR Path	DocumentReference.context.period.start (referenced from MedicinalProductDefinition.attachedDocument)

1.18.5. (Attached document) Language

Tag	Description
User Guidance	The language used in the attached document(s) of the specified country shall be specified as term ID. • The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	Yes
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072057

Tag	Description
Value(s)	Listed in the Language RMS list
ISO Element Name	Language
ISO Path	/MedicinalProduct/AttachedDocument/Language
FHIR Element Name	valueCodeableConcept
FHIR Path	DocumentReference.content.extension.language(referenced from MedicinalProductDefinition.attachedDocument) Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

Example(s):

French (100000072175), English (100000072147)

1.18.6. URL value (New)

Tag	Description
User Guidance	The URL of the document as identifiable in the Document API of PMS
Repeatable	No
Conformance	Mandatory
Data Type	url
RMS URI/URL	Not applicable
Value(s)	REST endpoint URL based on https://spor.ema.europa.eu/v*/documents
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	url
FHIR Path	DocumentReference.content.attachment.url(referenced from MedicinalProductDefinition.attachedDocument)

1.18.7. (Attached document) Status (New)

Tag	Description
User Guidance	This field is mandatory in the FHIR specification. The value 'current' shall be used always.
Repeatable	No
Conformance	Mandatory
Data Type	code
RMS URI/URL	Not applicable
Value(s)	Hardcoded to 'current'
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	status

Tag	Description
FHIR Path	DocumentReference.status (referenced from MedicinalProductDefinition.attachedDocument)

1.19. Product cross-reference

A cross-reference to one or more medicinal products is to be made, if applicable, using this section.

The section applies to the following scenarios:

1. If a medicinal product has been authorised under the following legal basis (or equivalent previous legislation):
   - Generic application (Article 10(1) of Directive No 2001/83/EC);
   - Hybrid application (Article 10(3) of Directive No 2001/83/EC)
   - Similar biological application (Article 10(4) of Directive No 2001/83/EC);
   - Informed consent application (Article 10(c) of Directive No 2001/83/EC);

   the PMS ID of the innovator medicinal product should be provided.

   In addition, duplicate applications of any legal basis submitted under Article 82(1) of Regulation (EC) No 726/2004 should also be cross-referenced.
2. If a medicinal product is a Parallel Imported medicinal product (based on Article 76(3)), the PMS ID of the following related products may be provided as follows:
   - Source medicinal product of Parallel Import: medicinal product authorised in a different country acting as source of the imported medicinal product in the destination country.
   - Reference medicinal product of Parallel Import: medicinal product already authorised in the destination country and which serves as a reference for the parallel imported product intended to be imported into the destination country.

If the above scenarios apply for medicinal products, product cross-reference should be made even if the originator product has been withdrawn of the market.

In the context of the iteration 1 implementation, only PMS ID can be referenced in this data element and Investigational Medicinal Product Identifiers (including EV Codes as assigned by the XEVMPD system for development products) are out of scope.

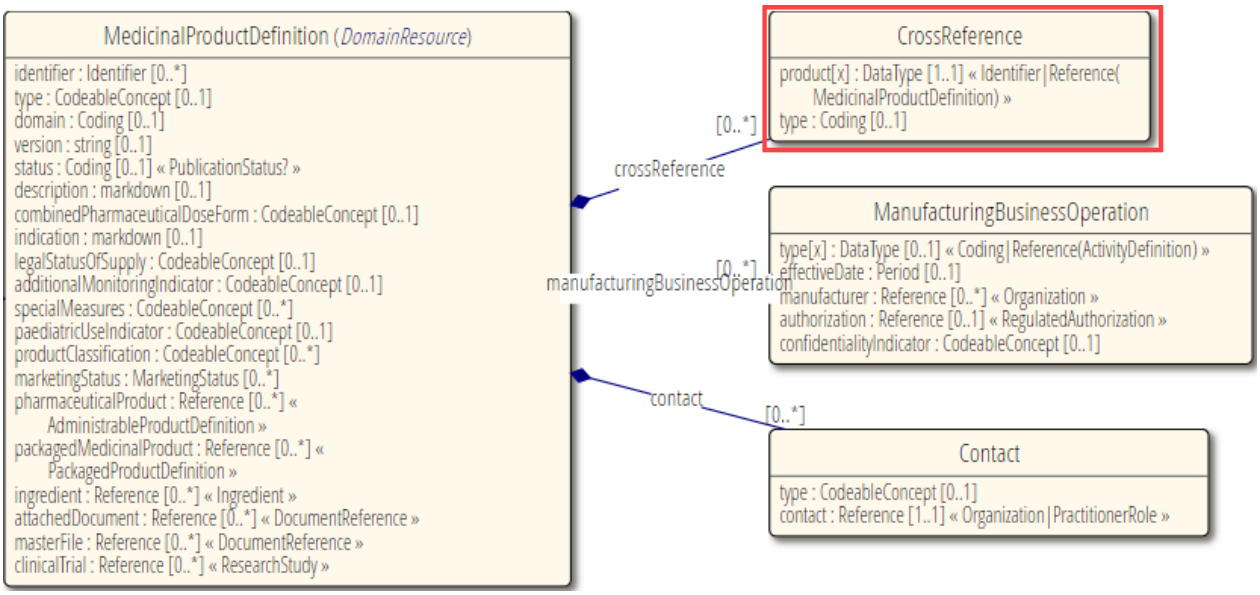


Figure 14: Extract of the Product cross-reference resource (source: http://www.hl7.org/fhir)

The Product cross-reference class including the individual attributes are conditional and not repeatable.

Product cross-reference Class	Description
Repeatable	Yes
Conformance	Conditional

1.19.1. Product cross-reference type

Tag	Description
User Guidance	If applicable, the type of medicinal product that is referenced shall be specified as a term ID. The applicable value shall be selected from the term ID as listed in the Referentials Management Service (RMS) list. This list is to be updated with additional required values.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/220000000017
Value(s)	As listed in the Product Cross Reference Type RMS list.
ISO Element Name	Referenced Product Type
ISO Path	/MedicinalProduct/ProductCross-Reference/ReferencedProductType
FHIR Element Name	Type
FHIR Path	MedicinalProductDefinition.crossReference.type

Example(s):

Generic of (220000000020), Biosimilar to (220000000018), Reference medicinal product of parallel import (200000026060), Source medicinal product of parallel import (200000026059)

1.19.2. Product cross-reference resource identifier

The Product Cross-Reference class is conditional. Should the Product Cross-Reference class be applicable, the following guidance applies:

Tag	Description
User Guidance	The PMS ID of the medicinal product that is referenced shall be provided. This applies to products under specific legal basis (e.g., Generic, Hybrid, Biosimilar) as reflected in introduction to section 1.19. Product cross-reference. Any reference in the resource identifier cross-reference section shall not be a nullified version of the medicinal product. This section is mandatory in case that product reference type is selected.
Repeatable	No
Conformance	Mandatory
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	PMS ID
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	productReference
FHIR Path	MedicinalProductDefinition.crossReference.productReference

Example(s):

PMS ID: 00005005

PMS ID: 00009105

1.20. Manufacturing business operation

This section describes how to populate information related to manufacturing sites and their operations. This includes all activities performed by the manufacturing site involved in the processing of a medicinal product or an active substance e.g., manufacturing, quality control, packaging and batch certification.

This section shall be completed for each individual manufacturing site that performs any operation with regards to the manufacturing of the finished product as reflected in module 3.2.P.3.1, and of the active substance as reflected in 3.2.S.2.1. The 'Manufacturing Business Operation' class is mandatory in the context of PMS implementation. This section is repeatable depending on the number of operation types to include. If a manufacturing site performs more than one operation type with regards to the manufacturing of the finished product and of the active substance, this section shall be repeated to report the relevant information.

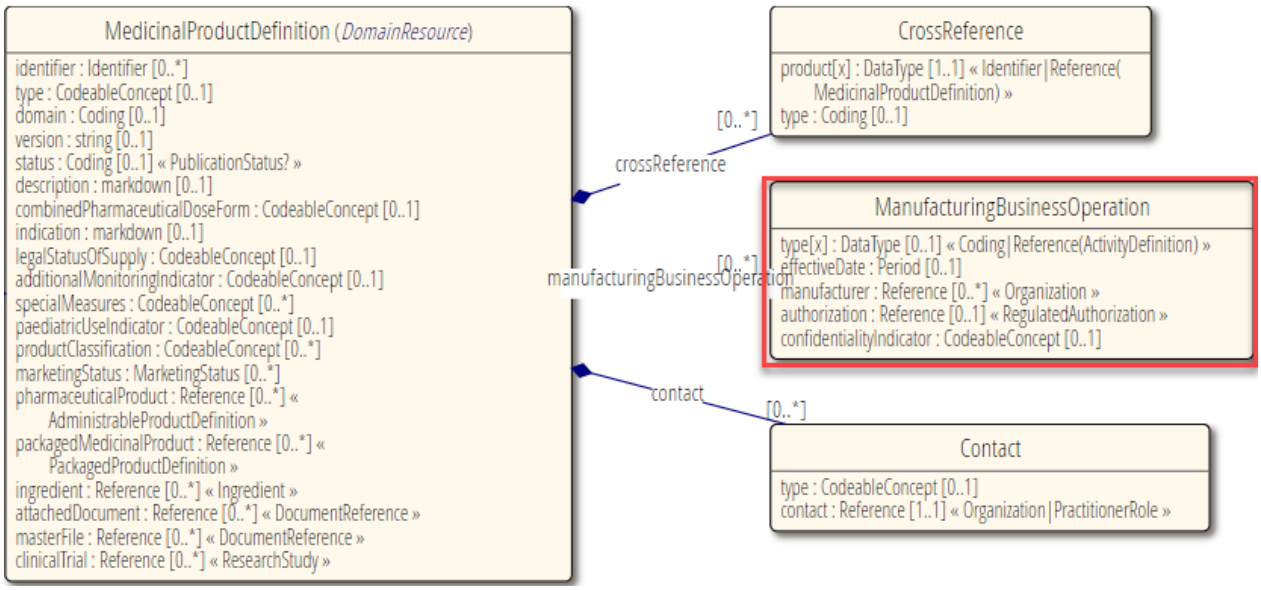


Figure 15: Extract of Manufacturing Business Operation resource (source: http://www.hl7.org/fhir)

The Manufacturing business operation class is mandatory and repeatable while the individual attributes of this class are not repeatable and shall be populated as applicable.

Manufacturing business operation Class	Description
Repeatable	Yes
Conformance	Mandatory

1.20.1. Manufacturer

Tag	Description
User Guidance	The Manufacturer shall be specified using the location identifier (LOC ID) linked to the organization as listed in the Organisation Management System (OMS) following a successful registration of the organisation's details. If the required organisation and/or related location are not available, the addition of the unlisted organisation and/or related location should be requested from OMS using the process described in the OMS Web User Manual in the 'Documents' section of the Organisation Management System (OMS). When the LOC ID is specified, the system would give the information to which ORG ID the selected location is linked in the back end. This information will be shown through the PMS User Interface.
Repeatable	No
Conformance	Mandatory
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	As listed in SPOR OMS service (LOC ID)
ISO Element Name	Manufacturer(Organisation)
ISO Path	MedicinalProduct/ManufacturerEstablishmentOrganisation/Manufacturer(Organisation)

Tag	Description
FHIR Element Name	manufacturingBusinessOperation
FHIR Path	ActivityDefinition.participant.extension.manufacturingBusinessOperation Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

1.20.2. Operation type

This section describes the operation(s) being performed by the manufacturing site for a 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 section *2.5 - Manufacturers* of the initial Marketing Authorisation Application electronic application form (in case of initial submission) and module 3.2.P.3.1 / 3.2.S.2.1 – Manufacturers (in case of changes to the terms of the marketing authorisation).

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

In addition, all manufacturing sites involved in the manufacturing process of the active substance, including quality control/ in-process testing sites should be listed. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks should also be included.

For details on the applicable manufacturing operations See Compilation of Union Procedures on Inspections and Exchange of Information document, (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 shall be specified as a term ID. The applicable value shall be selected from the term ID as listed in the Manufacturing Activity Referentials Management Service (RMS) list. The applicable manufacturing operation(s) to be completed as per section 2.5 of the initial Marketing Authorisation eAF. Manufacturing operations of finished product and/or active substance (include manufacturers of intermediates of the active substance) to be included as applicable.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000160406
Value(s)	Listed in the Manufacturing Activity RMS list
ISO Element Name	Operation Type
ISO Path	/MedicinalProduct/ManufacturerEstablishmentOrganisation/ManufacturingBusinessOperation/OperationType
FHIR Element Name	code
FHIR Path	ActivityDefinition.code

Example(s):

Primary packaging, Processing of sterile medicinal product – terminally sterilised,

Quality control testing – Biological,

Manufacture of active substance intermediate by chemical synthesis

1.20.3. Manufacturing operation start date

Tag	Description
User Guidance	The date when the manufacturing operation is approved/included in the terms of the marketing authorisation of the medicinal product, shall be provided: • For manufacturing operations requiring regulatory approval to be included in the terms of the marketing authorisation, the date of finalisation of the applicable regulatory procedure should be provided. In this case, this data field can only be populated with the necessary information upon end of the regulatory procedure as this information will not be available at the time of the submission of the FHIR message (initial sequence). • For manufacturing operations not requiring regulatory approval to be included in the terms of the marketing authorisation (e.g., Type IA variations), the date of the implementation of this change in the Quality System should be provided.
Repeatable	No
Conformance	Conditional
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Not Applicable
ISO Path	Not Applicable
FHIR Element Name	start
FHIR Path	ActivityDefinition.effectivePeriod.start

1.20.4. Manufacturing operation end date

Tag	Description
User Guidance	The date when the manufacturing operation is discontinued, and consequently removed from the terms of the marketing authorisation of the medicinal product shall be provided: • For manufacturing operations not requiring regulatory approval to be included in the terms of the marketing authorisation (e.g., Type IA

Tag	Description
	variations), the date of the implementation of this change in the Quality System should be provided. • For manufacturing operations requiring regulatory approval to be included in the terms of the marketing authorisation, the date of finalisation of the applicable regulatory procedure should be provided.
Repeatable	No
Conformance	Conditional
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e.,, YYYY-MM).
ISO Element Name	Not Applicable
ISO Path	Not Applicable
FHIR Element Name	end
FHIR Path	ActivityDefinition.effectivePeriod.end

1.20.5. Confidentiality indicator

Confidentiality indicator shows whether the manufacturing operation performed by a manufacturing site is classified as confidential or public information. This information shall be associated with a manufacturing operation.

Manufacturer information and its link to specific medicinal products that are included in the public domain (e.g., batch release site, manufacturer of active substance for biological products) as mandated by the current regulatory framework shall be classified as public/non-restricted information. Remaining manufacturing operations are classified as confidential, therefore are not accessible to the public.

Confidentiality is completed at the level of the manufacturing operations being performed by a given manufacturer. E.g., Manufacturer **ABCD** may perform primary packaging and batch release operations for a given product. In this case, the operation/activity batch release is specified as public information whereas primary packaging is specified as confidential information.

Tag	Description
User Guidance	The type of level of confidentiality of the manufacturing operation should be specified as Confidential/Public information The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list Data Classification.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept

Tag	Description
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000004983
Value(s)	The value(s) "Confidential" or "Public" shall be selected from the term ID as listed in the Data Classification RMS list.
ISO Element Name	Confidentiality Indicator
ISO Path	/MedicinalProduct/ManufacturerEstablishmentOrganisation/ManufacturingBusinessOperation/ConfidentialityIndicator
FHIR Element Name	confidentialityIndicator
FHIR Path	MedicinalProductDefinition.manufacturingBusinessOperation.confidentialityIndicator

Example(s):

Confidential (200000004984), Public (200000004985)

1.20.6. Manufacturing authorisation reference number

The reference number of the authorisation issued by the relevant Medicines Regulatory Agency (national competent authority) for the manufacturing of medicinal products shall be selected.

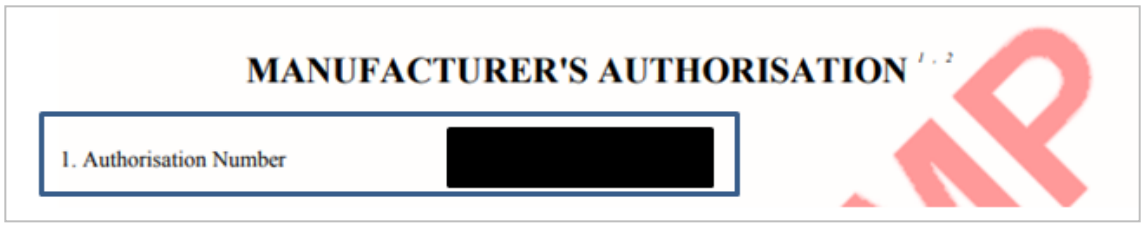
- If the manufacturing site is in the EEA: Reference Number of the Manufacturing and Importation authorisation (MIA).
- If manufacturing site is located outside the EEA: Reference number of the equivalent of the manufacturing authorisation.
- If manufacturing site is located outside the EEA and the site has been inspected by an EEA authority: reference number of the relevant GMP certificate.

Tag	Description
User Guidance	The reference number of the authorisation for manufacturing or its equivalent as provided by the medicines regulatory agency (national competent authority), shall be specified. • If manufacturing site is **located in the EEA**: Authorisation number to be extracted from section 1 of the Union format for Manufacturer's Authorisation or from "MIA number" column in EudraGMDP. • If manufacturing site is located **outside the EEA**: Reference number of the equivalent of the manufacturing authorisation. • If manufacturing site is located **outside the EEA and the site has been inspected by an EEA authority**: Authorisation number is to be extracted from section "Certificate number" within the certificate or from "Certificate number" column in EudraGMDP.
Repeatable	No
Conformance	Conditional
Data Type	Identifier
RMS URI/URL	Not applicable

Tag	Description
Value(s)	Reference Number
ISO Element Name	Manufacturing Authorisation Reference Number
ISO Path	/MedicinalProduct/Manufacturer-Establishment_Organisation/Manufacturing-BusinessOperation/ManufacturingAuthorisationReferenceNumber
FHIR Element Name	identifier
FHIR Path	RegulatedAuthorization.identifier (subject reference to relevant ActivityDefinition)
FHIR Complementary Information	RegulatedAuthorization.identifier.system value is "http://ema.europa.eu/fhir/manufacturingAuthorizationNumber"

Example(s):

Manufacturing Authorisation certificate number



482927, 0000000069/19/1

GMP certificate reference numbers

1.20.7. Effective date

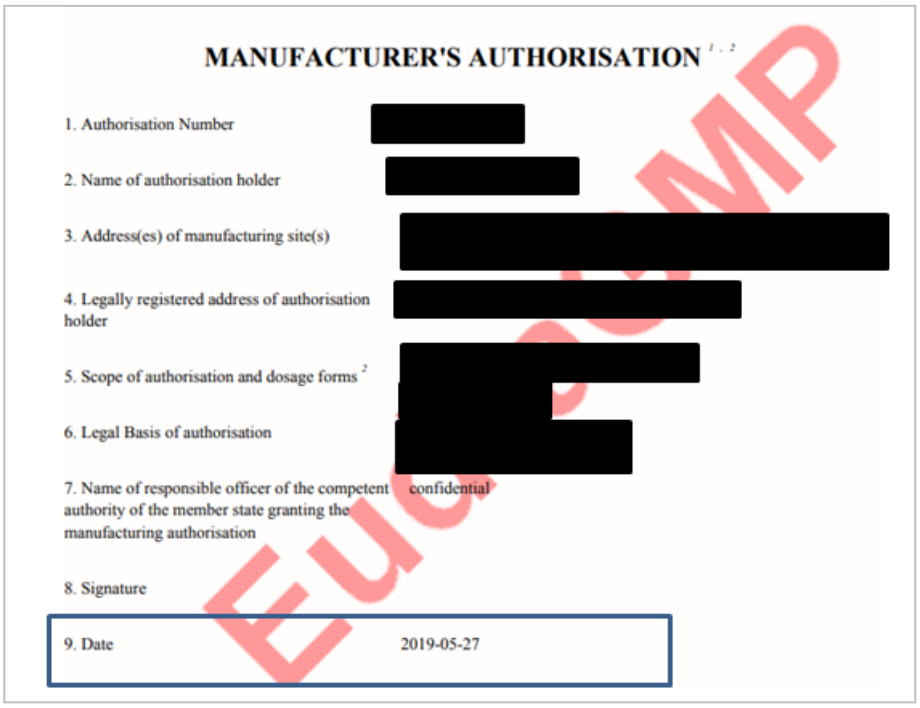
Tag	Description
User Guidance	The effective date of the Manufacturing Authorisation as stated in the authorisation should be indicated if known. If manufacturing site is **located in the EEA**: Effective date to be extracted from section 9 of the Union format for Manufacturer's Authorisation or from "Authorisation Date" column in EudraGMDP. If manufacturing site is **located outside the EEA**: • Effective date extracted from the equivalent applicable authorisation issued by the local authority. • Effective date extracted from the GMP certificate issue by an EEA authority or from column "Inspection End Date" in EudraGMDP.

Tag	Description
	• This value is an attribute within Manufacturing Authorisation Reference Number.
Repeatable	No
Conformance	Conditional (if Manufacturing Authorisation Reference Number is introduced and effective date is available)
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Effective Date
ISO Path	/MedicinalProduct/ManufacturerEstablishmentOrganisation/Manufacturing-BusinessOperation/EffectiveDate
FHIR Element Name	start
FHIR Path	RegulatedAuthorization.validityPeriod.start (subject reference to relevant ActivityDefinition)

Example(s):

2017-06-21

2012-12



1.20.8. (Manufacturing business operation) Medicines Regulatory Agency Organisation

The applicable Medicines regulatory agency, also referred as national competent authority or supervisory authority, responsible for issuing the manufacturing authorisation should be indicated.

Tag	Description
User Guidance	Medicines regulatory authority shall be specified using the organisation (ORG ID) and the related location identifier (LOC ID) as listed in the Organisation Management System (OMS) following a successful registration of the organisation's details. If the required organisation and or related location are not available, the addition of the unlisted organisation and/or related location should be requested from OMS using the process described in the OMS Web User Manual in the 'Documents' section of the Organisation Management System (OMS). If the required address of the medicines regulatory authority is not specified in the documentation, the LOC ID can be left empty. When the LOC ID is specified, the system would give the information to which ORG ID the selected location is linked in the back end. This information will be shown through the PMS User Interface
Repeatable	No
Conformance	ORG ID: Mandatory LOC ID: Conditional (if Manufacturing Authorisation Reference Number is introduced and the information is available)
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	As listed in SPOR OMS service (ORG ID; LOC ID)
ISO Element Name	MedicinesRegulatoryAgency(Organisation)
ISO Path	MedicinalProduct/ManufacturerEstablishmentOrganisation/MedicinesRegulatoryAgency(Organisation)
FHIR Element Name	regulator
FHIR Path	RegulatedAuthorization.regulator (subject reference to relevant ActivityDefinition)

2. Marketing authorisation information

In this section, information about the marketing authorisation shall be specified.

Marketing authorisation is issued by a competent authority, in 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 medicinal product on a market in that specific region. If a marketing authorisation for a 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 human 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 medicines throughout the EU. See the Authorisation of medicines webpage for related information.

Where no formal marketing authorisation holder is established, the distributor shall be specified (e.g., parallel imported medicinal products submitted on a voluntary basis). However, the obligation to electronically submit information on all medicinal products for human use, authorised in the European Union to the EMA, applies to marketing-authorisation holders only. No information needs to be submitted by parallel distributors in PMS based on the current legal basis and scope of the submission.

The full information on Marketing Authorisation as presented in the FHIR *Resource RegulatedAuthorization* is shown in Figure 8 below:

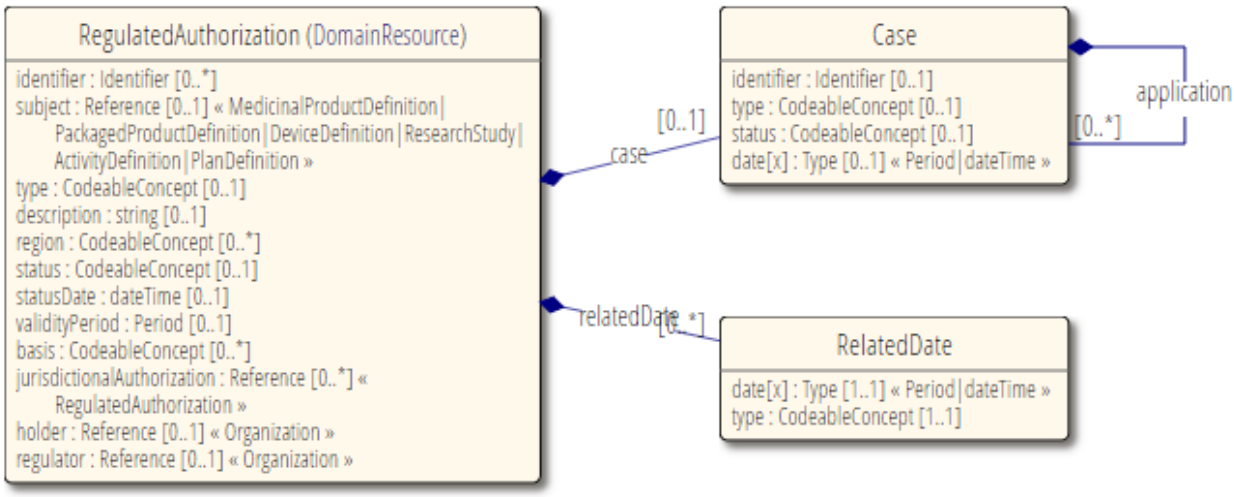


Figure 16: Resource RegulatedAuthorization (source: http://www.hl7.org/fhir)

The Marketing Authorisation class is mandatory and not repeatable while the individual attributes of this class are not repeatable and shall be populated as applicable.

Marketing authorisation Class	Description
Repeatable	No
Conformance	Mandatory

In the context of the Iteration 1 of the PMS implementation, the following elements are in scope and information should be provided according to the rules and guidance described in this section.

2.1. Regulatory authorisation type

Regulatory applications may be submitted to obtain different types of authorisations or regulatory entitlements, such as orphan designations, ATMP classification, marketing authorisations etc. in accordance with the current European regulatory framework for medicinal products. The regulatory authorisation type "Marketing Authorisation" shall be specified in this section.

In case the marketing authorisation is assigned at the level of the packaged medicinal product, refer to section 4.7.2. of this Chapter.

Tag	Description
User Guidance	The type of regulatory authorisation shall be specified when the marketing authorisation is assigned at the level of medicinal product. Please note that the RegulatedAuthorization type shall be set as Marketing Authorisation. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/220000000060
Value(s)	As listed in the Regulatory Entitlement Type RMS list. The RMS term "Marketing Authorisation" shall be selected.
ISO Element Name	Not Applicable
ISO Path	Not Applicable
FHIR Element Name	Type
FHIR Path	RegulatedAuthorization.type

2.2. Marketing authorisation number

Marketing authorisation number or equivalent identifier assigned by the competent authority as indicated in section *8. Marketing authorisation number(s) of the corresponding SmPC* or other regulatory document(s), shall be specified.

- If the MA number was assigned by the EU Commission, then the MA number as stated in section 8. Marketing authorisation number(s) of the corresponding SmPC or as stated in the EC decision document shall be specified.
- If the MA number or equivalent identifier was assigned by the national competent authority and by EEA countries, then the MA as stated in section 8. Marketing authorisation number(s) of the corresponding SmPC and applicable NCA's database or regulated document shall be specified.
- Only one MA number or equivalent identifier can be referenced in this data element.
- Where the authorisation number or equivalent identifier is assigned at Packaged Medicinal Product level, the stable "root' number" only shall be provided at the medicinal product level (e.g., EU/1/YY/NNNN, applicable to centrally authorized medicinal products). Any authorisation numbers or equivalent identifier assigned to the individual packages shall be provided at the package level

as described in section 4.7.2. Marketing authorisation number (Package level). This is to avoid creation of duplication of product entries based of the granularity of authorisation number. This rule applies to authorised medicinal products with one or more than one presentation.

- Where the authorisation number or equivalent identifier is assigned at Packaged Medicinal Product level and no stable "root number" common to all packaged medicinal products is assigned, then this section is to be left blank and it is mandatory to provide the marketing authorisation number or equivalent identifier at packaged medicinal product level (refer to section 4.7). This rule applies to authorised medicinal products with one or more than one presentation.
- Where the authorisation number or equivalent identifier is assigned at the level of the Medicinal Product and the same authorisation number or equivalent identifier applies to more than one package, the authorisation number or equivalent identifier shall be reported in this section only. This is to avoid creation of duplication of same product entries based on the number of authorised Packaged Medicinal Products.

Tag	Description
User Guidance	Marketing Authorisation number shall be specified. • Where the authorisation number is assigned at Packaged Medicinal Product level, the stable "root number" common to all packaged medicinal products shall be specified. • Where the authorisation number is assigned at Packaged Medicinal Product level and no stable "root number" common to all packaged medicinal products is assigned, this section is to be left blank and it is mandatory to provide the marketing authorisation number at packaged medicinal product level (refer to section 4.7.2). This section is to be completed when the information is available. Because the Marketing Authorisation Number or equivalent identifier is released by the competent authority after the end of the regulatory procedure, this data field can only be populated with the necessary information upon formal conclusion of the regulatory procedure as this information will not be available at the time of the submission of the FHIR message (initial sequence).
Repeatable	No
Conformance	Conditional
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	The number as assigned by the competent authority of a country/jurisdiction shall be specified as free text. The format of the EU number root number shall be "EU/1/YY/NNN " or "EU/1/YY/NNNN" (as applicable)
ISO Element Name	Marketing Authorisation Number
ISO Path	/MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationNumber
FHIR Element Name	Identifier
FHIR Path	RegulatedAuthorization.identifier
FHIR Complementary Information	RegulatedAuthorization.identifier.system value is "http://ema.europa.eu/fhir/marketingAuthorizationNumber"

Example(s):

Where the local national competent authority assigns authorisation numbers as per example below, where each number is corresponding to a different package with a common root number to all packages:

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/1/13/016/001

EU/1/13/016/002

EU/1/13/016/003

The authorisation number captured at this level should be entered as EU/1/13/016, whereas the full MA (EU Number): EU/1/13/016/001, EU/1/13/016/002, EU/1/13/016/003 will be captured at package level.

2.3. Country

Tag	Description
User Guidance	The country code of the country where the marketing authorisation was granted shall be specified as a term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. • For medicinal products authorised via the centralised procedure, "European Union (EU)" shall be specified. • For medicinal products authorised in Liechtenstein, Norway and Iceland via the centralised procedure, the country code (i.e., LI/NO/IS) shall be specified. • For medicinal products authorised via national or MRP/DCP procedure, the EEA country shall be specified. • For medicinal products authorised outside the EU/EEA area, a non-EEA country shall be specified. Medicinal products authorised outside the EU/EEA area may be optionally submitted. Such medicinal products are not within the scope of Article 57(2) requirements. This value is an attribute within Marketing Authorisation domain.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000002
Value(s)	As listed in the Country RMS list

Tag	Description
ISO Element Name	Country
ISO Path	/MedicinalProduct/MarketingAuthorisation/Country
FHIR Element Name	Region
FHIR Path	RegulatedAuthorization.region

Example(s):

100000000529 – Kingdom of Spain

100000000390 - European Union

2.4. Authorisation status

Tag	Description
User Guidance	The status of the marketing authorisation of the medicinal product throughout its lifecycle shall be specified as a term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. A different authorisation status can apply to each package of the same medicinal product (e.g., one package can be withdrawn while another is still valid). The authorisation status of the medicinal product can only be one. Therefore, the following rules shall be followed to fill the authorisation status field at medicinal product level: • If all the packages have the same authorisation status, this value should be used at product level. • If different values apply to the different packages, then, the following priority list should be used. That means that the first term in this list used in any package will define the authorisation status at product level. Valid > Valid Transferred > Valid Renewed > Valid after lifting of suspension > Suspended > Expired due to Sunset Clause > Expired > Withdrawn > Not renewed > Revoked This value is an attribute within Marketing Authorisation domain.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072049
Value(s)	As listed in the Regulatory Entitlement Status RMS list
ISO Element Name	Authorisation Status
ISO Path	/MedicinalProduct/MarketingAuthorisation/AuthorisationStatus
FHIR Element Name	Status
FHIR Path	RegulatedAuthorization.status

Example(s):

Not renewed

Expired

Revoked

Valid

2.5. Authorisation status date

Tag	Description
User Guidance	• The date at which the authorisation status has become effective shall be specified when available. • The date when the first authorisation was granted by the authorising body or the date when the renewal was granted (whichever is the latest) shall be specified in line with section *9. Date of first authorisation/renewal of the authorisation* of the SmPC or any other regulatory document. • The date of expiry/revocation/withdrawal of the MA shall be specified if the MA was: – withdrawn by the MAH, – revoked by the competent authority, – not renewed by the competent authority, – not submitted for renewal by the MAH, – expired due to Sunset Clause. • The date of **suspension** of the MA shall be entered if the authorisation status is set to *Suspended*. • The date of **renewal** of the MA shall be entered if the authorisation status is set to *Valid – after renewal* • In case that status "Valid after lifting of suspension is selected" in previous attribute the date of lifting of the suspension shall be entered.
Repeatable	No
Conformance	Conditional
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Authorisation Status Date
ISO Path	/MedicinalProduct/MarketingAuthorisation/AuthorisationStatusDate
FHIR Element Name	statusDate
FHIR Path	RegulatedAuthorization.statusDate

2.6. Date of first authorisation

Tag	Description
User Guidance	The date when the first authorisation (either from an initial marketing authorisation application regulatory procedure or line extension application regulatory procedure) was granted by the competent authority. This

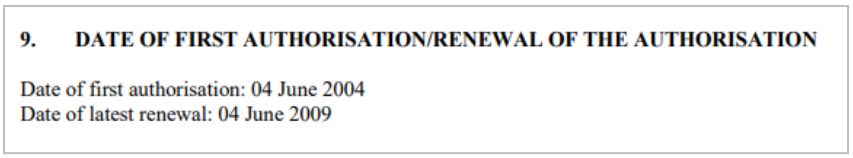
Tag	Description
	information shall be specified once the medicinal product has been authorised. This information shall be in line with the information indicated in section *9. Date of first authorisation/renewal of the authorisation* of the corresponding SmPC, if this refers to: the first authorisation and not to a renewal, to other regulatory documents (e.g., European Commission decision for CAPs) or databases from a National Competent Authorities/Regulator. For medicinal products authorised in Liechtenstein, Norway and Iceland through the centralised procedure the Date of First Authorisation (i.e., LI/NO/IS) might be different. In this case, this date is country specific and therefore, different first approval dates can be reported per country/region. In cases of old medicinal products where the first marketing authorisation was granted in early 1900s and the Date of First Authorisation is unknown this data element can be populated with the generic value: "Unknown".
Repeatable	No
Conformance	Mandatory
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM). When the date is not known the value part of the dateDateTime element can be missed out (keeping the element itself), and the reason for this specified using the data absent reason extension, with a value of "unknown".
ISO Element Name	Date of First Authorisation
ISO Path	/MedicinalProduct/MarketingAuthorisation/DateOfFirstAuthorisation
FHIR Element Name	dateDateTime
FHIR Path	RegulatedAuthorization.relatedDate.dateDateTime or RegulatedAuthorization.relatedDate.dateDateTime.extension.dataAbsentReason
FHIR Complementary Information	RegulatedAuthorization.relatedDate.type.system value is "http://ema.europa.eu/fhir/authorisationDateType" RegulatedAuthorization.relatedDate.type.code is "dateOfFirstAuthorisation"

Example(s):

The SmPC states the following:

Date of first authorisation should therefore reference 2005-10-05. **Example(s):**

The SmPC states the following:



Date of first authorisation should therefore reference 2004-06-04.

2.7. International birth date

The international birth date (IBD), is defined as the date of the first marketing authorisation for any medicinal product for human use containing the active substance, granted to any company in any country in the world.

The European birth date (EBD) is defined as the date of the first marketing authorisation granted by a decision of the European Commission for a medicinal product for human use to the MAH in the EU.

In the case that the medicinal product containing the active substance is first authorised in European Union, the European Birth Date equals the IBD.

If the IBD is unknown to the user, the user can refer to the information available under European Union reference date (EURD) column of the EU reference dates and frequency of submission of PSURs (EURD list), to populate this data element.

The user should consider that the European Union reference date corresponds to the date of the first or the earliest known date of the marketing authorisation in the Union of a medicinal product containing the active substance or combination of active substances [DIR Art 107c (5) (a,b)]. Where the term "Not available*" is indicated in the list it means that the EURD has not been provided during the various rounds of consultation on the EURD list with the NCAs and the MAHs. In this case the user should make his best effort to populate the data element with the relevant and most complete information.

In cases of old medicinal products where the first marketing authorisation was granted in early 1900s) the IDB might be unknown and not reported in the EURD list. In such cases the user should include the value "Unknown".

Tag	Description
User Guidance	The date at which the very first marketing authorisation for a new medicinal product in any country in the world was granted shall be specified. This information shall be specified when International Birth Date is available. In cases the first authorisation is being obtained in the EU and corresponds with this product, this information is to be completed once available.

Tag	Description
	If the medicinal product is authorised first in the Europe Union, the International birth date can be the same of the European Union reference date. If the medicinal product is authorised first in country other than the European Union, the International birth date does not correspond to the European Birth Date, however in some cases it might still be found in the EURD list. • In case of very old medicinal products, where the IBD is unknown (therefore is not available in the EURD list) the IBD can be populated with the generic value: "Unknown". In case of medicinal product with no active ingredient, the IBD can be left blank
Repeatable	No
Conformance	Mandatory
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM). When the date is not known the value part of the dateDateTime element can be missed out (keeping the element itself), and the reason for this specified using the data absent reason extension, with a value of "unknown".
ISO Element Name	International Birth Date
ISO Path	/MedicinalProduct/MarketingAuthorisation/InternationalBirthDate
FHIR Element Name	dateDateTime
FHIR Path	RegulatedAuthorization.relatedDate.dateDateTime or RegulatedAuthorization.relatedDate.dateDateTime.extension.dataAbsentReason
FHIR Complementary Information	RegulatedAuthorization.relatedDate.type.system value is "http://ema.europa.eu/fhir/authorisationDateType" RegulatedAuthorization.relatedDate.type.code is "internationalBirthDate"

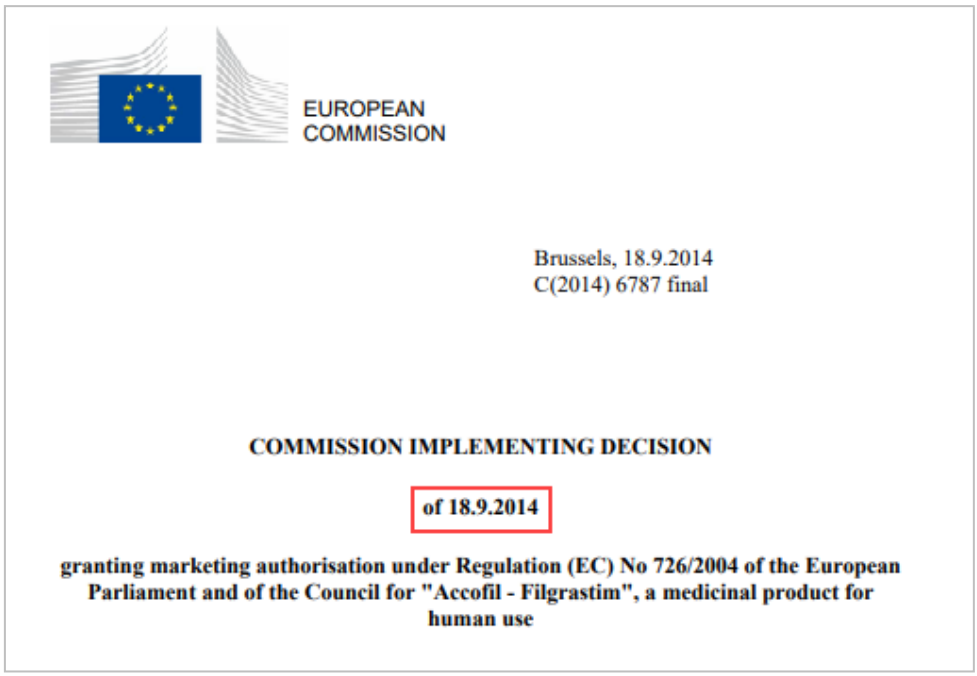
Example(s): Medicinal product authorised first time in the world in country other than European Union.

The SmPC of the medicinal product "Accofil" states the following:

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 18.09.2014
Date of latest renewal: 12th June 2019

The relevant EC European Commission decision states the following:



EUROPEAN
COMMISSION

Brussels, 18.9.2014
C(2014) 6787 final

COMMISSION IMPLEMENTING DECISION

of 18.9.2014

granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Accofil - Filgrastim", a medicinal product for human use

Date of first authorisation should therefore reference 2014-09-18.

In the EURD list, at the corresponding section of the active ingredient "filgrastim" contained in the medicinal product above reported states the following:

ID	Active substances and combinations of active substances	European Union reference date (EURD) Not Available* = EURD not provided during the consultation phase
1391	filgrastim	15/03/1991

International birth date should therefore reference 1991-03-15.

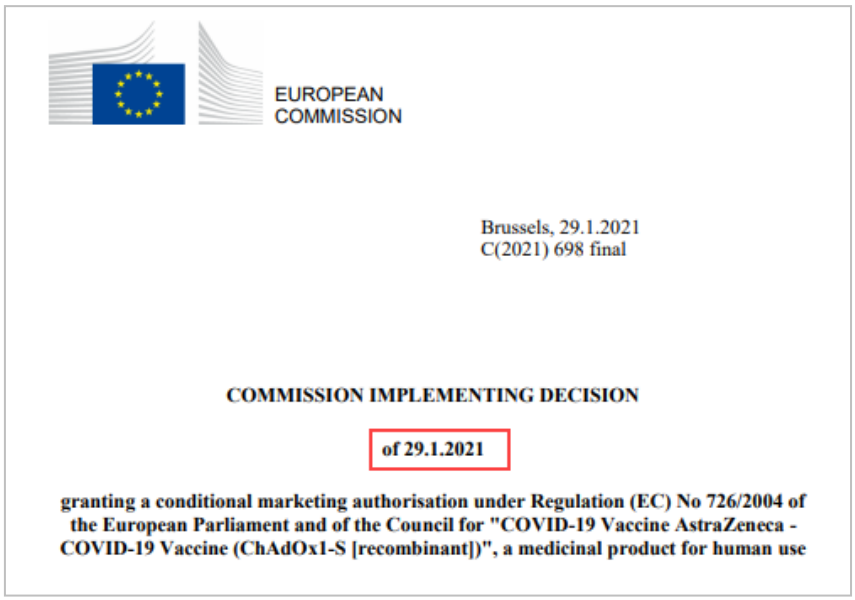
Example(s): Medicinal product authorised first time in the world in country other than European Union.

The SmPC of the medicinal product "Vaxzevria" states the following:

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 January 2021

The relevant EC European Commission decision states the following:



EUROPEAN
COMMISSION

Brussels, 29.1.2021
C(2021) 698 final

COMMISSION IMPLEMENTING DECISION

of 29.1.2021

granting a conditional marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "COVID-19 Vaccine AstraZeneca - COVID-19 Vaccine (ChAdOx1-S [recombinant])", a medicinal product for human use

Date of first authorisation should therefore reference 2021-01-29.

In the EURD list, at the corresponding section of the active ingredient "COVID-19 Vaccine (ChAdOx1-S [recombinant])" (COVID-19 Vaccine AstraZeneca) contained in the medicinal product above reported states the following:

ID	Active substances and combinations of active substances	European Union reference date (EURD) Not Available* = EURD not provided during the consultation phase
10912	COVID-19 Vaccine (ChAdOx1-S [recombinant]) (COVID-19 Vaccine AstraZeneca)	29/12/2020

International birth date should therefore reference 2020-12-29.

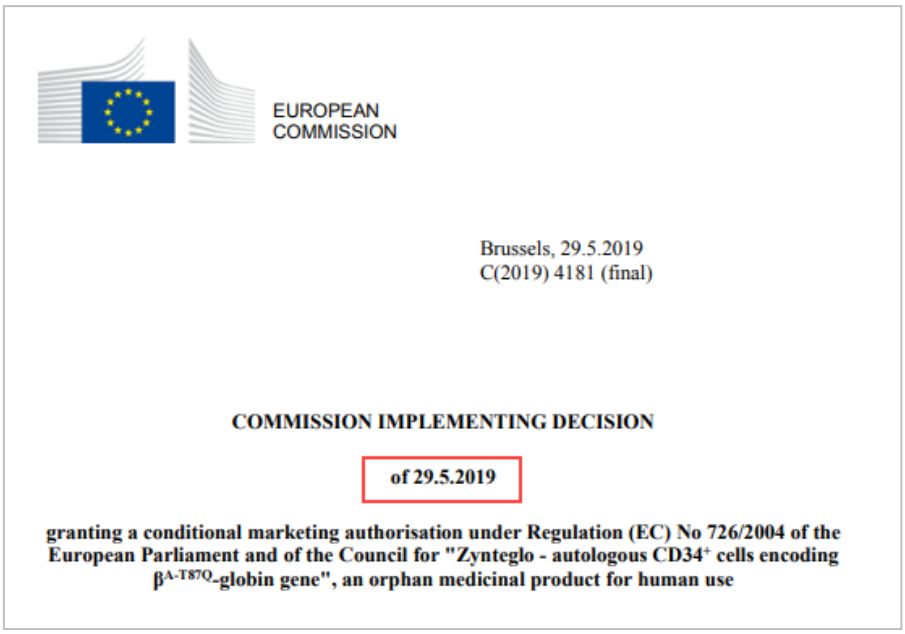
Example(s): Medicinal product authorised first time in the world in European Union.

The SmPC of the medicinal product "Zynteglo" states the following:

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 May 2019

The relevant EC European Commission decision states the following:



EUROPEAN COMMISSION

Brussels, 29.5.2019
C(2019) 4181 (final)

COMMISSION IMPLEMENTING DECISION

of 29.5.2019

granting a conditional marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Zynteglo - autologous CD34^{+} cells encoding β^{A-T87Q}-globin gene", an orphan medicinal product for human use

Date of first authorisation should therefore reference 2019-05-29.

In the EURD list, at the corresponding section of the active ingredient "betibeglogene autotemcel" contained in the medicinal product above reported states the following:

ID	Active substances and combinations of active substances	European Union reference date (EURD) Not Available* = EURD not provided during the consultation phase
10769	betibeglogene autotemcel	29/05/2019

International birth date should therefore reference 2019-05-29.

2.8. Marketing authorisation holder (organisation)

The information on the holder of the marketing authorisation (*RegulatedAuthorization.holder*) of the medicinal product, in each country, as indicated in section *7. Marketing Authorisation Holder* of the SmPC or other regulatory document (e.g., European Commission Decision for CAPs) shall be specified as an Identifier and following a successful registration of organisation's information into the Organisation Management System (OMS).

Parallel distributed/imported medicinal products which may be distributed without a marketing authorisation under regional law [Article 76(3) and (4) of Directive No2001/83/EC], and are out of scope or Article57 submission, may be provided to the EMA on a voluntary basis. The details of the distributor, as specified on the package, the container or the package insert shall be provided in place of the MAH details.

Tag	Description
User Guidance	The Marketing authorisation holder shall be specified using the location identifier (LOC ID) linked to the organisation as listed in the Organisation

Tag	Description
	Management System (OMS) following a successful registration of the organisation's details. If the required organisation and/or related location are not available, the addition of the organisation and/or related location should be requested from OMS, using the process described in the OMS Web User Manual available in the 'Documents' section of the Organisation Management System (OMS). When the LOC ID is specified, the system would give the information to which ORG ID the selected location is linked in the back end. This information will be shown through the PMS User Interface
Repeatable	No
Conformance	Mandatory
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	As listed in SPOR OMS (LOC ID)
ISO Element Name	MarketingAuthorisationHolder(Organisation)
ISO Path	MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationHolder(Organisation)
FHIR Element Name	Authorisation.holder
FHIR Path	RegulatedAuthorization.holder

2.9. (Marketing authorisation) Regulator

The regulator (*RegulatedAuthorization.regulator*) shall be specified as an Identifier and following a successful registration of organisation's information into the Organisation Management System (OMS).

Tag	Description
User Guidance	Medicines regulatory authority shall be specified using the organisation identifier (ORG ID) and the related location identifier (LOC ID) as listed in the Organisation Management System (OMS) following a successful registration of the organisation's details. If the required organisation and/or related location are not available, the addition of the organisation and/or related location should be requested from OMS using the process described in the OMS Web User Manual available in the 'Documents' section of the Organisation Management System (OMS). If the required address of the medicines regulatory authority is not specified in the documentation, the LOC ID can be left empty. When the LOC ID is specified, the system would give the information to which ORG ID the selected location is linked in the back end. This information will be shown through the PMS User Interface.
Repeatable	No
Conformance	ORG ID: Mandatory LOC ID: Conditional
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	As listed in SPOR OMS (ORG ID; LOC ID)

Tag	Description
ISO Element Name	Identifier
ISO Path	MedicinalProduct/MarketingAuthorisation/Organisation (MedicinesRegulatoryAgency)/Identifier
FHIR Element Name	Regulator
FHIR Path	RegulatedAuthorization.regulator

2.10. Marketing authorisation procedure

Marketing Authorisation Procedure class is used for submitting information related to Marketing authorisation approval routes (e.g., centralised procedure, mutual recognition procedure, decentralised procedure and national Procedure) and regulatory procedure applications (e.g., initial marketing authorisation application, variations, transfers, periodic safety update reports etc..), that impact the product information as included in this guidance.

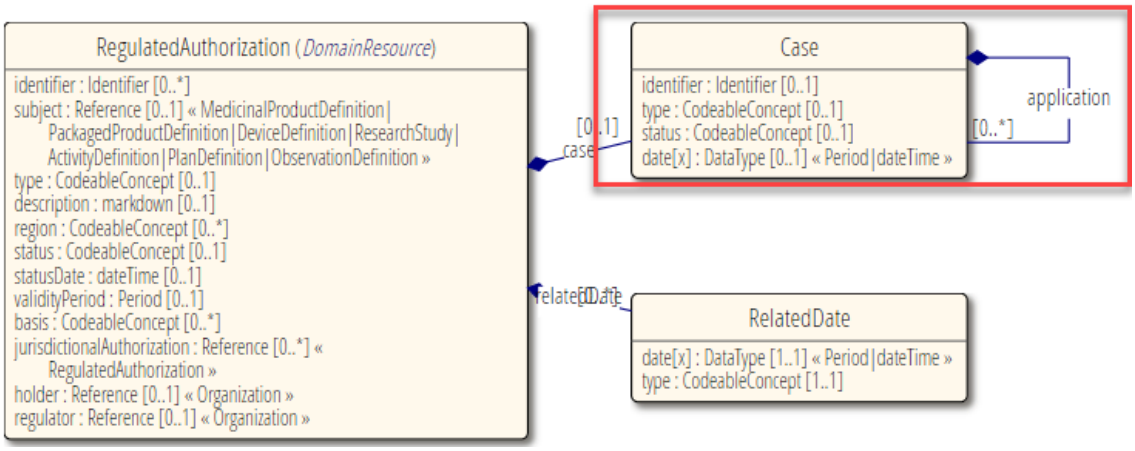


Figure 17: Extract of the Marketing authorization procedure class (source: http://www.hl7.org/fhir

The class is mandatory and repeatable for medicinal products authorised in the EU/EEA.

This class is optional and repeatable for medicinal products authorised outside the EU/EEA and submitted on a voluntary basis.

The individual attributes of this class are not repeatable and shall be populated as applicable.

Marketing authorisation procedure Class	Description
Repeatable	No (medicinal products authorised in/outside EU /EEA)
Conformance	Mandatory (medicinal products authorised in EU/EEA) Optional (medicinal products authorised outside EU/EEA)

2.10.1. Procedure Identifier

The procedure number assigned by the competent authority to a specific authorisation procedure shall be specified.

Procedure Identifier relates exclusively to the initial authorisation procedure registration route and should be completed once. In addition, in case of a switch from a purely National Procedure to Mutual recognition procedure (MRP) this attribute shall be completed again (updated).

- Mutual recognition procedure (MRP) number or Repeat Use Procedure (RUP) shall be specified when the authorisation procedure is entered as 'Mutual Recognition Procedure'. The format of the MRP number:
  - shall be the same as Module 1.2 - Electronic Application Form or as stated in the MR Index on the Heads of Medicines Agency's website (without the reference to the marketing application, i.e., the text "/MR" or "E")

  Information on application number referring to initial marketing authorisation or line extension is not to be reflected in the procedure number (no addition behind the procedure number in bold **CC/D/nnnn/sss**/QQ/vvv, therefore no QQ/vvv part added, e.g., IE/H/0234/001). The format as reflected in CMDh Guidance Document on the Numbering System for the Procedures for Mutual Recognition and Decentralised Procedure should be used.
- Decentralised authorisation procedure (DCP) number shall be specified when the authorisation procedure is entered as Decentralised Procedure. The format of the DCP number should be as stated in in Module 1.2 - Electronic Application Form or the MR Index on the Heads of Medicines Agency's website, i.e., without the reference to the marketing application (if included, without the reference to the marketing application, i.e., the text "/DC") . EMA "EMEA procedure number" (i.e., "Agency Product Number" as referred to/published on the EMA corporate website shall be specified when the authorisation procedure is entered as Centralised Procedure.

  The format of the EMEA procedure number shall be EMEA six-digit procedure number (i.e., EMEA/H/C/123456).
- For purely national authorisation procedures, the local procedure number or national identifier shall be provided.
- For procedures carried outside EU, the relevant procedure identifier may be included (on a voluntary basis) when entering a medicinal product authorised outside the EEA.

Tag	Description
User Guidance	Procedure number should be specified in accordance with information in Module 1.2 - Electronic Application Form. This section is to be completed when the information is available.
Repeatable	No
Conformance	Conditional
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	The applicable procedure number shall be specified as free text.
ISO Element Name	Procedure Identifier / Number
ISO Path	/MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationProcedure/ProcedureIdentifier-Number
FHIR Element Name	Identifier
FHIR Path	RegulatedAuthorization.case.identifier

Tag	Description
FHIR Complementary Information	RegulatedAuthorization.case.identifier.system value is "http://ema.europa.eu/fhir/procedureIdentifierNumber"

Example(s):

SE/H/1111/222

DE/H/1111/001

EMEA/H/C/123456

2.10.2. Procedure type – Medicines approval system

The type of procedure (EU medicinal marketing authorisation approval routes) corresponds with the medicines approval system through which the initial marketing authorisation application is being assessed or was granted (for already approved products) by the regulatory authority. This information shall be specified.

- Centralised procedure is to be specified when entering a centrally authorised medicinal product.
  - The authorisation country code shall have been specified as 'EU' in section 2.3 "Country";
  - For medicinal products authorised in Liechtenstein, Norway and Iceland via the centralised procedure, the applicable country (i.e., LI/NO/IS) shall have been specified in section 2.3 "Country"
- Mutual recognition procedure is to be specified when entering a mutually recognised medicinal product and in the of case of a repeat-use procedure.
  - The authorisation country shall 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 shall have been specified as one of the EEA countries in section 2.3 "Country".
- Decentralised procedure is to be selected when entering a medicinal product authorised via a decentralised procedure:
  - The authorisation country shall have been specified as one of the EEA countries in section 2.3 "Country".
- Non-EU Authorisation Procedure is to be selected when a medicinal product is authorised via a procedure carried outside EU and when entering a medicinal product authorised outside the EEA (on a voluntary basis).
  - The authorisation country code shall not have been specified as "EU" or any of the EEA countries in section 2.3 "Country".

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 shall be specified. The value(s) shall be selected from the term ID as listed in the Referentials Management Service (RMS) list.

Tag	Description
	NOTE: The relevant RMS list contains terms which can be used for medicinal products that can be submitted into PMS in a voluntary basis.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000154442
Value(s)	As listed in the EU Regulatory Authorisation/Registration Procedure RMS list
ISO Element Name	Procedure Type
ISO Path	/MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationProcedure/ProcedureType
FHIR Element Name	Type
FHIR Path	RegulatedAuthorization.case.type

Example(s):

Centralised Procedure

Decentralised Procedure

Mutual Recognition Procedure

National Procedure

Non-EU authorisation procedure

2.10.3. Procedure start date

Tag	Description
User Guidance	The date when the marketing authorisation procedure started may be specified when available.
Repeatable	No
Conformance	Conditional
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Procedure Date Start
ISO Path	/MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationProcedure/ProcedureDateStart
FHIR Element Name	Start
FHIR Path	RegulatedAuthorization.case.datePeriod.start

2.10.4. Procedure end date

Tag	Description
User Guidance	The date when the marketing authorisation procedure was completed shall be specified when available. • For centralised procedure, this date corresponds with the date of European Commission (EC) decision of the initial marketing authorisation. If the medicinal product was registered through a line extension, the date of European Commission (EC) decision of the related product with a different strength/pharmaceutical form shall be selected. • For mutual recognition procedure, this date corresponds with the date of each national competent authority decision of the initial marketing authorisation (date when the MA is granted). • For decentralised procedure, this date corresponds with the date of each national competent authority decision of the initial marketing authorisation (date when the MA is granted). • For national procedures, this date corresponds with the date of national competent authority decision of the initial marketing authorisation (date when the MA is granted).
Repeatable	No
Conformance	Conditional
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Procedure Date End
ISO Path	/MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationProcedure/ProcedureDateEnd
FHIR Element Name	End
FHIR Path	RegulatedAuthorization.case.datePeriod.end

2.10.5. Regulatory application

A marketing authorisation and associated lifecycle activities are linked to regulatory procedures. These include the initial marketing authorisation application and subsequent applications for changes to the existing marketing authorisation (e.g., line extensions, renewals, variations), that occur during the lifecycle of the medicinal product).

The initial regulatory procedure application leading to the registration of the medicinal product for the first time (e.g., initial marketing authorisation, line extension if other strengths/pharmaceutical products of the same global marketing authorisation) shall be recorded.

If applicable, details of the marketing authorisation application related to the subsequent changes of the marketing authorisation should be captured as described in the following section. It is important to note that in FHIR both procedures and applications are modelled as cases, and that there is a recursive

relationship between cases (a case can be a parent of other cases). It is expected that applications that belong to a procedure are expressed as elements of the procedure (children).

The regulatory application class and the individual attributes of this class are conditional (except for the regulatory application type data field) and not repeatable

Regulatory application Class	Description
Repeatable	No
Conformance	Conditional

2.10.5.1. Regulatory application Identifier/Number

Tag	Description
User Guidance	The number assigned to the marketing authorisation application (including post-authorisation procedure applications such as variations, renewals and other regulatory procedure applications) by the regulatory agency shall be described in text. Note 1: In some member states a regulatory applications identifier/number is **not** assigned for medicinal products approved through national procedure route. In these cases, this field should be left blank. This section is to be completed when the information is available. Note 2: only the regulatory application procedures affecting attributes included in the PMS data model will trigger the need to update this section. Regulatory application procedures information not affecting attributes in the PMS data model do not need to be recorded.
Repeatable	No
Conformance	Conditional
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	The applicable procedure number shall be specified as free text.
ISO Element Name	Application Identifier / Number
ISO Path	/MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationProcedure/MarketingAuthorisationApplication/ApplicationIdentifier-Number
FHIR Element Name	Identifier
FHIR Path	RegulatedAuthorization.case.application.identifier
FHIR Complementary Information	RegulatedAuthorization.case.application.identifier.system value is “http://ema.europa.eu/fhir/applicationIdentifierNumber”

Example(s):

EMEA/H/C/123456/X/001

EMEA/H/C/123789/000

EMEA/H/C/123789/II/003

DE/H/1111/001/II/001

EE/H/0220/003/IB/012

DE/H/0210/001/WS/136

2.10.5.2. Regulatory application type

Tag	Description
User Guidance	The type of regulatory application shall be described using a term ID. • The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. • In case of grouping of variations, the application submission type with the highest ranking of variation shall be selected. This value is an attribute within the Regulatory application procedure Identifier/Number.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000155688
Value(s)	As listed in the Application Submission Type RMS list
ISO Element Name	Application Type
ISO Path	/MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationProcedure/MarketingAuthorisationApplication/ApplicationType
FHIR Element Name	Type
FHIR Path	RegulatedAuthorization.case.application.type

Example(s):

Initial Marketing Authorisation Application (100000155689)

Renewal (100000155697)

Variation Type IB (100000155692)

Variation Type II (100000155693)

2.10.5.3. Regulatory application end date

Tag	Description
User Guidance	The date when the regulatory application procedure was completed (if available) shall be specified, when available. • For **centralised procedure**, this date corresponds with: – date of European Commission (EC) decision: procedures that requires of EC decision; – date of finalisation of the linguistic review: procedures without EC decision and where a linguistic review of the Product information is needed; – date of the regulatory procedure opinion in cases where no linguistic review and EC decision is required. • For **mutual recognition** and **decentralised procedure**, this date corresponds with:

Tag	Description
	– the regulatory application end date is not what is usually called the End of Procedure in the European phase of the MRP/DCP approval process for applications for new products, extensions or variations. It corresponds to the date of each national competent authority decision: procedures that requires of NCA decision; – – date of finalisation of the linguistic review: procedures without NCA decision and where a linguistic review of the Product information is needed; – date of the regulatory procedure opinion in cases where no linguistic review and NCA decision is required. • Fore pure **national procedures**, the applicable date is dependent on the national procedures.
Repeatable	No
Conformance	Conditional
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e.,, YYYY-MM).
ISO Element Name	Application Date
ISO Path	/MedicinalProduct/MarketingAuthorisation/MarketingAuthorisationProcedure/MarketingAuthorisationApplication/ApplicationDate
FHIR Element Name	dateDateTime
FHIR Path	RegulatedAuthorization.case.application.dateDateTime

3. Therapeutic (product) indication

Therapeutic (product) indications will be implemented using the FHIR *ClinicalUseIssue Resource (see Figure 9)*. In the context of the Iteration 1 of the PMS implementation, the elements in red rectangle are in scope and shall be provided according to the rules and guidance described in this section.

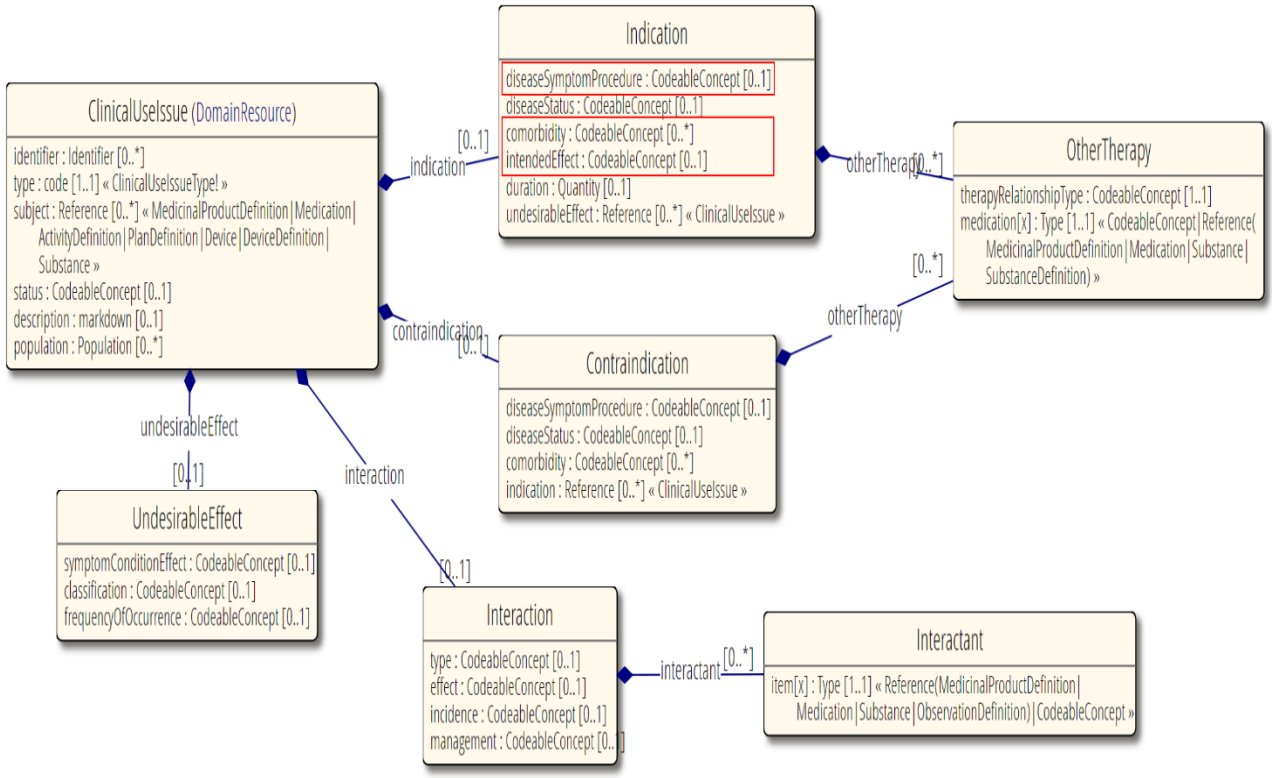


Figure 18: Resource ClinicalUseIssue (source : http://www.hl7.org/fhir)

The Therapeutic (product) indication class is mandatory and repeatable while the different attributes shall be populated as applicable and are not repeatable (except for the Co-morbidity data element).

Therapeutic (product) indication Class	Description
Repeatable	Yes
Conformance	Mandatory

3.1. Indication as "Disease/Symptom/Procedure"[10]

Tag	Description
User Guidance	The coding of the authorised indication(s) as disease, symptom or procedure as reflected in Section *4.1 Therapeutic Indications* of the corresponding SmPC or other regulatory document shall be specified as an RMS term ID. • The applicable Lowest Level Terms (LLT) from the Medical Dictionary for Regulatory Activities (MedDRA) value(s) shall be selected from the

[10] Description of the authorised full therapeutic indication(s) as text, as reflected in Section 4.1 Therapeutic Indications of the corresponding SmPC or other regulatory document, has been described in section 1.11.

Tag	Description
	term ID as available in applicable Referentials Management Service (RMS) list. The selected term will be shown only in English language only. This differ from the possibility to have the information in multiple languages in the 1.11 Full indication text data element. • The chosen MedDRA term should be as specific as possible, targeting to capture the most detailed level of information presented in the indication section. Note: To achieve a greater specificity of the coded term, it is recommended to select the MedDRA term that accounts for as much information as possible, such as: • Both the disease and its cause as provided in the SmPC, (e.g., 'Osteoporosis steroid -induced'); • Aspects of 'Disease status specification' (e.g., Pancreatic adenocarcinoma metastatic); • Details related to the target population (e.g., 'Osteoporosis postmenopausal) • Timing/duration (e.g., 'Hepatitis chronic persistent')
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000006
Value(s)	As listed in the RMS list containing the terms from the Medical Dictionary For Regulatory Activities list (MedDRA)
ISO Element Name	Indication as "Disease / Symptom / Procedure"
ISO Path	/MedicinalProduct/TherapeuticIndication/IndicationAsDisease-Symptom-Procedure
FHIR Element Name	diseaseSymptomProcedure
FHIR Path	ClinicalUseIssue.indication.diseaseSymptomProcedure

Example(s):

100000054740 Migraine headache; 100000006570 Vascular hypotensive disorders; 100000034529 Pain relief

3.2. Co-morbidity

Tag	Description
User Guidance	The description of any comorbidity [i.e., concurrent condition(s)] or co-infections included in the authorised indication(s) as reflected in Section *4.1 Therapeutic Indications* of the SmPC may be specified using the RMS term ID. This refers to further conditions (concurrent conditions or co-infections) that define the patient population apart from the 'Disease/symptoms/procedure' aspect of the indication. • The applicable Lowest Level Terms (LLT) from the Medical Dictionary for Regulatory Activities (MedDRA) value(s) shall be selected from the term ID as available in applicable Referentials Management Service

Tag	Description
	(RMS) list. The selected term will be shown only in English language only. This differ from the possibility to have the information in multiple languages in the 1.11 Full indication text data element. • The chosen MedDRA term should be as specific as possible, targeting to capture the most detailed level of information presented in the indication section.
Repeatable	Yes
Conformance	Conditional
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000006
Value(s)	As listed in the Medical Dictionary For Regulatory Activities RMS list
ISO Element Name	Comorbidity
ISO Path	/MedicinalProduct/Contraindication/Comorbidity
FHIR Element Name	comorbidity
FHIR Path	ClinicalUseIssue.indication.comorbidity

To exemplify the separation between 'Indication as Disease/Symptom/Procedure' and 'Comorbidity/concurrent disease', where the indication text states: "Treatment of pancreatic insufficiency in patients with cystic fibrosis", then 'pancreatic insufficiency' needs to be included as indication, whereas 'cystic fibrosis' represents the 'Comorbidity/concurrent conditions' aspect of the indication and it should not be included at this stage in the indication field.

Careful consideration of the drug's mechanism of action and impact on the disease is required when assessing whether the diseases mentioned in the indication text are considered to be 'comorbidity' or whether they constitute the therapeutic indication (and need to be included). Treatment of typical signs and symptoms of a disease may represent treatment of the disease.

Looking at an example where indication states: "For the treatment of hyperglycaemia in type II diabetes", then it needs to be considered that treatment of hyperglycaemia (i.e., achieving normoglycaemia), is the goal of all antidiabetic treatment, and type II diabetes should therefore be considered as the indication for treatment and not a concurrent disease.

Example(s):

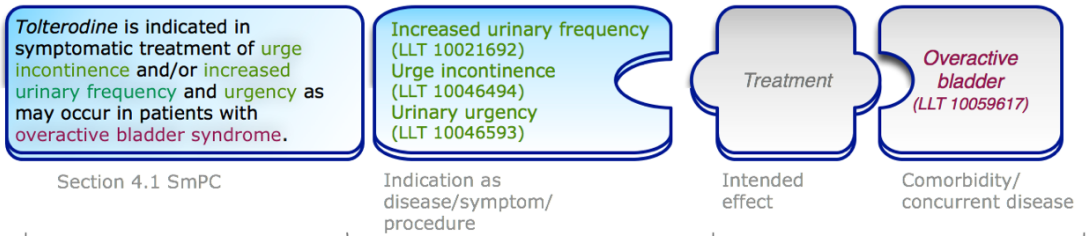


Figure 19: section 4.1 SmPC, Indication as disease/symptom/procedure, Intended effect, Comorbidity/concurrent disease

As general principle, one ClinicalUseIssue resource shall be created per each of the listed therapeutic indications. In the example reported in figure 10 there are three therapeutic indications, one intended effect and one comorbidity, therefore three ClinicalUseIssue resource shall be created:

- TI (Increased urinary frequency) + Intended effect (Treatment) + Comorbidity (Overactive bladder);
- TI (Urge incontinence) + Intended effect (Treatment) + Comorbidity (Overactive bladder)
- TI (Urinary urgency) + Intended effect (Treatment) + Comorbidity (Overactive bladder)

An example where both indications as captured in SmPC are to be coded:

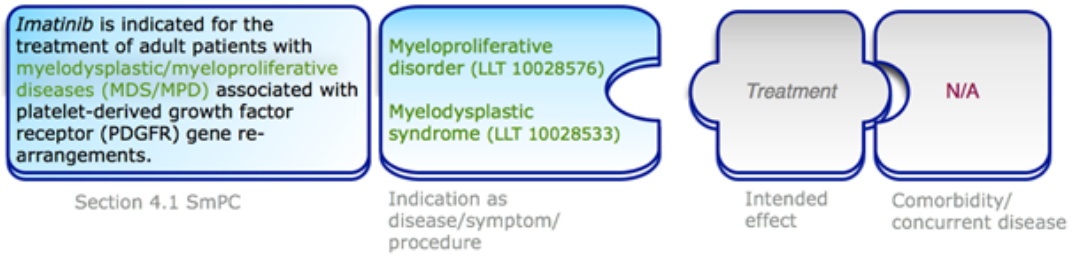


Figure 20: Coding both indications as captured in SmPC

An example where most detailed information is captured, capturing also the context of the symptom (comorbidity/concurrent disease).

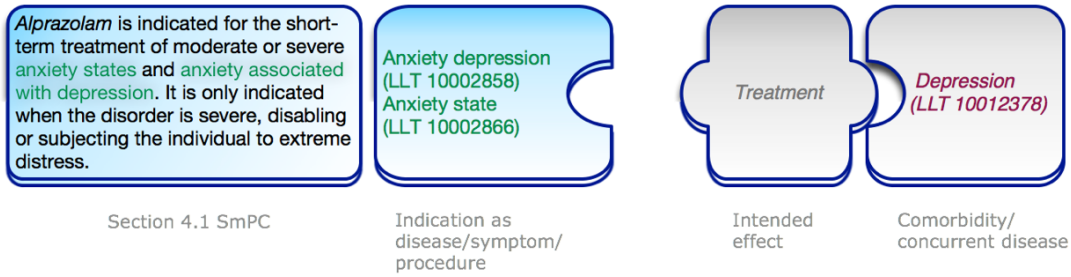


Figure 21: Detailed information as captured together with the context of the symptom (comorbidity/concurrent disease)

3.3. Intended effect

Tag	Description
User Guidance	The intended effect (i.e., the part of the indication that describes the result/type of outcome intended for the target condition), aim or strategy to be achieved by the indication as reflected in Section 4.1 Therapeutic Indications of the corresponding SmPC or other regulatory document shall be specified using an RMS term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. Note: Special attention should be given to situations where a drug is indicated also for treatment and not only for prevention. If a medicinal product is also authorised for the treatment of a disease, then the respective disease should also be coded.
Repeatable	Yes

Tag	Description
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/rmswi/#/lists/200000003186
Value(s)	As listed in the Medicine Profile RMS List This RMS list is hierarchical. Users can only see and select the first level of terms to applies to PMS for data entry purposes.
ISO Element Name	Intended Effect
ISO Path	/MedicinalProduct/TherapeuticIndication/IntendedEffect
FHIR Element Name	intendedEffect
FHIR Path	ClinicalUseIssue.indication.intendedEffect

Example(s):

Treatment, Prophylaxis, Diagnosis

Figure 22 shows an example where the indication needs to be carefully considered in its context (migraine is not a concurrent condition in this case - it represents the disease to be treated). Also shows how the intended effect should be captured:

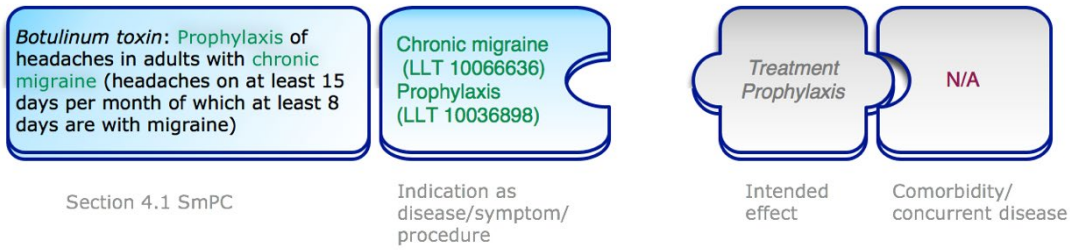


Figure 22: Example where indication needs to be carefully considered in its context

Figure 23 shows an example where both treatment and prophylaxis are to be coded in indication section, as the medicinal product is used for both purposes

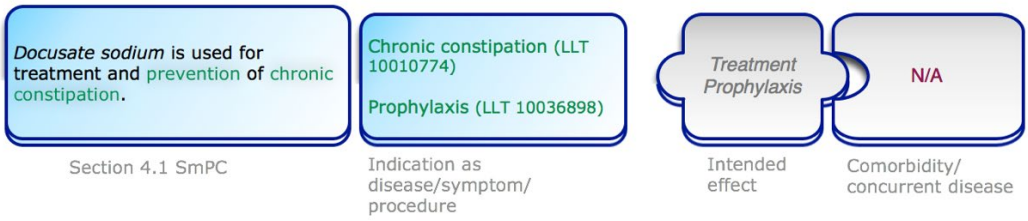


Figure 23: Treatment and prophylaxis coded in indication section

Figure 24 shows an example where the capturing of indication of a replacement therapy is presented:

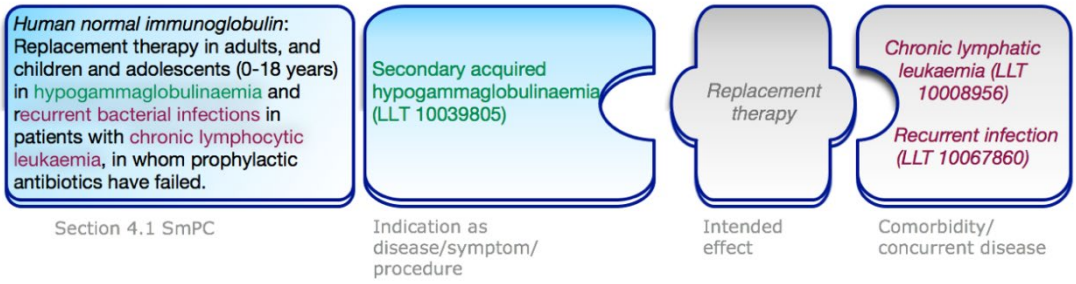


Figure 24: Capturing of indication of a replacement therapy

4. Packaged medicinal product

This section describes the packaging/container(s) information of a medicinal product and any associated device(s) which are an integral part or provided in combination with a medicinal product, as supplied for sale or distribution/supply. This section should be completed as follows:

- a Medicinal Product shall be associated to one or more Packaged Medicinal Products;
- a Packaged Medicinal Product is associated with the PCID.

The package of the medicinal product shall be described from the outer to inner part of the medicinal product and down to the individual ingredient(s) of each packaged pharmaceutical form. For this purpose, the following classes apply:

- The Packaged Medicinal Product class: overarching class
  - The Package Item (Container) class [i.e., the outer and inner primary and secondary package(s)]
  - The Manufactured item/ingredient(s) class [i.e., the individual pharmaceutical form(s)/ingredient(s)]
  - Device class (i.e., administration device co-packaged with the medicinal product or when medicinal product is integrated within a device such as pre-filled syringes)
  - Shelf-Life / Storage Conditions associated to the Packaged Medicinal Product.

The **Packaged Medicinal Product class** is the overarching class which collects all information on the individual package within the medicinal product i.e., the 'Package Item (Container)' class for each separate item packaged.

The **Package Item (Container) class** allows for a recursive relationship, which is required to be used when there are packages within packages, e.g., cartridges within a blister sleeve within a box. A Package Item (Container) has the following characteristics:

- It may have 'Package (Component)' parts such as closures.
- A Package Item (Container) can be identified by one or more Data Carrier Identifiers (e.g., Global Trade Item Number™ (GTIN™), National Trade Item Number (NTIN).

Manufactured Item is defined by individual Ingredients and Physical Characteristics and is linked to specific package item containers.

In the context of implementation of PMS iteration 1, the Packaged Medicinal Product can be accompanied by a Device (class 'Device').

In addition, the Packaged Medicinal Product will have associated a Shelf-Life / Storage Conditions as this is associated to the Package Item Container.

Example(s):

Packaged Medicinal Product	
PCID	EU-100000396-00020080-0001
Package Description	Pack of one vial (type I glass) of 2.5 ml suspension with a stopper (butyl rubber) and one vial (type I glass) of 2.5ml emulsion with a stopper (butyl rubber)
Package Item Container (1)	**Box**
Package Item Container Quantity	1
Package Item Material	Recycled Cardboard
Packaged Item Reference	Reference to Package item 2 and Package item 3
Manufacturing item Reference	Not Applicable
Data Carrier Identifier (s)	02890138016090
Package Item Container (2)	**Vial**
Package Item Container Quantity	1
Package Item Material	Type I glass
Package Item Component Type	Stopper
Package Item Component Material	Butyl Rubber
Manufactured Item (Manufactured Dose Form)	Suspension for emulsion for injection
Packaged Item Reference	Not applicable
Manufacturing item Reference	Reference to Suspension for Emulsion for Injection
Package Item Container (3)	**Vial**
Package Item Container Quantity	1
Package Item Material	Type I glass
Package Item Component Type	Stopper
Package Item Component Material	Butyl Rubber
Manufactured Item (Manufactured Dose Form)	Emulsion for emulsion for injection
Packaged Item Reference	Not applicable
Manufacturing item Reference	Reference to Emulsion for Emulsion for Injection

The descriptions of the attributes and the relevant business rules are described in the sections below. The example above is fictitious.

The full information on Packaged Medicinal Product, as described by ISO 11615, is implemented based on the HL7 FHIR *Resource PackagedProductDefinition,* as shown in Figure 16.

In the context of the Iteration 1 of the PMS implementation, the following elements are in scope and information shall be provided according to the rules and guidance described in this section:

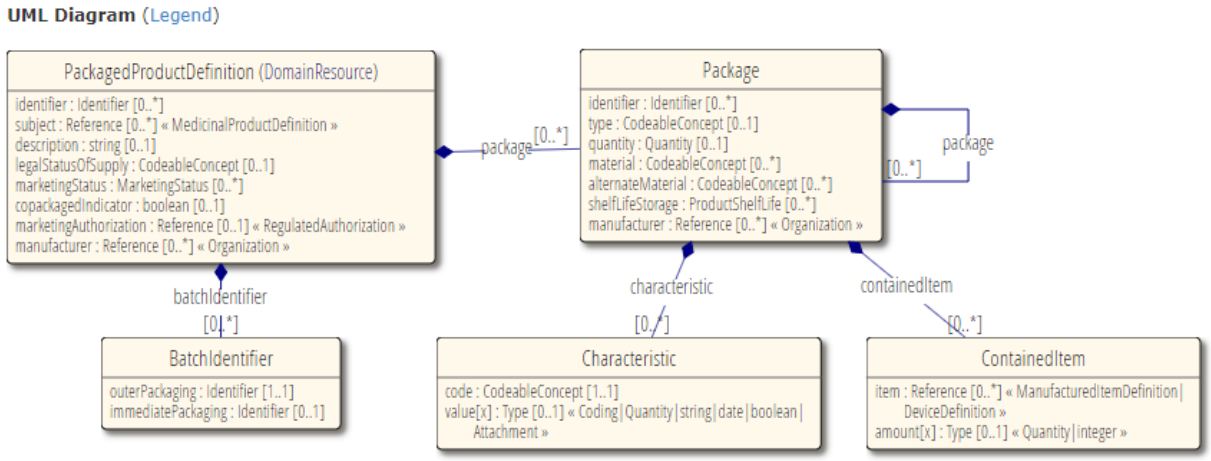


Figure 25: FHIR Resource: PackagedProductDefinition (Source: www.hl7.org/fhir)

The Packaged Medicinal Product class is a mandatory and repeatable while the individual attributes of this class are repeatable and shall be populated as applicable.

Packaged medicinal product Class	Description
Repeatable	Yes
Conformance	Mandatory

Note: The contents of the document [i.e., Module 1.2 – Electronic Application form (eAF), Relevant sections in Module 3 – Quality, Summary of Product Characteristics (SmPC)] supporting the regulatory process shall be aligned, where applicable, to ensure the discrepancies between the documents are minimized. The content should enhance the quality of the product data reported in Product Management Service (PMS). This requirement applies to new medicinal products single entry in PMS.

Based on the above principle, the SmPC as authorised/to be authorised is the main referring document for data entry purposes.

However, for medicinal product entry already available in PMS, following the data load from XEVMPD to PMS database (existing product data), whenever the common contents of each of the above supporting documentation are not aligned, the information available in the relevant sections in Module 3 can be used to harmonize the values in PMS. This requirement applies provided data confidentiality is ensured and if no additional complexity is added to the data entry in PMS. For additional information, refer to section 1.3.1 of EU IG Chapter 8 – Practical example.

Note: Further information referring to existing product data will be made available in the EU IG Chapter 9 - Process for submitting existing data on medicinal products authorised for human use. This chapter is under development and it will be made available at later stage.

4.1. Packaged Medicinal Product Identifier (PCID[11])

Tag	Description
User Guidance	For each Packaged Medicinal Product, a unique PCID is assigned by the PMS system based on the data submitted. It is supplementary to any existing authorisation/approval number at package level assigned by the Commission or national competent authorities. There are two components of a PCID: - MPID for the Medicinal Product; - Package description code segment, which refers to a unique identifier for each package e.g., 0001, 0002 etc. Note: For authorisations which cover only one pack, one PCID will be assigned, with 0001 as the package description code segment. For authorisations which cover more than one pack, a PCID will be assigned to each pack. Any change of the values related to these code segments shall result in the assignment of a new PCID. A unique PCID is assigned according to the following defining attributes of the package code segment: - package item (container)(s) — the type, quantity (items per package), material(s); - package component(s) — type, material(s) - manufactured item(s) — manufactured dose form, unit of presentation, quantity (items per package). When the above defining attributes sets differ in any way a new PCID will be assigned by the system
Repeatable	No
Conformance	For first data submission and data maintenance: Not applicable – ID generated by the system.
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	ID generated by the system
ISO Element Name	PCID
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PCID
FHIR Element Name	Identifier
FHIR Path	PackagedProductDefinition.identifier
FHIR Complementary Information	PackagedProductDefinition.identifier.system value is "http://ema.europa.eu/fhir/pcId"

Example(s):

SE-100001745-00040001-0001

EU-100000396-00020080-0001

[11] Concept of PCID - © CEN, reproduced with permission

4.2. Package description

Tag	Description
User Guidance	A description of the packaged medicinal product in relation to the pack size(s) in line with the information indicated in section *6.5 Nature and contents of container* of the corresponding SmPC or other regulatory document shall be specified as text. **Products authorised through MRP/DCP/NP routes** • The package description is to be provided in English or in the local language(s) of authorisation, or optionally in all of them. **Products authorised through the centralised procedure** • The package description is to be provided in English
Repeatable	Yes
Conformance	Mandatory
Data Type	Markdown
RMS URI/URL	Not applicable
Value(s)	The description of the packaged medicinal product shall be provided as text.
ISO Element ID	Package description
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageDescription
FHIR Element ID	Description
FHIR Path	PackagedProductDefinition.description

Example(s):

Section 6.5 Nature and contents of container:

84 or 100 tablets in an amber glass bottle.

Information to be entered in Package description of first package:

84 tablets in an amber glass bottle.

Information to be entered in Package description of second package:

100 tablets in an amber glass bottle.

Section 6.5 Nature and contents of container:

Confezione da 14, 28 o 98 compresse rivestite con film in blister

Information to be entered in Package description of PCID1:

Confezione da 14 compresse rivestite con film in blister

Information to be entered in Package description of PCID2:

Confezione da 28 compresse rivestite con film in blister

Information to be entered in Package description of PCID3:

Confezione da 98 compresse rivestite con film in blister

Section 6.5 Nature and contents of container:

Ampoule en verre neutre de 1 ml. 5 ampoules dans un carton.

Information to be entered in Package description of PCID1:

Ampoule en verre neutre de 1 ml. 5 ampoules dans un carton.

4.2.1. 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 shall be specified. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072057
Value(s)	As listed in the Language RMS list
ISO Element Name	Not Applicable
ISO Path	Not Applicable
FHIR Element Name	valueCode
FHIR Path	PackagedProductDefinition.description.extension.language Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.3. Manufacturer (New)

Tag	Description
User Guidance	The reference to the relevant Manufacturer of the packaged medicinal product shall be selected from the list of manufacturers recorded in section 1.20 Manufacturing business operation.
Repeatable	Yes
Conformance	Conditional
Data Type	Reference
RMS URI/URL	Not applicable
Value(s)	Reference to the relevant ActivityDefinition resource describing the manufacturing business operation.
ISO Element Name	Manufacturer(Organisation)
ISO Path	MedicinalProduct/PackagedMedicinalProduct/ManufacturerEstablishmentOrganisation/Manufacturer(Organisation)
FHIR Element Name	manufacturer
FHIR Path	PackagedProductDefinition.manufacturer.extension.manufacturingBusinessOperation

Tag	Description
	Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.4. Pack size

Tag	Description
User Guidance	For each Packaged Medicinal Product, the pack size defined as the total number of units of the manufactured item or package item and represented per unit of presentation shall be provided. For **medicinal products with multiple pharmaceutical products** (e.g., tablet and cream) the pack size shall be differentiated and repeated by manufactured item/package item. *Example 1*: *28 tablets and 1 tube (cream) – In this case the pack size field is repeated including quantity and unit of presentation for tablets and quantity and unit of presentation (tube) for the cream.* For medicinal products in **solid dosage forms with multiple pharmaceutical products that present the same unit of presentation** (e.g., contraceptive tablets of different colours and formulation), the pack size shall be accounted as the total number of tablets. *Example 2*: *28 film coated tablets containing:* *2 dark yellow tablets each containing 3 mg estradiol valerate* *5 medium red tablets each containing 2 mg estradiol valerate and 2 mg dienogest* *17 light yellow tablets each containing 2 mg estradiol valerate and 3 mg dienogest* *2 dark red tablets each containing 1 mg estradiol valerate* *2 white tablets do not contain active substance* In this case the pack size field is completed with the following value: 28 tablets. Note: The details of each individual manufactured item will be recorded in the applicable manufactured item section (in this example those attributes shall be recorded in other section includes the number of tablets per manufacturing item and description including colour). For **liquid formulations requiring reconstitution** (e.g., powder and solvent for solution for injection), the unit of presentation shall be differentiated, and this data field is repeated per manufactured item. *Example 3: powder (25 mg vial) and solvent (1 ml pre-filled syringe). In this case the pack size field is repeated including quantity and unit of*

Tag	Description
	presentation for the powder (vial) and quantity and unit of presentation (syringe) for the solvent. Value: 1 vial + 1 pre-filled syringe The applicable numeric value(s) and unit of presentation shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	Yes
Conformance	Mandatory
Data Type	Quantity
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000000014
Value(s)	Numeric value and unit. The units shall be specified as a Term ID listed in RMS Units of Presentation list as applicable
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	containedItemQuantity
FHIR Path	PackagedProductDefinition.extension.containedItemQuantity Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

Example(s):

20 tablets

1 vial (solvent) + 1 vial (powder)

1 tube (cream) + 27 tablets

150 (15 x 10 x 1) capsules (unit dose) (multipack)

Note: Content between brackets is for information and it is not included while completing this field.

4.4.1. Quantity operator (New)

Tag	Description
User Guidance	The applicable value corresponding to the quantity operator shall be specified as term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000008
Value(s)	As listed in the Quantity Operator RMS list. If the RMS term can be mapped to a FHIR Quantity comparator, the FHIR comparator field should also be specified for interoperability.
ISO Element Name	Not applicable

Tag	Description
ISO Path	Not applicable
FHIR Element Name	Quantity Operator
FHIR Path	PackagedProductDefinition.extension.containedItemQuantity.extension.quantityOperator PackagedProductDefinition.extension.containedItemQuantity.comparator Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.5. Legal status of supply

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

This section is only applicable where individual packages have different legal statuses of supply. In this situation, legal status of supply at medicinal product level (section 1.7) should be populated with the RMS term "*Medicinal product subject to medical prescription exempt for some pack sizes*".

In cases where legal status of supply is identical for all package sizes of the medicinal product, this field should be left empty, and the legal status of supply shall be reflected only at medicinal product level (section 1.7).

Tag	Description
User Guidance	The legal status of the medicinal product's supply, as authorised by the competent authority and applicable in the region, shall be specified using a term ID. The value(s) shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. • For **CAPs**, this information is retrieved from Annex II.B - CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE and from section 4.2 Posology of the Product information • For **NAPs**, this information may be retrieved from different sources that includes from Product information (SmPC, Package Leaflet or other annexes) to National Register of Medicinal Products. • The legal status for the supply can be defined at packaged medicinal product level. In this scenario it should be specified as Medicinal product subject to medical prescription or Medicinal product not subject to medical prescription.
Repeatable	No
Conformance	Conditional
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072051
Value(s)	As listed in the Legal Status for the Supply RMS list
ISO Element ID	LegalStatusOfSupply

Tag	Description
ISO Path	/MedicinalProduct/ PackagedMedicinalProduct/MarketingAuthorisation/LegalStatusOfSupply
FHIR Element ID	legalStatusOfSupply
FHIR Path	PackagedProductDefinition.legalStatusOfSupply

4.6. Marketing status

This section provides information on the marketing status of the packaged medicinal product. Marketing status considers the concepts of placing in the market and market cessation. The terms "actual marketing" and "placing on the market" should be defined as when the medicinal product is "released into the distribution chain" e.g., out of control the Marketing authorisation holder. The "cessation of placing on the market" shall be defined, by analogy to the placing on the market, as the "cessation of release into the distribution chain" with the consequence that the concerned product may no longer be available for the supply to the patients.

Therefore, the marketing status describes the date when a packaged medicinal product is available on the distribution chain and on the market (placing in the market) or the date as of which it is no longer available which is considered the date of the last release into the distribution chain (market cessation).

In the case of centralised authorised products (CAPs), this section needs to be completed for each individual EU/EEA country.

This section considers the marketing status at the level of packaged medicinal product. As the concept of marketing status for a medicinal product is linked to the moment that a medicinal product package is released/removed from the market, it is important that information recorded at package medicinal product level is accurate.

This section is to be completed when the information is available. Because the authorized medicinal product can be placed on the market only after the product is authorized, this section should be populated with the relevant information (when applicable) upon formal conclusion of the regulatory procedure of marketing authorisation.

The data elements inside red rectangles apply for iteration 1 implementation:

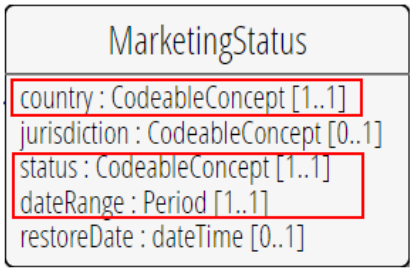


Figure 26: Marketing Status (source: http://www.hl7.org/fhir)

This class is mandatory and repeatable while the individual attributes of this class are not repeatable and shall be populated as applicable.

Marketing status Class	Description
Repeatable	Yes
Conformance	Mandatory

4.6.1. 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. The value(s) shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. In the case of CAPs, all individual countries of the EU where the product is marketed/not marketed should be selected.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000002
Value(s)	As listed in the Country RMS list
ISO Element Name	Country
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingStatus/Country
FHIR Element Name	Country
FHIR Path	PackagedProductDefinition.marketingStatus.country

Example(s):

100000000373 – Republic of Croatia

100000000529 - Kingdom of Spain

4.6.2. Marketing status

Tag	Description
User Guidance	The status of the marketing of the medicinal product may be specified as a term ID. The value(s) shall be selected from the term ID as listed in the Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072052
Value(s)	As listed in Marketing Status RMS list
ISO Element Name	Marketing Status
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingStatus/Status
FHIR Element Name	Status
FHIR Path	PackagedProductDefinition.marketingStatus.status

Example(s):

Marketed, Not marketed, Temporarily unavailable

4.6.3. (Marketing status) start date

Tag	Description
User Guidance	The date when the authorised Medicinal Product is placed on the market in a country, shall be provided by the Marketing Authorisation Holder (or where applicable, the manufacturer/distributor). Note "Placed on the market" is defined as the release of the authorised Medicinal Product into the distribution chain i.e., out of direct control of the Marketing Authorisation Holder. This section is to be completed when the information is available.
Repeatable	No
Conformance	Conditional
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Marketing Date Start
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingStatus/MarketingDateStart,
FHIR Element Name	dateRange.start
FHIR Path	PackagedProductDefinition.marketingStatus.dateRange.start

4.6.4. (Marketing status) end date

Tag	Description
User Guidance	Note: "cessation of placing on the market" is defined, by analogy to the placing on the market, as the "cessation of release into the distribution chain" with the consequence that the concerned product may no longer be available for the supply to the patients. This section is only applicable when a medicinal product is removed from the market. Otherwise, it is to be blank. This section is to be completed when the information is available.
Repeatable	No
Conformance	Conditional
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Marketing Date Stop
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingStatus/MarketingDateStop

Tag	Description
FHIR Element Name	dateRange.end
FHIR Path	PackagedProductDefinition.marketingStatus.dateRange.end

4.6.5. Risk of supply shortage

The information related to the risk of short and long-term shortages or other problems related to the availability of medicines that can impact the medicine supply chain, can be reported through this data element.

The risk of supply shortage refers to the potential risk of unavailability of the authorised medicinal product marketed in a given member state of the European Union (EU).

The definition of "shortages" referred to in this guidance are to be understood in the context of the harmonised definition agreed by EMA-HMA in the "Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA)":

'A shortage of a medicinal product for human use occurs when supply does not meet demand at a national level'.

The definition applies to all shortages that are already affecting or that are expected to affect one or more EU member states in the future.

It applies to prescription and non-prescription medicines alike.

Tag	Description
User Guidance	The indication on whether there is a risk of a product shortage shall be specified. The risk of shortage is intended the potential risk to affect or is likely to affect more than one European Union (EU) Member State where the authorised medicinal product is marketed. This data element should be specified when the marketing status is either temporarily unavailable or not marketed. Yes – The availability of the medicinal product can lead to the potential risk of supply shortage in the EU member state in which the product is placed on the market and released into the distribution chain. No – The availability of the medicinal product does not lead to the potential risk of supply shortage in the EU member state in which the product is placed on the market and released into the distribution chain.
Repeatable	No
Conformance	Conditional
Data Type	Boolean
RMS URI/URL	Not applicable
Value(s)	True / False
ISO Element Name	Risk of supply shortage

Tag	Description
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingStatus/RiskOfSupplyShortage
FHIR Element Name	riskOfSupplyShortage
FHIR Path	PackagedProductDefinition.marketingStatus.extension.riskOfSupplyShortage

4.6.6. Risk of supply shortage comment

Tag	Description
User Guidance	The risk of supply shortage comment attribute shall be used to indicate any additional information related to the potential risk of supply shortage of authorised medicinal products within a given member state of the European Union, where the product is placed on the market and released into the distribution chain. This data element should be specified when the marketing status is either temporarily unavailable or not marketed.
Repeatable	No
Conformance	Conditional
Data Type	Markdown
RMS URI/URL	Not applicable
Value(s)	The details about the risk of supply shortage shall be provided as text.
ISO Element Name	Risk of supply shortage comment
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingStatus/RiskOfSupplyShortageComment
FHIR Element Name	riskOfSupplyShortageComment
FHIR Path	PackagedProductDefinition.marketingStatus.extension.riskOfSupplyShortageComment Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.6.7. Status reason

The Status Reason class describe the reason of the legal action taken on the marketing with reference to the attribute 4.5.2 Marketing status in case of any change to the availability of the authorised medicinal product on the market of the given European Union (EU) member state.

This applies to cases when the product is temporarily unavailable (i.e., temporarily cessation) or withdrawal of the product from the market (i.e., non marketed).

The information specified in this class can support the management of risk of supply shortage across the European Union.

This class and its individual attributes are conditional and not repeatable.

Status Reason Class	Description
Repeatable	No

Status Reason Class	Description
Conformance	Conditional

4.6.7.1. Reason

Tag	Description
User Guidance	The information related to the reason of any action taken on the unavailability of the authorised medicinal product on the market of the given European Union (EU) member state shall be specified to prevent the risk of supply shortage. Information shall be provided in cases when the authorised medicinal product is temporarily unavailable (i.e., temporarily cessation) or withdrawal of the product from the market (i.e., non marketed).
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000018799
Value(s)	As listed in the Reason for Marketing Unavailability RMS list
ISO Element Name	Reason
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingStatus/StatusReasons/Reason
FHIR Element Name	reason
FHIR Path	PackagedProductDefinition.marketingStatus.extension.reason Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

Example(s):

- Safety - Medicine is harmful (Art. 116, 117(1a) of Directive No 2001/83/EC)
- *Efficacy – Lack of efficacy (Art. 116, 117(1b) of Directive No 2001/83/EC)*
- *Risk/benefit - Not favourable (Art. 116, 117(1c) of Directive No 2001/83/EC)*
- *[..]*

4.6.7.2. Restore date

Tag	Description
User Guidance	The date when the authorised medicinal product is estimated to be reintroduced into the market of the given European Union (EU) member state can be provided. The estimated date or reintroduction applies only for temporary cessations of the authorised medicinal product.
Repeatable	No
Conformance	Optional
Data Type	dateTime
RMS URI/URL	Not applicable

Tag	Description
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	RestoreDate
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingStatus/StatusReasons/RestoreDate
FHIR Element Name	restoreDate
FHIR Path	PackagedProductDefinition.marketingStatus.restoreDate

4.7. 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 shall be specified according to the FHIR *Resource RegulatedAuthorization* and guidance provided in section 2. Marketing authorisation information.

If the marketing authorisation number or equivalent identifier is assigned at package level, the 'root' number (e.g., EU/1/YY/NNNN) only is provided at the level of medicinal product (as described in section *2.2.*). The individual package authorisation number part shall be specified for the individual package in this section including the root number.

If the authorisation number or equivalent identifier is assigned at Packaged Medicinal Product level and no stable "root number" common to all packaged medicinal products is assigned, the marketing authorisation number is to be left blank at medicinal product level (as described in section 2.2.).

Also, it is mandatory to provide the marketing authorisation number at packaged medicinal product level as described in this section.

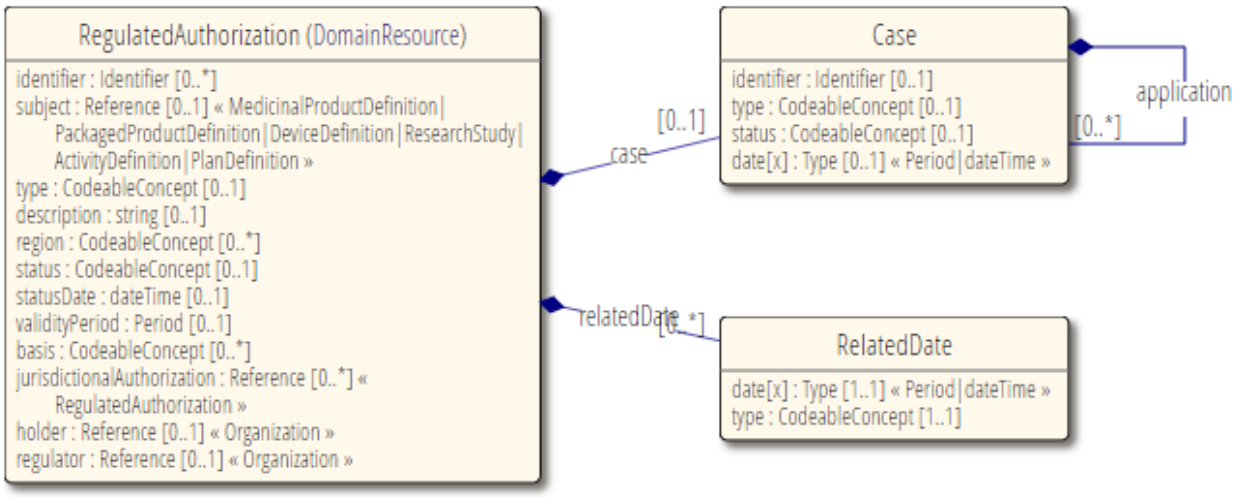


Figure 27: Resource RegulatedAuthorization (source: http://www.hl7.org/fhir)

The Marketing authorisation (Package level) class is a mandatory and not repeatable while the individual attributes of this class are not repeatable and shall be populated as applicable.

Marketing authorisation (Package level) Class	Description
Repeatable	No
Conformance	Mandatory

4.7.1. Regulatory authorisation type

Tag	Description
User Guidance	The type of regulatory authorisation shall be specified when the marketing authorisation is assigned at the level of packaged medicinal product. Please note that the RegulatedAuthorization type shall be set as Marketing Authorisation The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Conditional
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/220000000060
Value(s)	• As listed in the Regulatory Entitlement Type RMS list • The RMS term "Marketing Authorisation" shall be selected.
ISO Element Name	Not Applicable
ISO Path	Not Applicable
FHIR Element Name	Type
FHIR Path	RegulatedAuthorization.type

4.7.2. Marketing authorisation number (Package level)

Tag	Description
User Guidance	Marketing Authorisation number or equivalent identifier as assigned by the component authority to the medicinal product package shall be specified. This section is to be completed when the information is available Because the Marketing Authorisation Number or equivalent identifier is released by the competent authority after the end of the regulatory procedure, this data field can only be populated with the necessary information upon formal conclusion of the regulatory procedure as this information will not be available at the time of the submission of the FHIR message (initial sequence).
Repeatable	No
Conformance	Conditional
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	The number assigned by the competent authority of a country/jurisdiction shall be specified as free text.

Tag	Description
	• The format of the EU number shall be "EU/1/YY/NNN/XXX " or "EU/1/YY/NNNN/XXX" (as applicable)
ISO Element Name	Marketing Authorisation Number
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingAuthorisation/MarketingAuthorisationNumber
FHIR Element Name	Identifier
FHIR Path	RegulatedAuthorization.identifier
FHIR Complementary Information	RegulatedAuthorization.identifier.system value is http://ema.europa.eu/fhir/marketingAuthorizationNumber

4.7.3. Country

Tag	Description
User Guidance	The country code of the country where the marketing authorisation of the packaged medicinal product was granted, shall be specified as a term ID. • The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. • For medicinal products authorised via the centralised procedure, "European Union (EU)" shall be specified. • For medicinal products authorised in Liechtenstein, Norway and Iceland via the centralised procedure, the applicable country code (i.e., LI/NO/IS) shall be specified. • For medicinal products authorised via national or MRP/DCP procedure, the applicable EEA country shall be specified. • For medicinal products authorised outside the EU/EEA area, a non-EEA country shall be specified. • Medicinal products authorised outside the EU/EEA area may be submitted on voluntary basis. Such medicinal products are not within the scope of Article 57(2) requirements.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000002
Value(s)	As listed in the Country RMS list
ISO Element Name	Country
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingAuthorisation/Country
FHIR Element Name	Region
FHIR Path	RegulatedAuthorization.region

Example(s):

100000000529 – Kingdom of Spain

100000000390 - European Union

4.7.4. Authorisation status

Tag	Description
User Guidance	The status of the marketing authorisation of the packaged medicinal product throughout its lifecycle shall be specified as a term ID. • The applicable value shall be selected from the term ID as listed in applicable the Referentials Management Service (RMS) list. • The value "Valid after lifting of suspension" shall be entered when the marketing authorisation returned to status valid after the suspension of a marketing authorisation has been lifted. • The value "Valid - Renewed" shall be entered when the marketing authorisation is renewed.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072049
Value(s)	As listed in the Regulatory Entitlement Status RMS list
ISO Element Name	Authorisation Status
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingAuthorisation/ AuthorisationStatus
FHIR Element Name	Status
FHIR Path	RegulatedAuthorization.status

Example(s):

Withdrawn

Not Renewed

Expired

Revoked

Valid

4.7.5. Authorisation status date (Package level)

Tag	Description
User Guidance	The date at which the authorisation status of the package medicinal product has become effective shall be specified. This data element is to be completed when the information is available. • The date when the first authorisation was granted by the authorising body or the date when the renewal was granted (whichever is the latest) shall be specified in line with section *9. Date of first*

Tag	Description
	authorisation/renewal of the authorisation of the SmPC or any other regulatory document. • The date of expiry of the MA shall be specified if the MA was: – withdrawn by the MAH; – revoked by the competent authority; – not renewed by the competent authority; – not submitted for renewal by the MAH; – expired due to Sunset Clause. • The date of **suspension** of the MA shall be entered if the authorisation status is set to *Suspended*. • The date of **renewal** of the MA shall be entered if the authorisation status is set to *Valid – after renewal* • In case that status "Valid after lifting of suspension is selected" in previous attribute the date of lifting of the suspension shall be entered.
Repeatable	No
Conformance	Conditional
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Authorisation Status Date
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/MarketingAuthorisation/ AuthorisationStatusDate
FHIR Element Name	statusDate
FHIR Path	RegulatedAuthorization.statusDate

4.8. Package item (container)

The description of the container(s) of the manufactured medicinal product shall be described in this section. Container can be described as an item holding or carrying another item of the medicinal product. Therefore, containers can involve the primary or secondary packaging of the medicinal product.

The package item can be a single item, or a package of multiple items (e.g., two vials contained in a carton box, three blisters contained in a carton box or a single individual bottle).

For instance, a Packaged medicinal product consisting of a blister within a box will contain two Package items. One Package item will be the carton box, and the second container will be the blister, which is considered a sub-container.

Another example corresponds with a carton box (secondary packaging) containing two vials; solvent and powder (primary packaging). This packaged medicinal product contains therefore three package item containers (1) carton, (2) vial containing powder and (3) vial containing solvent.

Reference on this recursive relationship needs to be included accordingly as reflected in Manufacturing item reference(s).

A more detailed example is included below.

Example(s):

Packaged Medicinal Product	
PCID	EU-00001457-00040001-0001
Package Description	Pack of one vial (type I glass) of 2.5 ml suspension with a stopper (butyl rubber) and one vial (type I glass) of 2.5ml emulsion with a stopper (butyl rubber)
Package Item Container (1)	Box
Package Item Container Quantity	1
Package Item Material	Recycled Cardboard
Packaged Item Reference	Reference to Package item 2 and Package item 3
Manufacturing item Reference	Not Applicable
Data Carrier Identifier (s)	02890138016090
Package Item Container (2)	Vial
Package Item Container Quantity	1
Package Item Material	Glass type I
Package Item Component Type	Vial
Package Item Component Material	Glass type I
Package Item Component Type	Stopper
Package Item Component Material	Butyl Rubber
Manufactured Item (Manufactured Dose Form)	Suspension for emulsion for injection
Packaged Item Reference	Not applicable
Manufacturing item Reference	Reference to Suspension for Emulsion for Injection
Package Item Container (3)	Vial
Package Item Container Quantity	1
Package Item Material	Glass type I

Package Item Component Type	Vial
Package Item Component Material	Glass type I
Package Item Component Type	Stopper
Package Item Component Material	Butyl Rubber
Manufactured Item (Manufactured Dose Form)	Emulsion for emulsion for injection
Packaged Item Reference	Not applicable
Manufacturing item Reference	Reference to Emulsion for Emulsion for Injection

The Package item (container) class is a mandatory and repeatable. Some of the individual attributes of this class are not repeatable and shall be populated as applicable with the exception of package item (container) type and material data elements which are mandatory.

Package item (container) Class	Description
Repeatable	Yes
Conformance	Mandatory

4.8.1. Package item (container) type

Tag	Description
User Guidance	This element describes the physical type of the container of the medicinal product and shall be specified using a term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000073346
Value(s)	As listed in the Packaging RMS list
ISO Element name	Package item (container) type
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/PackageItem_ContainerType
FHIR Element name	Type
FHIR Path	PackagedProductDefinition.package.type

Example(s):

Bottle

Blister

Box

Vial

Blister Sleeve

Pre-filled Syringe

4.8.2. Package item reference(s)

Relationships among package items in the scenario that a package item container (e.g., carton, secondary packaging) contains one or more package item such as additional secondary packaging or primary packaging only (e.g., vials or blisters within a carton) needs to be indicated.

This structure is only applicable in a parent/child relationship and not the opposite (child/parent relationship). This means that the relationship is established at the level of the package item acting as a container for other package container and not the opposite.

Tag	Description
User Guidance	This is not a regular attribute but a reference to a list of package items contained within a package item (if applicable). For example, a cardboard carton box that contains 2 vials will carry the reference to the 2 vials contained within the box. This is also applicable to reference the relationships of a single or multiple component contained within a package container. For example, a container vial that contains a component stopper (butyl rubber) vial will carry the reference to the butyl rubber stopper. This field is only applicable in a parent/child relationship and not the opposite (child/parent relationship).
Repeatable	Yes
Conformance	Conditional
Data Type	BackboneElement
RMS URI/URL	Not applicable
Value(s)	Structured data elements describing the included packages.
ISO Element name	Package item (container)
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItemContainer/
FHIR Element name	Package
FHIR Path	PackagedProductDefinition.package.package

Example(s):

Carton containing two vials

This is a simplified JSON version

"packageItem" : [{

"identifier" : 123

"type" : { Cardboard Box },

"quantity" : { 1 },

"packageItem" : [{

"identifier" : 456

"type" : { Vial },

"quantity" : { 2 }, }]

}]

4.8.3. Manufactured item reference(s)

Relationships among package items and manufactured items need to be completed. This attribute is for mandatory completion where the package item is/contains the manufacturing item (e.g., a vial containing the pharmaceutical form powder for solution for injection).

If the package item does not contain any manufactured item (e.g., empty vial, carton), this field is to be left blank.

Tag	Description
User Guidance	This is not a regular attribute but a reference to a manufactured item contained within a package item (if applicable) For example, a vial containing powder will carry the reference to manufacturing item powder for solution for injection. This structure is only applicable at the level of package item involves the primary packaging and contains a manufacturing item
Repeatable	Yes
Conformance	Conditional
Data Type	BackboneElement
RMS URI/URL	Not applicable
Value(s)	Structured data elements referencing the included manufactured items and the respective quantities.
ISO Element name	Manufactured item
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItemContainer/ManufacturedItem
FHIR Element name	Containeditem
FHIR Path	PackagedProductDefinition.package.containeditem

4.8.4. Device reference(s)

A packaged medicinal product may include medical devices for different purposes (e.g., administration device).

Relationships among package items and medical devices need to be completed where applicable. This attribute is for mandatory completion where the package medicinal product contains a medical device. Two situations can be foreseen:

- The medical device is included as independent elements within the packaged medicinal product (e.g., spoon, syringes, pens) – In this case the relationship of the medical device with the package item is established at least one-level above the primary packaging (e.g., carton).
- The medical device is integrated and contains the medicinal product already as packaged for sale (e.g., pre-filled syringes, pre-filled pen) - In this case the relationship of the medical device with the package item is established at the level of the primary packaging (e.g., pen, syringe). As

consequence, the device (e.g., pen, syringe) will be both a package item container and a medical device.

If there is no medical device included within the packaged medicinal product, this field is to be left blank.

Tag	Description
User Guidance	This is not a regular attribute but a reference to two possible situations • Medical device contained within a package item (e.g., a spoon contained within the secondary packaging of the medicinal product) • A medical device which is also the primary packaging/package item container for the medicinal product (e.g., pre-filled syringe) This structure is only applicable if there is a medical device included in the packaged medicinal product.
Repeatable	Yes
Conformance	Conditional
Data Type	BackboneElement
RMS URI/URL	Not applicable
Value(s)	Structured data elements referencing the included devices and the respective quantities.
ISO Element name	Device
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItemContainer/Device
FHIR Element name	ContainedItem
FHIR Path	PackagedProductDefinition.package.containedItem

4.8.5. Package item (container) quantity

The number of the package item containers shall be specified. Because the package item class may contain recursive relationships to describe containers within containers, the first container (top-level package item/outer-most packaging) will always have a quantity of one (i.e., '1').

Example 1: Medicinal product A 500mg tablets with 30 tables in 3 blisters (10 tablets per blister) packaged in a single carton box.

- *Carton x 1*
  - *Blister x 3*

There is no need to indicate the number of tablets since this information is included in section 4.11.2. Manufactured item quantity.

Note: If the same packaged medicinal product contains different configurations (e.g., Medicinal Product ABC 500mg 30 tablets contained in either 2 blisters of 15 tablets each or 3 blisters of 10 tablets per blister) which are not defined in the terms of the marketing authorisation or packaged description, Package item (container) quantity at the level of the immediate packaging is to be left blank.

Example 2: Medicinal product B comprises combined pharmaceutical form powder (40 micrograms) and solvent (1 ml) for solution for injection. This package example consists of two vials with solvent and two vials with powder, all vials packaged in a single carton box.

- *Carton x 1*
  - *Vial (solvent) x 2*
  - *Vial (powder) x 2*

There is no need to indicate the content of each vial since this information is included in section Manufactured Item.

Tag	Description
User Guidance	The number of the package item shall be specified, when applicable. The first container (top-level package Item/outer packaging) will always have a quantity of one (i.e., '1').
Repeatable	No
Conformance	Conditional
Data Type	Quantity
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000000014
Value(s)	Quantity value and unit. The units shall be specified as a Term ID as listed in the Units of Presentation RMS list.
ISO Element Name	Package item (container) quantity
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/PackageItem_ContainerQuantity
FHIR Element Name	Quantity
FHIR Path	PackagedProductDefinition.package.quantity

4.8.5.1. Quantity operator (New)

Tag	Description
User Guidance	The applicable value corresponding to the quantity operator shall be specified as term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000008
Value(s)	As listed in the Quantity Operator RMS list. If the RMS term can be mapped to a FHIR Quantiy comparator, the FHIR comparator field should also be specified for interoperability.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Quantity Operator
FHIR Path	PackagedProductDefinition.package.quantity.extension.quantityOperator PackagedProductDefinition.package.quantity.comparator

Tag	Description
	Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.8.6. Data carrier identifier

When using different packaging levels of medicinal products (e.g., secondary packaging, primary packaging), data carrier identifiers (e.g., barcodes) and the type of identifier may be specified. For the purpose of this iteration, only the data carrier identifier in the outer-most package should be specified.

In the European context, should the medicinal product fall within the scope of the EU Falsified Medicines Directive - FMD (Directive 2011/62/EU) which amended Directive 2001/83/EC, the Identifier available in the central information may be specified. This is the value uploaded by the MAH to the EMVS database ('hub') as referred to in Article 32 of the Commission Delegated Regulation (EU) 2016/161.

The data carrier identification number of the outer-most packaging of the packaged medicinal product shall be specified using the Global Trade Item Number (GTIN) or National Trade Item Number (NTIN) identification system as recorded in the European Medicines Verification System (EMVS) or the Pharmacy Product Number (PPN). Rules regarding GTIN or NTIN are specified in EMVS annex 2.

In case of multiple identifiers per PCID (e.g., language versions), all the relevant identifiers shall be specified.

The set of Data carrier identifier attributes are optional and repeatable.

Attachment document Class	Description
Repeatable	Yes
Conformance	Optional

4.8.6.1. Identifier value (New)

Tag	Description
User Guidance	The outer-most packaging carrier identifier (GTIN/NTIN/PPN) may be specified. e.g.,
Repeatable	No
Conformance	Mandatory
Data Type	String
RMS URI/URL	Not applicable
Value(s)	String
ISO Element Name	Data Carrier Identifier
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/DataCarrierIdentifier
FHIR Element Name	

Tag	Description
	value
FHIR Path	PackagedProductDefinition.package.identifier.value

Example(s):

GTIN: 028901563801609

PPN: 30 A123456789 09

NTIN: 0 90 8985 391109 8

Note: Examples are fictitious

4.8.6.2. Identifier system (New)

Tag	Description
User Guidance	The source system relevant to the reported identifier can be specified. The applicable term shall be provided as a term ID from the Source of Information RMS list.
Repeatable	No
Conformance	Mandatory
Data Type	URI
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000009
Value(s)	URI referencing to the applicable RMS term from the Source of Information RMS list (i.e., https://spor.ema.europa.eu/v1/lists/100000000009 /terms/100000075665).
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	system
FHIR Path	PackagedProductDefinition.package.identifier.system

Example(s):

GS1 Global Trade Item Number (100000167575)Pharmacy Product Number (200000027029)

National Trade Item Number (200000027030)

4.8.7. Material

Tag	Description
User Guidance	The material the package item is made from shall be specified using a term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. If several materials are identified in the SmPC (e.g., Aluminium, PVC for blisters) this field needs to be repeated listing all relevant materials.
Repeatable	Yes
Conformance	Mandatory

Tag	Description
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000003199
Value(s)	As listed in the Material RMS list
ISO Element name	Material
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/Material
FHIR Element name	Material
FHIR Path	PackagedProductDefinition.package.material

Example(s):

Paper, plastic, glass

4.9. Package (component)

This class shall be used to further describe any part of the packaging of the packaged medicinal product. The package item container (primary packaging) may be described with additional components of the container (e.g., closure and seal of vials, needle guards). In particular components with an impact on the drug product's stability shall be reported (example: desiccant). This applies occur either when the desiccant is part of the package item (i.e., desiccant included in the bottle) or when the desiccant is include as separate item (i.e., desiccant bag).

The description can be of a complete container or a part of a container, such as a closure.

If the indicated package container corresponds to the primary packaging (direct contact with the product itself) the same term used to describe the packaged component type shall be applied to indicate the packaged component type.

If the indicated packaged container does not correspond to the primary packaging the relevant term shall not be repeated as packaged (component) type in PMS. Refer to Chapter 8 Annex I – Complete representation.

This information should be provided as part of the submission.

The information in section 6.5 of the SmPC should be used as a basis for the description of the package components. Two examples are included below to illustrate this concept.

Example(s):

Description	Cartridge (type 1 glass) with a plunger (bromobutyl) and a laminate rubber sheet (bromobutyl/polyisoprene) contained in a pre-filled multidose disposable pen made of polyolefin and polyacetal.
Package Item Container	Cartridge in a pre-filled pen
Package Item Container Material	Glass type I
Package Item Component Type (1)	Plunger

Package Item Component Material (1)	Bromobutyl
Package Item Component Type (2)	Rubber sheet
Package Item Component Material (2)	Bromobutyl/polyisoprene

Note: Polyolefin and polyacetal are materials of the device and not the package item container and should not be captured.

Example(s):

Description	30 ml of concentrate in a vial (Type I glass) with a stopper (butyl, siliconised), and a seal (aluminium) with flip-off cap (polypropylene).
Package Item Container	Vial
Package Item Container Material	Glass type I
Package Item Component Type (1)	Vial
Package Item Component Material (1)	Glass type I
Package Item Component Type (2)	Stopper
Package Item Component Material (2)	butyl, siliconized
Package Item Component Type (3)	Seal
Package Item Component Material (3)	Aluminium
Package Item Component Type (4)	Cap
Package Item Component Material (4)	Polypropylene

The Package (component) class is mandatory and repeatable while the individual attributes of this class are not repeatable (with the exception of component material data element) and shall be populated as applicable.

Package item (component) Class	Description
Repeatable	Yes
Conformance	Mandatory

4.9.1. Component type

Tag	Description
User Guidance	The type of component, whose material is being described, shall be specified. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.

Tag	Description
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000073346
Value(s)	As listed in the Packaging RMS list
ISO Element name	Component Type
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/Package_Component/ComponentType
FHIR Element name	Type
FHIR Path	PackagedProductDefinition.package.package.type

Example(s):

Child-Resistant Closure

Stopper

Plunger

4.9.2. Component material

Tag	Description
User Guidance	The material(s) of the component may be specified using a term ID, as applicable. The applicable value(s) shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list. If several different materials are identified for the same component, this field needs to be repeated listing all relevant materials.
Repeatable	Yes
Conformance	Conditional
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000003199
Value(s)	As listed in the Material RMS list
ISO Element name	Component Material
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/Package_Component/ComponentMaterial
FHIR Element name	Material
FHIR Path	PackagedProductDefinition.package.package.material

Example(s):

Paper, plastic, glass

4.10. Medical device

As defined in the Directive 2001/83/EC, medicinal products can be marketed for use in combination with a medical device, usually to enable the delivery of the medicine. Information on the medical

device, based on the elements described in this section should be provided when the medicinal product is presented in combination with medical devices. Overall, there are two types of combination:

- integral: the medicinal product and device form a single integrated product e.g., pre-filled syringes and pre-filled pens, certain types of patches for transdermal drug delivery and pre-filled inhalers;
- co-packaged: the medicinal product and the device are separate items contained in the same pack e.g., reusable pen for insulin cartridges, tablet delivery system with controller for pain management.

In addition, the device may be combined with the medicinal product and support the pharmacological/metabolic/immunological action of the medicinal product (collagen scaffold). In these cases, the device's purpose goes beyond the administration and supports the mechanism of action of the medicinal product. These types of devices are considered an integral part of the pharmaceutical product administered to the patient and should be recorded in this section as well as section 6.5 Medical Device.

The full information on Device as presented in the FHIR *Resource DeviceDefinition* is shown in the figure 18 below. In Iteration 1 of the PMS implementation, the elements inside the red rectangles are in scope and shall be provided according to the rules and guidance described in this section:

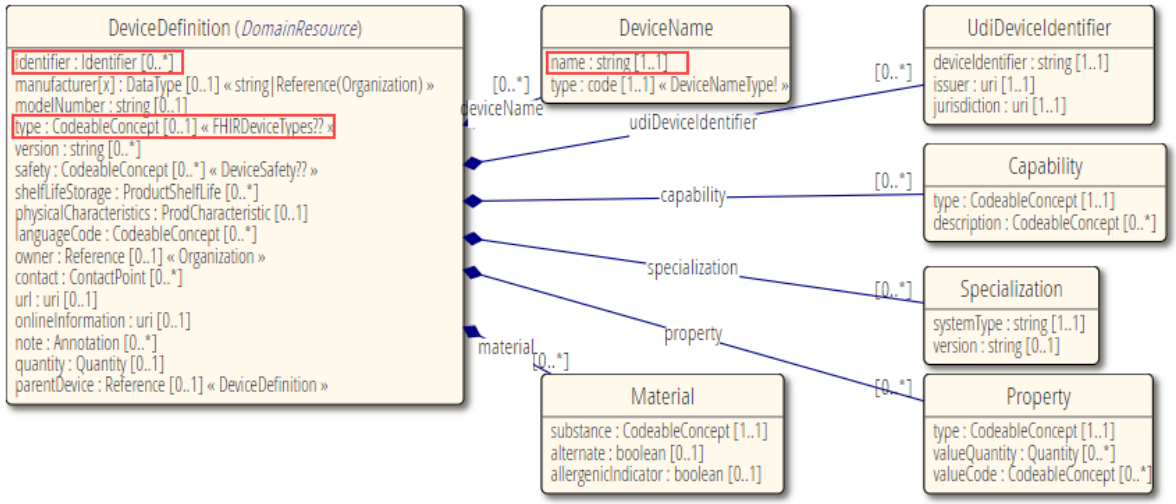


Figure 28: Resource DeviceDefinition (Source : http://www.hl7.org/fhir/)

The Device class is conditional and repeatable while the individual attributes of this class are not repeatable and shall be populated as applicable.

Device Class	Description
Repeatable	Yes
Conformance	Conditional

4.10.1. Type of medical device used in combination with medicinal product

Tag	Description
User Guidance	The type of medical device used in combination with medicinal product shall be specified when using a term ID if applicable. The applicable value shall be selected from the term ID listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/rmswi/#/lists/200000025965/
Value(s)	As listed in the Medical Device Legislative Category RMS list
ISO Element name	DeviceType
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/Device
FHIR Element name	typeOfCombination
FHIR Path	DeviceDefinition.extension.typeOfCombination

Example(s):

Integral – Not administration device (200000025966)

Integral – Administration device (200000025967)

Combined advanced therapy medicinal product (200000025968)

Co-packaged (200000025969)

Referenced in the product information of the medicinal product (200000025970)

Companion diagnostic (200000025971)

4.10.2. Medical device type

Tag	Description
User Guidance	The Type of the device or device system of the medicinal product shall be specified when using a term ID if applicable. The applicable value shall be selected from the term ID listed in in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Based on the following terms specified in 4.10.1.: • Mandatory: - Integral – Not administration device - Integral – Administration device - Combined Advanced Medicinal Product Therapies (ATMP) - Co-packaged - Referenced in the PI of the medicinal product

Tag	Description
	- Companion diagnostic (IVD)
Data Type	CodeableConcept
RMS URI/URL	The applicable value as listed from the RMS list [list will be created in v2.2]
Value(s)	As listed in the Medical Device Type RMS list
ISO Element name	Device Type
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/Device/DeviceType
FHIR Element name	Type
FHIR Path	PackagedProductDefinition.manufacturer type

Example(s):

Measuring spoon, cup, cannula, spatula, injection needle, injection syringe,

4.10.3. Medical device identification

Article 27 and Article 28 of the New Medical Device Legislation (EU) 2017/745 establishes an electronic system for the unique device identification. This facilitates the identification and traceability of devices and the establishment of a European Database on Medical Devices (EUDAMED). This database is currently under development by the European Commission.

The Unique Device Identifier (UDI), is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market.

Integrated devices may be governed by the Medicinal Products Directive (EC) 2001/83, and therefore the MDR obligations related to UDI may not be required and are not be applied to the package of the combination product. The UDI may be assigned to integral devices with CE mark. Overall, the UDI shall be provided where available and applicable.

The Unique Device Identifier (UDI) shall be specified when available.

Tag	Description
User Guidance	The Unique Device Identifier (to the level of UDI device identifier (UDI-DI) at the level of the medical device model recorded in the European database on medical devices (EUDAMED) shall be specified, if applicable, to the medicinal product. Note: The Unique Device Identifier at the level of batch/product (UDI-PI) shall **not** be provided
Repeatable	No
Conformance	Based on the following terms specified in 4.10.1.: • Conditional: – Integral – Not administration device – Integral – Administration device – Combined Advanced Medicinal Product Therapies (ATMP) – Co-packaged

Tag	Description
	• Not applicable: – Referenced in the PI of the medicinal product – Companion diagnostic (IVD)
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	Unique Device Identifier
ISO Element name	Device Identifier
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/Device/DeviceIdentifier
FHIR Element name	Identifier
FHIR Path	DeviceDefinition.identifier
FHIR Complementary Information	DeviceDefinition.identifier.system value to be defined based on RMS term entry for Source of Information RMS list.

4.10.4. Medical device trade name

Tag	Description
User Guidance	The name of the device should be specified, if applicable, as recorded in the European database on medical devices (EUDAMED) or as recorded in medicinal product regulatory submission and SmPC for medical devices falling under Directive (EC) 2001/83.
Repeatable	No
Conformance	Based on the following terms specified in 4.10.1.: • Conditional: – Integral – Not administration device – Integral – Administration device – Combined Advanced Medicinal Product Therapies (ATMP) – Co-packaged – Referenced in the PI of the medicinal product – Companion diagnostic (IVD)
Data Type	String
RMS URI/URL	Not applicable
Value(s)	Medical Device Trade Name
ISO Element name	Device Trade Name
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/Device/DeviceTradeName
FHIR Element name	Name
FHIR Path	DeviceDefinition.deviceName.name
FHIR Complementary Information	DeviceDefinition.deviceName.type value is “other”

Example(s):

OptiKlack

InsuAll

Note: Examples are fictitious

4.10.5. Medical device quantity

Tag	Description
User Guidance	The quantity (number of units) of the device(s) in the medicinal product package, shall be specified as a value and units (as per section 6.5 of the SmPC). If RMS list "Unit of presentation" does not contain the applicable type of device, the term "countable unit(s)" from Unit of Measurement List shall be selected.
Repeatable	No
Conformance	Based on the following terms specified in 4.10.1.: • Mandatory: – Integral – Not administration device – Integral – Administration device – Combined Advanced Medicinal Product Therapies (ATMP) – Co-packaged • Not applicable: – Referenced in the PI of the medicinal product – Companion diagnostic (IVD)
Data Type	Quantity
RMS URI/URL	• https://spor.ema.europa.eu/v1/lists/100000110633 • https://spor.ema.europa.eu/v1/lists/200000000014
Value(s)	Numeric value and unit. The units shall be specified as a Term ID listed in the Units of Measurement List or Units of Presentation list as applicable
ISO Element name	DeviceQuantity
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/Device/DeviceQuantity
FHIR Element name	amount
FHIR Path	PackagedProductDefinition.package.containedItem.amountQuantity

4.10.5.1. Quantity operator (New)

Tag	Description
User Guidance	The applicable value corresponding to the quantity operator shall be specified as term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory

Tag	Description
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000008
Value(s)	As listed in the Quantity Operator RMS list. If the RMS term can be mapped to a FHIR Quantity comparator, the FHIR comparator field should also be specified for interoperability.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	quantityOperator
FHIR Path	PackagedProductDefinition.package.containedItem.amountQuantity.extension.quantityOperator PackagedProductDefinition.package.containedItem.amountQuantity.comparator Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.10.6. Medical device description (New)

Tag	Description
User Guidance	The high-level description of the applicable medical device shall be reported in this data element. Information comprehensive of the different and single component(s) of the medical device used (i.e., smart tools etc) shall also be provided, when available. **Products authorised through MRP/DCP/NP routes** • The medical device description is to be provided in English or in the local language(s) of authorisation, or optionally in all of them. **Products authorised through the centralised procedure** The medical device description is to be provided in English.
Repeatable	Yes
Conformance	Based on the following terms specified in 4.10.1.: • Mandatory: – Integral – Not administration device – Integral – Administration device – Combined Advanced Medicinal Product Therapies (ATMP) – Co-packaged – Referenced in the PI of the medicinal product – Companion diagnostic (IVD)
Data Type	Markdown
RMS URI/URL	Not applicable

Tag	Description
Value(s)	Free text or markdown text for rich content
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	description
FHIR Path	DeviceDefinition.extension.description Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.10.6.1. Language (New)

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

Tag	Description
User Guidance	The language of the medical device description as specified in previous section shall be specified. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072057
Value(s)	As listed in the Language RMS list
ISO Element Name	Not Applicable
ISO Path	Not Applicable
FHIR Element Name	valueCode
FHIR Path	DeviceDefinition.extension.description.extension.language Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.10.7. Medical device description of intended purpose (New)

Tag	Description
User Guidance	The description of the intended purpose of the type of medical device shall be reported in this data element. The description of the intended purpose shall reflect the text as reported in the CE certificate released by the relevant Notified Body. **Products authorised through MRP/DCP/NP routes** • The medical device description of intended purpose is to be provided in English or in the local language(s) of authorisation, or optionally in all of them.

Tag	Description
	Products authorised through the centralised procedure The medical device description of intended purpose is to be provided in English.
Repeatable	Yes
Conformance	Based on the following terms specified in 4.10.1.: • Mandatory: – Integral – Not administration device – Integral – Administration device – Combined Advanced Medicinal Product Therapies (ATMP) – Co-packaged – Referenced in the PI of the medicinal product – Companion diagnostic (IVD)
Data Type	Markdown
RMS URI/URL	Not applicable
Value(s)	Free text or markdown text for rich content
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	intendedPurpose
FHIR Path	DeviceDefinition.extension.intendedPurpose Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.10.7.1. Language (New)

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

Tag	Description
User Guidance	The language of the medical device description as specified in previous section shall be specified. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072057
Value(s)	As listed in the Language RMS list
ISO Element Name	Not Applicable
ISO Path	Not Applicable
FHIR Element Name	valueCode
FHIR Path	DeviceDefinition.extension.intendedPurpose.extension.language

Tag	Description
	Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.10.8. Medical device classification (New)

Tag	Description
User Guidance	The relevant classification of the type of medical device shall be specified by using a term ID, as applicable. The applicable value(s) shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Based on the following terms specified in 4.10.1.: • Mandatory: – Integral – Not administration device – Integral – Administration device – Combined Advanced Medicinal Product Therapies (ATMP) – Co-packaged – Referenced in the PI of the medicinal product • Not applicable: – Companion diagnostic (IVD)
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/rmswi/#/lists/200000025960
Value(s)	As listed in the Medical Device Classification RMS list
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	classification
FHIR Path	DeviceDefinition.extension.classification Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

Example(s):

Class I

Class IIa

Class IIb

Class III

4.10.9. Medical device manufacturer (New)

Tag	Description
User Guidance	The reference to the relevant Manufacturer of the medical device shall be selected from the list of manufacturers recorded in section 1.20 Manufacturing business operation.
Repeatable	Yes
Conformance	Based on the following terms specified in 4.10.1.: • Mandatory: – Integral – Not administration device – Integral – Administration device – Combined Advanced Medicinal Product Therapies (ATMP) – Co-packaged – Referenced in the PI of the medicinal product – Companion diagnostic (IVD)
Data Type	Reference
RMS URI/URL	Not applicable
Value(s)	Reference to the relevant ActivityDefinition resource describing the manufacturing business operation.
ISO Element Name	Manufacturer(Organisation)
ISO Path	MedicinalProduct/PackagedMedicinalProduct/ManufacturerEstablishmentOrganisation/Manufacturer(Organisation)
FHIR Element Name	manufacturer
FHIR Path	DeviceDefinition.manufacturerReference.extension.manufacturingBusinessOperation Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.11. Manufactured item

The product as it is authorised and, where applicable, before transformation into the administrable pharmaceutical form shall be described in this section. There after 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 and corresponding to one or more pharmaceutical products.

Examples of single manufactured item and single pharmaceutical product:

- "Film-coated tablet" involves a single manufactured item. This manufactured item corresponds with the administrable dose form and pharmaceutical product (no previous preparation/combination with other manufactured item is needed).
- Solution for Injection involves a single manufactured item. This manufactured item corresponds with the administrable dose form and pharmaceutical product (previous preparation/combination

with other manufactured item is needed to prepare the administrable dose form, however the medicinal product does not include the solvent).

Examples of multiple manufactured items and single pharmaceutical products:

- Powder for solution for injection and Solvent for Solution for injection in combined pharmaceutical form Powder and Solvent for Solution for injection. This involves two manufactured items that should be combined to prepare the administrable dose form and pharmaceutical product.

Examples of multiple manufactured items and multiple pharmaceutical products:

- "Oral Capsule" & "External Cream" correspond with two different administrable dose forms which does not need combining for administration to the patient.

The full information on Manufactured Item as presented in the FHIR *ManufacturedItemDefinition* is shown in the figure 19 below. Only the elements described below are within the scope of iteration 1 implementation:

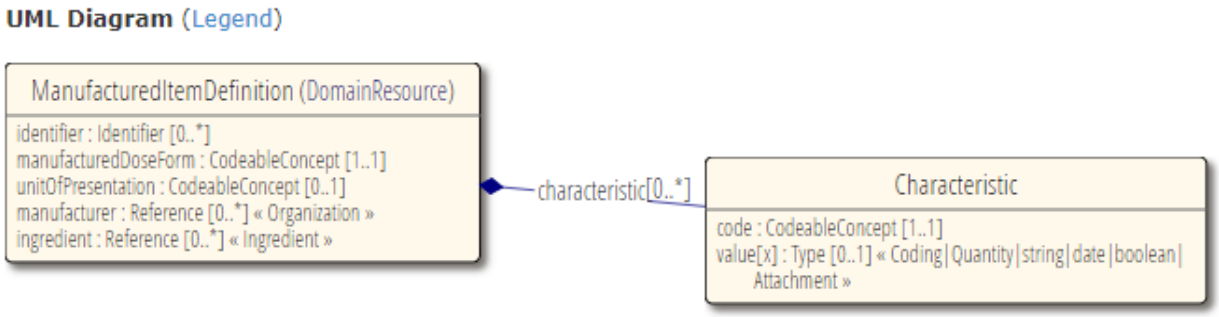


Figure 29: ManufacturedItemDefinition captured by FHIR (source: http://www.hl7.org/fhir/)

The Manufactured item class is mandatory and repeatable while the individual attributes of this class are not repeatable (except for Ingredient class of data elements) and shall be populated as applicable.

Manufactured item Class	Description
Repeatable	Yes
Conformance	Mandatory

4.11.1. 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 shall be specified as a term ID. The applicable value shall be selected from the term ID listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000000014
Value(s)	As listed in the Units of Presentation RMS list, or reference for externally maintained list in order to allow international information exchange.
ISO Element Name	Unit of Presentation

Tag	Description
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/ManufacturedItem/UnitOfPresentation
FHIR Element Name	unitOfPresentation
FHIR Path	ManufacturedItemDefinition.unitOfPresentation

Example(s):

- units of presentation: actuation, patch, tablet

4.11.2. Manufactured item quantity

Tag	Description
User Guidance	The quantity (or count number) of the manufactured item in the medicinal product package, shall be specified as a value and units as per section 6.5 of the SmPC. For solid dose forms and other items measured by counting (i.e., tablets, capsules), discrete countable entities, the unit for quantity is the term "countable unit" from the RMS Units of Measurements List and the "unit of presentation" is the item counted within the immediate container to be populated in the data element 4.10.1 Unit of presentation. For formulations contained in a vial, the unit for quantity is volume/quantity expressed with the relevant units of measurement term (i.e., mg, mL) and the "unit of presentation" is the discrete countable entity, in which a pharmaceutical product or manufactured item is presented. This last data to be reported in the data element 4.10.1. Unit of presentation. Example: • In case of tablets/capsules the number of tablet/capsules in the immediate shall be specified: 28 tablets, 24 capsules are to be is to be populated as 28 and 24 countable unit(s) respectively. The UoP "tablets" and "capsules" are to be included in 4.10.1. respectively. • In case of formulations contained in a vial (e.g., liquids) the total quantity/volume should be expressed: 5 mg, 2 mL are to be populated as 5 ml and 2 mL respectively. The UoP "vial" is to be included in 4.10.1. • In case of lyophilised formulations contained in a vial (e.g., powder), the total quantity/volume should be expressed: 1 vial is to be populated as 1 countable unit(s). The UoP "vial" is to be included in 4.10.1. For the purpose of data entry, it is recommended that this information is specified in the SmPC of the medicinal product as much complete as possible.
Repeatable	No
Conformance	Conditional

Tag	Description
Data Type	Quantity
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000110633
Value(s)	Numeric value and unit. The units shall be specified as a Term ID listed in the Units of Measurement RMS list as applicable.
ISO Element Name	Manufactured Item Quantity
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/ManufacturedItem/ManufacturedItemQuantity
FHIR Element Name	amountQuantity
FHIR Path	PackagedProductDefinition.package.containedItem.amountQuantity

Example(s):

- 28 dispersible tablets is:

Manufactured item	
Unit of presentation	Tablet
Manufactured item quantity	28 countable unit(s)
Manufactured dose form	Dispersible tablet

- 25 ml in a syringe is:

Manufactured item	
Unit of presentation	Syringe
Manufactured item quantity	25 ml
Manufactured dose form	Solution for injection

4.11.2.1. Quantity operator (New)

Tag	Description
User Guidance	The applicable value corresponding to the quantity operator shall be specified as term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000008
Value(s)	As listed in the Quantity Operator RMS list. If the RMS term can be mapped to a FHIR Quantity comparator, the FHIR comparator field should also be specified for interoperability.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Quantity Operator

Tag	Description
FHIR Path	PackagedProductDefinition.package.containedItem.amountQuantity.extension.quantityOperator PackagedProductDefinition.package.containedItem.amountQuantity.comparator Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.11.3. Manufactured dose form

The manufactured dose form corresponds with the dose form presented in the manufactured item. See the following examples:

Example 1:

Medicinal Product ABC 20mg/ml powder and solvent for solution for injection (combined pharmaceutical form) in a vial 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 section *3. Pharmaceutical Form* of the SmPC or other regulatory document (description prior to any transformation into the final form administered to the patient) shall be specified as a term ID. • The required authorised pharmaceutical form shall be specified as a term ID as listed in the applicable Referentials Management Service (RMS) list. • If multiple values apply to the same medicinal product, then multiple manufactured items shall be created. • Deprecated (i.e., non-current) dose form terms may be referenced.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000000004
Value(s)	Listed in the Pharmaceutical Dose Form RMS list.
ISO Element Name	Manufactured Dose Form

Tag	Description
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/ManufacturedItem/ManufacturedDoseForm
FHIR Element Name	ManufacturedDoseForm
FHIR Path	ManufacturedItemDefinition.manufacturedDoseForm

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: powder and solvent for solution for injection, gel in sachet, syrup in sachet, emulsion for injection/infusion in pre-filled syringe.

The manufactured dose form will be chosen only from the RMS list Pharmaceutical Dose Form and not from the other three RMS lists that are also used for the Authorised Dose Form (Combined pharmaceutical dose form, Combined terms or Combination Packs, section 1.5 (Authorised) pharmaceutical form).

4.11.4. Ingredient

The ingredient(s) of a manufactured item shall be specified by selecting the relevant ingredients present in the manufactured item, from the Ingredients lists based on the Resource *Ingredient* as outlined in section 5. Ingredient.

The Ingredient class is mandatory. For further details relating to technical information and business rules, please refer to section 5. Ingredient.

This value is an attribute within Packaged Product domain.

Tag	Description
User Guidance	The reference to the ingredient(s) of the pharmaceutical product shall be selected from the list of ingredients recorded in sections 5. Ingredient
Repeatable	Yes
Conformance	Mandatory
Data Type	Reference
RMS URI/URL	Not applicable
Value(s)	Structured data elements referencing the included ingredients in the manufactured item
ISO Element Name	Ingredient
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient
FHIR Element Name	Ingredient
FHIR Path	ManufacturedItemDefinition.ingredient

4.11.5. Manufactured item description

The description of manufactured item shall be provided whenever the medicinal product contains more than one manufactured item product in order to allow a readily differentiation in the database.

The provision of manufactured item characteristics is not needed for medicinal products with a single manufactured item.

In medicinal products containing more than one manufactured item (e.g., contraceptive having different strengths and fixed dose combination as part of the same medicinal product), differentiation of manufacturing items is not easily visualised with the information provided in the rest of individual data fields (in certain cases it can only be differentiated on specific substance of the qualitative and quantitative composition of the pharmaceutical product).

Information on manufacturing item description is free text and should be provided in the form of: "Physical Characteristics" + "Unit of presentation".

Physical Characteristics of the manufacturing item includes colour or shape among others which allow differentiation from remaining manufacturing items.

Note: Additional clarifications on the manufacturing item description will be provided in the EU IG v2.2 release.

Tag	Description
User Guidance	The high-level description of manufactured item shall be provided whenever the medicinal product contains more than one pharmaceutical product (e.g., different types of tablets in the same package). Information on manufacturing item description is free text and should be provided in the form of: "Physical Characteristics" + "Manufactured dose form" + "Package item container (immediate packaging)" as relevant. **Products authorised through MRP/DCP/NP routes** • The manufactured item description is to be provided in English or in the local language(s) of authorisation, or optionally in all of them. **Products authorised through the centralised procedure** • The manufactured item description is to be provided in English.
Repeatable	Yes
Conformance	Conditional
Data Type	Markdown
RMS URI/URL	Not applicable
Value(s)	Free text or markdown text for rich content
ISO Element name	Not Applicable
ISO Path	Not Applicable
FHIR Element name	text
FHIR Path	ManufacturedItemDefinition.property.valueCodeableConcept.text

Example(s):

Dark yellow film-coated tablet to differentiate from Medium red film-coated tablet

4.11.5.1. Language

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

Tag	Description
User Guidance	The language of the manufactured item description, as approved by the regulatory authority and indicated in the corresponding regulatory document(s) shall be specified as a term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072057
Value(s)	As indicated in the Language RMS list
ISO Element Name	Not Applicable
ISO Path	Not Applicable
FHIR Element Name	language
FHIR Path	ManufacturedItemDefinition.property.valueCodeableConcept.text.extension.language Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

4.12. Shelf life / Storage

The description of the shelf life and storage information of the packaged medicinal product, as approved in the terms of the marketing authorisation, should be specified. The shelf life and storage conditions/scenarios should be listed in the Product information and section 2.2.3 of the electronic application form (eAF). This includes shelf life and storage conditions as packaged for sale, shelf life/storage conditions after dilution or reconstitution or any other scenario.

This entity is repeatable to allow the introduction of different shelf-life/storage conditions in the same product (e.g., shelf life and storage conditions for medicinal products as packaged for sale and after dilution or reconstitution). An example is shown below:

Example(s):

Packaged Medicinal Product	
Package description	Type I glass vial with rubber stopper containing 100 mg of *active substance abc*. Pack of 1 vial.

Description (as per SmPC)	**Unopened vial** *3 years.* Do not store above 30ºC **Reconstituted and infusion solutions** When prepared as directed, reconstituted and infusion solutions of *Medicine ABC* contain no antimicrobial preservatives. Chemical and physical in-use stability of reconstituted and infusion solutions of *Medicine ABC* were demonstrated for *24 hours at refrigerated temperature.* From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not be longer than 24 hours at 2°C to 8°C.
Shelf life type (1)	Shelf life of the medicinal product as packaged for sale
Shelf life time and Period (1)	3 years
Storage Conditions (1)	Do not store above 30ºC
Shelf life type (2)	Shelf life after dilution or reconstitution according to directions
Shelf life time and Period (2)	24 hours
Storage Conditions (2)	Store in a refrigerator (2ºC – 8ºC)

Shelf Life/ Storage Condition should be linked to the Package Item Container to representing the overall packaged medicinal product (outer-most package item) unless different shelf-life and storage conditions for different packaged items are specified in sections *6.3 – Shelf Life and 6.4 - Special precautions for storage* of the relevant SmPC. In this case the Shelf Life/ Storage Conditions should be linked to the most relevant Package Item Container.

The full information on Storage / Shelf Life is shown in the figure 20 below. Only the elements inside the red rectangle apply for the iteration 1 implementation.

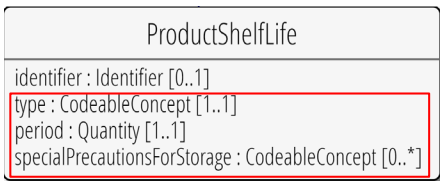


Figure 30: Shelf Life / Storage as captured by FHIR (source: http://www.hl7.org/fhir/)

The Shelf life/storage class is conditional and repeatable while the individual attributes of this class are not repeatable (with the exception of special precaution for storage data element) and are mandatory to be populated.

Shelf life/storage Class	Description
Repeatable	Yes

Shelf life/storage Class	Description
Conformance	Conditional

4.12.1. Shelf life type

Tag	Description
User Guidance	The type of the shelf life such as the shelf life applicable to the whole Packaged Medicinal Product itself, or more granular values such as the shelf-life after transformation, shelf life after the initial opening of a bottle or any other scenario covered in the product information, shall be specified as a term ID from the Shelf Life Type List in the Referentials Management Service (RMS) list. This information is to be completed as per section *6.3 – Shelf life* of the SmPC and section 2.2.3 of the electronic application form (eAF). This field is repeatable to cover multiple different Shelf-Life conditions.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000073343
Value(s)	As listed in the Shelf Life Type RMS list
ISO Element name	Shelf Life Type
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/Shelf Life-Storage/ShelfLifeType
FHIR Element name	Type
FHIR Path	PackagedProductDefinition.package.shelfLifeStorage.type

Example(s):

Shelf life of the medicinal product as packaged for sale.

Shelf life after first opening the immediate packaging.

4.12.2. Shelf life time period and units

Tag	Description
User Guidance	The shelf life time period shall be specified using a (1) numerical value for the period and (2) its unit of time measurement. Multiple shelf life periods may be listed for different types. This information is to be completed as per section *6.3 – Shelf life* of the SmPC and section 2.2.3 of the electronic application form (eAF). This field is repeatable to cover multiple different Shelf-Life conditions. This field is an attribute within Shelf Life Type.
Repeatable	No
Conformance	Mandatory
Data Type	Quantity

Tag	Description
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000110633
Value(s)	Value is a numerical value with implicit precision and should be reflected accordingly The units shall be specified as a Term ID as listed in the Units of Measurement RMS list
ISO Element name	Shelf Life Time Period
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/Shelf Life-Storage/ShelfLifeTimePeriod
FHIR Element name	Period
FHIR Path	PackagedProductDefinition.package.shelfLifeStorage.period

Example(s):

Value	Unit
5	Year(s)
12	Month(s)
24	Hour(s)

4.12.3. Special precautions for storage

Tag	Description
User Guidance	Special precautions for storage of the relevant Package Item Container of the packaged medicinal product should be specified using the appropriate value(s). The controlled term and the controlled term identifier shall be specified. The term "This medicinal product does not require any special storage condition" shall be selected if no special precautions for storage apply to the packaged medicinal product. This information is to be completed as per section *6.4* – Special precautions for storage of the SmPC and section 2.2.3 of the electronic application form (eAF). This field is repeatable to cover different Storage Conditions per Shelf life. This field is an attribute within Shelf Life Type.
Repeatable	Yes
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000073344
Value(s)	As listed in the Special Precaution for Storage RMS list
ISO Element name	Storage.SpecialPrecautionsforStorage
ISO Path	/MedicinalProduct/PackagedMedicinalProduct/PackageItem_Container/Shelf Life-Storage/SpecialPrecautionsForStorage

Tag	Description
FHIR Element name	specialPrecautionsForStorage
FHIR Path	PackagedProductDefinition.package.shelfLifeStorage.specialPrecautionsForStorage

Example(s):

Do not store above 25 °C

Do not store above 30 °C

Do not freeze

Store in a refrigerator (2°C - 8°C)

Store in the original package in order to protect from light

5. Ingredient

The full information on ingredient(s) of a manufactured item and of the pharmaceutical product is described by the FHIR Resource Ingredient as shown in figure 21 below. Note that when describing ingredients of manufactured item (section 4.11.4) and pharmaceutical product (section 6.4), applicable ingredients shall be selected from the list of ingredients relevant to the medicinal product as described in this section. Also, the same ingredient can be referenced in both the manufactured item and pharmaceutical product, when needed. The class is mandatory. In the context of the Iteration 1 of the PMS implementation, the following elements are in scope and information should be provided according to the rules and guidance described in this section.

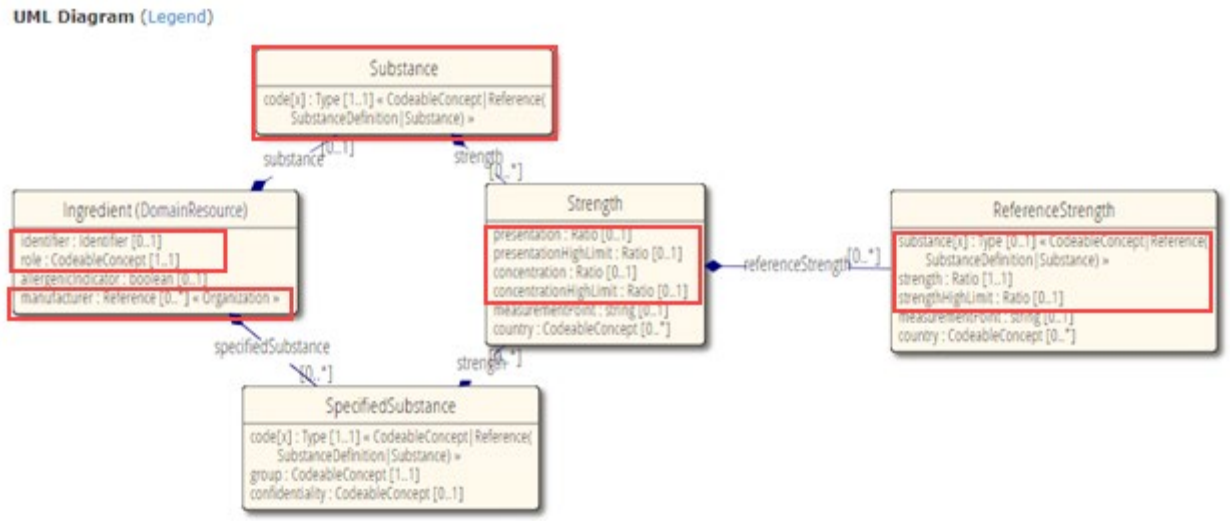


Figure 31: Resource Ingredient (Source : http://www.hl7.org/fhir)

The entire Ingredient class is mandatory and repeatable while the individual attributes of this class are not repeatable and shall be populated as applicable.

Ingredient Class	Description
Repeatable	Yes
Conformance	Mandatory

5.1. Ingredient role

Tag	Description
User Guidance	The role of the ingredient as part of the manufactured item/pharmaceutical product shall be specified as a term ID. The applicable value(s) shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072050
Value(s)	As listed in the Ingredient Role RMS list
ISO Element Name	Ingredient Role
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/IngredientRole For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/IngredientRole
FHIR Element Name	Role
FHIR Path	Ingredient.role

Example(s):

Active, excipient, adjuvant

5.2. Origin of the substance

Tag	Description
User Guidance	The origin of the source material of the substance can be specified.
Repeatable	No
Conformance	Optional
Data Type	CodeableConcept
RMS URI/URL	To be created
Value(s)	The applicable value as listed from the RMS list [list will be created in v2.2]
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	originOfSubstance
FHIR Path	Ingredient.extension.originOfSubstance

Example:

Animal Origin susceptible to TSE; Other Animal Origin; Human Origin

5.3. Composition grouping description

Tag	Description
User Guidance	Information to specify to which part of the manufactured item each ingredient belongs to (i.e., coating, printing ink) can be reported as free text.
Repeatable	No
Conformance	Optional
Data Type	CodeableConcept.text
RMS URI/URL	Not applicable
Value(s)	The composition grouping description as free text
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	group
FHIR Path	Ingredient.extension.group Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

5.4. Manufacturer

The manufacturer of the active substance (including active substance intermediate manufacturers) and the adjuvant for combined pharmaceutical forms, shall be specified from the list of manufacturers based on the resource *MedicinalProductDefinition.manufacturingBusinessOperation.manufacturer* as outlined in section 1.20.1.

The class is conditional, provided that ingredient role specified is the Active Substance or Adjuvant. For further details relating to technical information and business rules, please refer to section 1.20. Manufacturing business operation.

Manufacturers of active substance intermediates shall also be selected and associated to the Active Substance. The manufacturing sites performing the following operations are associated to substances and Adjuvants (if applicable):

- Manufacturing of the active substance (including active substance intermediates) product as reflected in module 3.2.S.2.1 and section 2.5 of the Initial Marketing Authorisation (initial MA) electronic Application Form (eAF).
- Manufacturer of the adjuvant as reflected in module 3.2.P.3.1 and section 2.5 of the Initial Marketing Authorisation (initial MA) electronic Application Form (eAF).
- The reference to the ingredient(s) of the pharmaceutical product shall be selected based on the list of ingredients recorded in sections 5. Ingredient

Tag	Description
User Guidance	The reference to the relevant Manufacturer of the active substance (including active substance intermediate manufacturers) and the adjuvant for combined pharmaceutical forms shall be selected from the list of manufacturers recorded in section 1.20 Manufacturing business operation.
Repeatable	Yes
Conformance	Conditional

Tag	Description
Data Type	Reference
RMS URI/URL	Not applicable
Value(s)	Reference to the relevant ActivityDefinition resource describing the manufacturing business operation.
ISO Element Name	Manufacturer(Organisation)
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Manufacturer(Organisation) For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/ Manufacturer(Organisation)
FHIR Element Name	manufacturer
FHIR Path	Ingredient.manufacturer.extension.manufacturingBusinessOperation Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

5.5. Substance

The entire Substance sub-class is mandatory and not repeatable while the individual attributes shall be repeated and populated as applicable.

Ingredient Class	Description
Repeatable	No
Conformance	Mandatory

5.5.1. Substance

Section 2. Qualitative and Quantitative composition of the SmPC, section *6.1. List of excipients* of the SmPC and *Module 3.2.P.1 – Description and Composition of the Drug Product* indicate the composition of pharmaceutical product(s) within the medicinal product.

Each pharmaceutical product or Manufactured Item shall contain information on:

- Active ingredient(s) - active ingredient substance name(s). For Pharmaceutical Product, the active ingredient(s) can be found in *Section 2. Qualitative and Quantitative composition* of the SmPC and Module 3.2.P.1 of the dossier.
- Excipient(s) - excipient substance name(s). For Pharmaceutical Product, the excipient(s) can be found in Module 3.2.P.1 of the dossier and Section *6.1. List of excipients* of the SmPC.
- In some instances, the composition of the medicinal product can also contain adjuvants. Adjuvant substance name(s) can be found in *Section 2. Qualitative and Quantitative composition* of the SmPC and Module 3.2.P.1 of the dossier.

The Substance(s) contained in pharmaceutical product or Manufactured Item shall be specified as a term ID.

If the required substance term and related identifier is not available, the addition of the unlisted term ID should be requested from SMS via EMA Service Desk portal.

Note 1: Substance Management Service (SMS) will release in future the guidance describing the process to submit substance change request(s) in SMS.

Note 2: every pharmaceutical product shall have at least one ingredient, regardless the ingredient role. If a pharmaceutical product contains no active ingredient, the excipients should be labelled as excipient and not as active ingredient (*example: water for injection as a solvent in a separate container, glucose solution 5%, NaCl solution 0.9%.; contraceptive tablets containing only lactose).* This rule differs from the existing xEVMPD business rule.

Tag	Description
User Guidance	The Substances contained within the medicinal product (either part of the pharmaceutical product(s) or the manufactured item(s)) shall be specified. Each pharmaceutical product or Manufactured Item shall contain information on: • active ingredient(s); • excipient(s); • in some instances, pharmaceutical product can also contain adjuvants. The Substance(s) contained in pharmaceutical product or Manufactured Item shall be specified as a term ID. The selected SMS ID refers to a particular substance, and the preferred term (PT) for that substance will always be the name displayed in PMS. In many cases, alternate names are stored for substances and the SMS ID can be found by using any of the names associated with a substance. Note: every pharmaceutical product shall have at least one ingredient. If a pharmaceutical product contains no active ingredient, the excipients shall be labelled as excipient.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	Not applicable
Value(s)	As listed in SPOR Substance Management System (SMS ID)
ISO Element Name	Substance
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance
FHIR Element Name	codeCodeableConcept
FHIR Path	Ingredient.substance.codeCodeableConcept

5.5.2. Substance strength (quantitative composition)

The Strength (quantitative composition) of the substance (active substances, excipients and adjuvants) should be declared as a quantity of the substance contained in a Manufactured Item or Pharmaceutical Product.

The strength (quantitative composition) shall be provided based on a numerator and denominator value and unit, i.e., unit of presentation or unit of measure/concentration.

When the strength of a medicinal product described as a technical concept of a "Pharmaceutical Product" that has undergone a transformation (for example reconstitution) is to be specified, it is to be specified using the strength resulting from transformation undertaken exactly in accordance with the regulated product information (i.e., in the SmPC as per Section 2. Qualitative and Quantitative Composition and Module 3.2.P.1 of the dossier). This information can also be found in other parts of the SmPc. No calculations/conversions should be performed to obtain a figure.

Where the active ingredient is an ester or pro-drug, the quantitative composition shall be stated in terms of the quantity of that ester or pro-drug. In this case, the strength of the active moiety should be entered in the reference strength section (refer to section 5.5.3.Substance reference strength (quantitative composition)). The following example illustrates this requirement:

Example(s):

Ingredient active substance contains a derivative

Field	Value
SmPC text	Each tablet contains 12 mg loperamide hydrochloride corresponding to 10 mg loperamide
Active substance	loperamide hydrochloride
Active substance strength presentation single value or low limit numerator	12 mg
Active substance strength presentation single value or low limit denominator	1 tablet
Reference substance	Loperamide
Reference substance strength presentation single value or low limit numerator	10 mg
Reference substance strength presentation single value or low limit denominator	1 tablet

Expression of the strength (quantitative composition)

The strength (quantitative composition) can be expressed as:

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

The unit of presentation is a qualitative term describing the discrete unit in which a Pharmaceutical Product is presented.

Example:

250 milligrams per tablet

10 mg per vial (for solution for injection)

120 mg per bottle (for powders or granules for liquid preparation)

10 mg per tube (for single use gels)

54 microgram per actuation (for inhaler with individual capsules, delivered dose shall be used)

- **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)

  The concentration strength is always expressed per single unit of measurement, e.g., 4 mg/1 ml. A strength expressed as e.g., 4 mg/0.8 ml is a presentation strength since the 0.8 ml is the amount of the solution in the presentation. The concentration strength equivalent to that would be 5 mg/1 ml.

  Example:

  10 milligrams per 1 millilitre (for parenteral products)

  10 milligrams per 24 hours (for transdermal patches)

  100 countable units per 1 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 section 2. *Qualitative and Quantitative Composition* of the corresponding SmPC and in Module 3.2.P.1 of the dossier shall be specified. **For further information related on the reporting of composition, refer to section 3.3 Expression of strength of EU IG Chapter 8.**

Overall, when expressing the strength of active ingredients, applicants and marketing authorisation holders should abide to the following principles:

- The SmPC should be used as a main reference for expressing the strength in ingredients to be linked both to the manufactured item and pharmaceutical product.
- The quantitative composition of the active ingredient should be expressed by means of Presentation strength and depending on cases Concentration strength. If the presentation strength is clearly stated in the relevant SmPC and/or Module 3, it shall be populated in addition to the concentration strength if both ways to express the strength are included in the SmPC/Module 3.
- Chapter 8 – Practical examples and QRD guidance on expression of strength provides guidance on how to express the strength per type of medicinal products.
- The expression of the strength in the SmPC has been approved by a regulatory scientific assessment and therefore should be used in all cases as the main reference to express the strength. In case of difference on how the strength is expressed for a specific medicinal product in the SmPC and the guidance provided in Chapter 8 – Practical examples and QRD guidance on expression of strength, the information on the SmPC prevails.
- Where the active ingredient is an ester or pro-drug, the quantitative composition shall follow how the substance is expressed in the SmPC. SmPC guidance says that the substance should be stated

in terms of the quantity of that ester or pro-drug. If the active moiety is an active substance in an already approved medicinal product, the reference substance should be given in terms of this active moiety (as per the SmPC guidelines, e.g., 75 mg of fosphenytoin is equivalent to 50 mg of phenytoin). If the active moiety has not been approved separately, then the reference substance should be the ester or pro-drug and not any presumed active moiety. See chapter 2, section 5.5.3 Substance reference strength (quantitative composition).

If the product contains excipient(s) and/or adjuvant(s), the provision of the amount(s) of the ingredient(s) shall be specified.

In cases where the quantitative composition of the excipient(s) and/or adjuvant(s) of the medicinal product is not reported in the relevant product information (i.e., SmPC), the substance strength is to be left empty and the substance reference strength is to be completed. For further information on this exceptional case (i.e., vaccines) refer to **Chapter 8 – Practical example**.

The strength of the excipient(s) and adjuvant(s) as listed in section 2. *Qualitative and Quantitative Composition (*or in *section 6. List of excipients)* of the corresponding SmPC and in Module 3.2.P.1 of the dossier shall be specified.

The entire Substance Strength (quantitative composition) sub-class is conditional and not repeatable while the individual attributes of this sub-class are not repeatable and shall be populated as applicable.

Ingredient Class	Description
Repeatable	No
Conformance	Conditional

5.5.2.1. Quantity operator

The Strength (quantitative composition) of the substance (active substances, excipients and adjuvants) should be declared as a quantity of the substance contained in a Manufactured Item or Pharmaceutical Product [for further details refer to section 5.5.2. Substance strength (quantitative composition)and192Substance reference strength (quantitative composition)].

To precisely express the strength of the substance ingredient(s) contained in the medicinal product, the corresponding quantity operator shall be selected.

The quantity operator applies to each of the below data elements based:

- Strength (Presentation) 5.5.2.2.1. Quantity operator
- Strength (Concentration) 5.5.2.3.1. Quantity operator

For further information on the technical details of this data element, refer to the below sections 5.5.2.2.1. and 5.5.2.3.1.

Example(s):

Equal to, less than, more than etc.

5.5.2.2. Strength (presentation)

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

The entire Strength (presentation) sub-class is conditional and not repeatable while the individual attributes of this sub-class are not repeatable and shall be populated as applicable.

Ingredient Class	Description
Repeatable	No
Conformance	Conditional

Note: If the Strength (presentation) is clearly stated in the relevant SmPC and/or Module 3, this field shall be populated. For further information, refer to the table reported in section 3.3. Expression of strength in **Chapter 8 – Practical example.**

5.5.2.2.1. Quantity operator

Tag	Description
User Guidance	The applicable value corresponding to the quantity operator shall be specified as term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000008
Value(s)	As listed in the Quantity Operator RMS list. If the RMS term can be mapped to a FHIR Quantity comparator, the FHIR comparator field should also be specified for interoperability.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	quantityOperator
FHIR Path	Ingredient.substance.strength.extension.quantityOperator Ingredient.substance.strength.presentation.numerator.comparato Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

5.5.2.2.2. Strength (presentation single value or low limit)

Tag	Description
User Guidance	The strength (quantitative composition) of the substances (including active substances, ingredients, adjuvant as applicable) shall be specified in this field with a numerator and denominator. When the strength is expressed as a range, the lower limit for the quantity of the substance in the unit of presentation shall be specified in this field. When the strength is not expressed as a range, the quantity of the substance shall be specified in this field.

Tag	Description
	The numerator should be expressed with a unit (numeric value) and a unit of measurement (e.g., mg). The denominator should be expressed with a unit (numeric value) and a unit of presentation (e.g., tablet, actuation).
Repeatable	No
Conformance	Mandatory
Data Type	Ratio
RMS URI/URL	• https://spor.ema.europa.eu/v1/lists/100000110633 • https://spor.ema.europa.eu/v1/lists/200000000014
Value(s)	The units for the numerator shall be specified as a value and a Term ID as listed in the Units of Measurement RMS list. The units for the denominator shall be specified as a value and a Term ID as listed in the Units of Presentation or the Units of Measurement RMS list.
ISO Element Name	Strength (Presentation)
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/Strength_Presentation For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/Strength_Presentation
FHIR Element Name	Presentation
FHIR Path	Ingredient.substance.strength.presentation

5.5.2.2.3. Strength (presentation high limit)

Tag	Description
User Guidance	The strength (quantitative composition) of the substances shall be specified in this field with a numerator and denominator, only applicable when the strength is expressed as a range. In this case, the upper limit for the quantity of the substance in the unit of presentation shall be specified in this field. When the strength is not expressed as a range, this field shall not be populated. The numerator should be expressed with a unit of numeric value and a unit of measurement (e.g., mg). The denominator should be expressed with a unit of numeric value and a unit of presentation (e.g., tablet).
Repeatable	No
Conformance	Conditional
Data Type	Ratio
RMS URI/URL	• https://spor.ema.europa.eu/v1/lists/100000110633 • https://spor.ema.europa.eu/v1/lists/200000000014

Tag	Description
Value(s)	The units for the numerator shall be specified as a value and a Term ID as listed in the Units of Measurement RMS list. The units for the denominator shall be specified as a value and a Term ID as listed in the Units of Presentation or the Units of Measurement RMS list.
ISO Element Name	Strength (Presentation)
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/Strength_Presentation For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/Strength_Presentation
FHIR Element Name	PresentationHighLimit
FHIR Path	Ingredient.substance.strength.presentationHighLimit

Example(s):

Tablet 500 mg

Strength presentation single value or low limit: numerator 500 mg, denominator 1 tablet

Strength presentation high limit: <blank>

Powder for solution for injection 88-90 mg in a vial

Strength presentation single value or low limit: numerator 88 mg, denominator 1 vial

Strength presentation high limit: 90 mg, denominator 1 vial

5.5.2.3. 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.

The entire Strength (concentration) sub-class is conditional and not repeatable while the individual attributes of this sub-class are not repeatable and shall be populated as applicable.

Ingredient Class	Description
Repeatable	No
Conformance	Conditional

5.5.2.3.1. Quantity operator

Tag	Description
User Guidance	The applicable value corresponding to the quantity operator shall be specified as term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000008
Value(s)	As listed in the Quantity Operator RMS list. If the RMS term can be mapped to a FHIR Quantiy comparator, the FHIR comparator field should also be specified for interoperability.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	quantityOperator
FHIR Path	Ingredient.substance.strength.extension.quantityOperator Ingredient.substance.strength.concentration.numerator.comparator Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

5.5.2.3.2. Strength (concentration single value or low limit)

Tag	Description
User Guidance	The strength (quantitative composition) of the substances shall be specified in this field with a numerator and denominator. When the strength is expressed as a range, the lower limit for the quantity of the substance in the unit of measurement shall be specified in this field. When the strength is not expressed as a range, the quantity of the substance shall be specified in this field. The numerator and the denominator should be expressed with a unit of numeric value and a unit of measurement (e.g., mg, ml).
Repeatable	No
Conformance	Mandatory
Data Type	Ratio
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000110633
Value(s)	The units for the numerator and the denominator shall be specified as a value and a Term ID as listed in the Units of Measurement RMS list.
ISO Element Name	Strength (Concentration)
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/Strength_Concentration For the Pharmaceutical product, the ISO path is:

Tag	Description
	/MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/Strength_Concentration
FHIR Element Name	Concentration
FHIR Path	Ingredient.substance.strength.concentration

5.5.2.3.3. Strength (concentration high limit)

Tag	Description
User Guidance	The strength (quantitative composition) of the substances shall be specified in this field with a numerator and denominator, only applicable when the strength is expressed as a range. In this case, the upper limit for the quantity of the substance in the unit of measurement shall be specified in this field. When the strength is not expressed as a range, this field shall not be populated. The numerator and the denominator should be expressed with a unit of numeric value and a unit of measurement (e.g., mg, ml).
Repeatable	No
Conformance	Conditional
Data Type	Ratio
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000110633
Value(s)	The units for the numerator and the denominator shall be specified as a value and a Term ID as listed in the Units of Measurement RMS list.
ISO Element Name	Strength (Concentration)
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/Strength_Concentration For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/Strength_Concentration
FHIR Element Name	ConcentrationHighLimit
FHIR Path	Ingredient.substance.strength.concentrationHighLimit

Example(s):

Solution for injection 20 mg/ml

Strength concentration single value or low limit: numerator 20 mg, denominator 1 ml

Strength concentration high limit: <blank>

Powder and solvent for solution for injection 95-100 mg/ml

Strength concentration single value or low limit: numerator 95 mg, denominator 1 ml

Strength concentration high limit: 100 mg, denominator 1 ml

5.5.3. Substance reference strength (quantitative composition)

Reference strength represents the strength (quantitative composition) of the active moiety of the active substance or of another substance used to express the strength of the product. There are situations when the active substance and active moiety are different resulting in different expression of the strength.

For example, if an active substance is in the form of a salt or hydrate, the reference strength shall 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 Pharmaceutical product or Manufactured Item can be found in section 2. Qualitative and Quantitative Composition of the corresponding SmPC.

The reference strength shall be provided for active substances and is repeatable. However, there are cases where the reference strength of the active substance may not be provided. For information about the special cases, please refer to the diagram available in section **3.3. Express strength of Chapter 8 – Practical example**.

In cases where the quantitative composition of the excipient(s) and/or adjuvant(s) of the medicinal product is not reported in the relevant product information (i.e., SmPC), the substance strength is to be left empty and the substance reference strength is to be completed.

For further information on the above exceptional cases (i.e., vaccines) refer to section **3.3. Express strength of Chapter 8 – Practical example**.

Note that the ISO standards do not explicitly differentiate between Strength (Presentation) versus Strength (Concentration) for Reference Strengths. PMS will do that, so the ISO paths below are not unique for these two different strength expressions.

Example(s):

Field	Value
SmPC text	Each tablet contains 12 mg loperamide hydrochloride corresponding to 10 mg loperamide
Active substance	loperamide hydrochloride
Active substance strength presentation single value or low limit numerator	12 mg
Active substance strength presentation single value or low limit denominator	1 tablet
Reference substance	Loperamide
Reference substance strength presentation single value or low limit numerator	10 mg
Reference substance strength presentation single value or low limit denominator	1 tablet

Field	Value
SmPC text	Containing 538.20 mg of valproate semisodium per tablet (equivalent to 500 mg of valproic acid).
Active substance	valproate semisodium
Active substance strength presentation single value or low limit numerator	538.20 mg
Active substance strength presentation single value or low limit denominator	1 tablet
Reference substance	valproic acid
Reference substance strength presentation single value or low limit numerator	500 mg
Reference substance strength presentation single value or low limit denominator	1 tablet

In addition, if the active substance is not a salt/hydrate, the strength [Section 5.5.2. Substance strength (quantitative composition)] and reference strength in the product composition will be the same and the strength information shall be repeated in the reference strength (reference strength is mandatory for active substances)

Example(s):

Field	Value
SmPC text	Each 0.2 ml single dose pre-filled syringe contains 20 mg of adalimumab
Active substance	Adalimumab
Active substance strength presentation single value or low limit numerator	20 mg
Active substance strength presentation single value or low limit denominator	0.2 ml
Reference substance	Adalimumab
Reference substance strength presentation single value or low limit numerator	20 mg
Reference substance strength presentation single value or low limit denominator	0.2 ml
Reference substance strength concentration single value or low limit numerator	100 mg
Reference substance strength concentration single value or low limit denominator	1 ml

The entire Reference strength sub-class is conditional based on the below business rules and not repeatable while the individual attributes of this sub-class are not repeatable and shall be populated as applicable.

Ingredient Class	Description
Repeatable	No
Conformance	Conditional

5.5.3.1. Reference substance

Tag	Description
User Guidance	The reference substance of the active substance(s) contained in pharmaceutical product or Manufactured Item, as expressed in section 2. *Qualitative and Quantitative Composition* of the corresponding SmPC and in Module 3.2.P.1 of the dossier, shall be specified. The reference substance shall be provided for active substances only.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	Not applicable
Value(s)	As listed in SPOR Substance Management System (SMS ID)
ISO Element Name	Reference Substance
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/ReferenceStrength/ReferenceSubstance For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/ReferenceStrength/ReferenceSubstance
FHIR Element Name	Substance
FHIR Path	Ingredient.substance.strength.referenceStrength.substanceCodeableConcept

5.5.3.2. Quantity operator

The Strength (quantitative composition) of the substance (active substances, excipients and adjuvants) should be declared as a quantity of the substance contained in a Manufactured Item or Pharmaceutical Product [for further details refer to section 5.5.2. Substance strength (quantitative composition) and5.5.3. Substance reference strength (quantitative composition)].

To precisely express the strength of the substance ingredient(s) contained in the medicinal product, the corresponding quantity operator shall be selected.

The quantity operator applies to each of the below data elements based:

- Reference strength (Presentation) 5.5.3.3.1. Quantity operator
- Reference strength (Concentration) 5.5.3.4.1. Quantity operator

For further information on the technical details of this data element, refer to the below sections 5.5.3.3.1. and 5.5.3.4.1.

Example(s):

Equal to, less than, more than etc.

5.5.3.3. Reference strength (Presentation)

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

The entire Reference strength sub-class is conditional and not repeatable while the individual attributes of this sub-class are not repeatable and shall be populated as applicable.

Ingredient Class	Description
Repeatable	No
Conformance	Conditional

5.5.3.3.1. Quantity operator

Tag	Description
User Guidance	The applicable value corresponding to the quantity operator shall be specified as term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000008
Value(s)	As listed in the Quantity Operator RMS list. If the RMS term can be mapped to a FHIR Quantiy comparator, the FHIR comparator field should also be specified for interoperability.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	quantityOperator
FHIR Path	Ingredient.substance.strength.extension.quantityOperator Ingredient.substance.strength.referenceStrength.strength.numerator.comparator Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

5.5.3.3.2. Reference strength (Presentation single value or low limit)

Tag	Description
User Guidance	The reference strength (quantitative composition) of the active substances shall be specified in this field with a numerator and denominator.

Tag	Description
	When the reference strength is expressed as a range, the lower limit for the quantity of the reference substance in the unit of presentation shall be specified in this field. When the reference strength is not expressed as a range, the quantity of the reference substance shall be specified in this field. The numerator shall be expressed with a unit of numeric value and a unit of measurement (e.g., mg). The denominator shall be expressed with a unit of numeric value and a unit of presentation (e.g., tablet). The reference strength shall be provided for active substances only.
Repeatable	No
Conformance	Mandatory
Data Type	Ratio
RMS URI/URL	• https://spor.ema.europa.eu/v1/lists/100000110633 • https://spor.ema.europa.eu/v1/lists/200000000014
Value(s)	The units for the numerator shall be specified as a value and a Term ID as listed in the Units of Measurement RMS list. The units for the denominator shall be specified as a value and a Term ID as listed in the Units of Presentation or Units of Presentation or the Units of Measurement RMS list..
ISO Element Name	ReferenceStrength
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/ReferenceStrength For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/ReferenceStrength
FHIR Element Name	Strength
FHIR Path	Ingredient.substance.strength.referenceStrength.strength
FHIR Complementary Information	referenceStrength.strength.denominator.system value should refer to the Unit of Presentation RMS list

5.5.3.3.3. Reference strength (Presentation high limit)

Tag	Description
User Guidance	The reference strength (quantitative composition) of the active substances shall be specified in this field with a numerator and denominator, only applicable when the reference strength is expressed as a range. In this case, the upper limit for the quantity of the reference substance in the unit of presentation shall be specified in this field. When the reference strength is not expressed as a range, this field shall not be populated.

Tag	Description
	The numerator should be expressed with a unit of numeric value and a unit of measurement (e.g., mg). The denominator should be expressed with a unit of numeric value and a unit of presentation (e.g., tablet). The reference strength shall be provided for active substances only.
Repeatable	No
Conformance	Conditional
Data Type	Ratio
RMS URI/URL	• https://spor.ema.europa.eu/v1/lists/100000110633 • https://spor.ema.europa.eu/v1/lists/200000000014
Value(s)	The units for the numerator shall be specified as a value and a Term ID as listed in the Units of Measurement RMS list. The units for the denominator shall be specified as a value and a Term ID as listed in the Units of Presentation or Units of Presentation or the Units of Measurement RMS list.
ISO Element Name	ReferenceStrength
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/ReferenceStrength For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/ReferenceStrength
FHIR Element Name	StrengthHighLimit
FHIR Path	Ingredient.substance.strength.referenceStrength.strengthHighLimit
FHIR Complementary Information	referenceStrength.strength.denominator.system value should refer to the Unit of Presentation RMS list

5.5.3.4. 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.

The entire Reference strength sub-class is conditional and not repeatable while the individual attributes of this sub-class are not repeatable and shall be populated as applicable.

Ingredient Class	Description
Repeatable	No
Conformance	Conditional

5.5.3.4.1. Quantity operator

Tag	Description
User Guidance	The applicable value corresponding to the quantity operator shall be specified as term ID.

Tag	Description
	The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000000008
Value(s)	As listed in the Quantity Operator RMS list. If the RMS term can be mapped to a FHIR Quantity comparator, the FHIR comparator field should also be specified for interoperability.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	quantityOperator
FHIR Path	Ingredient.substance.strength.extension.quantityOperator Ingredient.substance.strength.referenceStrength.strength.numerator.comparator Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

5.5.3.4.2. Reference strength (Concentration single value or low limit)

Tag	Description
User Guidance	The reference strength (quantitative composition) of the active substances shall be specified in this field with a numerator and denominator. When the reference strength is expressed as a range, the lower limit for the quantity of the reference substance in the unit of measurement shall be specified in this field. When the reference strength is not expressed as a range, the quantity of the reference substance shall be specified in this field. The numerator and the denominator shall be expressed with a unit of numeric value and a unit of measurement (e.g., mg, ml). The reference strength shall be provided for active substances only.
Repeatable	No
Conformance	Mandatory
Data Type	Ratio
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000110633
Value(s)	The units for the numerator and the denominator shall be specified as a value and a Term ID as listed in the Units of Measurement RMS list.
ISO Element Name	ReferenceStrength
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/ReferenceStrength For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/ReferenceStrength

Tag	Description
FHIR Element Name	Strength
FHIR Path	Ingredient.substance.strength.referenceStrength.strength
FHIR Complementary Information	referenceStrength.strength.denominator.system value should refer to the Unit of Measurement RMS list

5.5.3.4.3. Reference strength (Concentration high limit)

Tag	Description
User Guidance	The reference strength (quantitative composition) of the active substances shall be specified in this field with a numerator and denominator, only applicable when the strength is expressed as a range. In this case, the upper limit for the quantity of the reference substance in the unit of measurement shall be specified in this field. When the reference strength is not expressed as a range, this field shall not be populated. The numerator and the denominator should be expressed with a unit of numeric value and a unit of measurement (e.g., mg, ml). The reference strength shall be provided for active substances only. This value is an attribute within Reference Strength.
Repeatable	No
Conformance	Conditional
Data Type	Ratio
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000110633
Value(s)	The units for the numerator and the denominator shall be specified as a value and a Term ID as listed in the Units of Measurement RMS list.
ISO Element Name	ReferenceStrength
ISO Path	For the Manufactured Item, the ISO path is: /MedicinalProduct/PackagedMedicinalProduct/PackageItem/ManufacturedItem/Ingredient/Substance/Strength/ReferenceStrength For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient/Substance/Strength/ReferenceStrength
FHIR Element Name	StrengthHighLimit
FHIR Path	Ingredient.substance.strength.referenceStrength.strengthHighLimit
FHIR Complementary Information	referenceStrength.strength.denominator.system value should refer to the Unit of Measurement RMS list

5.5.4. (Certificate) master file

The (Certificate) master file should be used to include the following certificates referring to the composition of the medicinal product:

- **Certificate of suitability for Transmissible Spongiform Encephalopathies** (TSEs CEP). The TSE Certificates of suitability applies to medicinal products containing or using in the manufacturing process materials of animal and/or human origin with a risk of transmissible spongiform encephalopathy (TSE) in accordance with Directive 2001/82/EC and Directive 2001/83/EC, Part III. It certifies that the substance complies with the EMA Note for Guidance on minimising the TSE risk. This certificate should be provided when the applicable selected substance specified in section 5.5 Substance refers to the applicable ingredient role and the 5.2. Origin of the substance data element is specified.
- The **Certificate of Suitability** (CEP): Indicate if a Ph. Eur. Certificate of suitability has been issued for the active substance(s). This certificate certifies that the quality of a given substance is suitably controlled by the Ph.Eur. monograph with addition of tests if necessary (stated on the CEP).
- **Active Substance Master File** (ASMF) certification: to indicate if an ASMF has been used for the active substance(s). This certificate provides detailed information on the manufacturing of the active substance of a medicine. Depending on the type of certificate obtained (i.e., EU / EMA / National submission) the relevant reference details shall be provided (i.e., EU/ASMF reference number shall be specified in case of EU ASMF. The EU ASMF number can be used for Centralised, Mutual Recognition and Decentralised Procedures; EMEA/ASMF number should be specified only for ASMFs to be assessed through the Centralised procedure).
- **Vaccine Antigen Master File** (VAMF) certification: to indicate an EMA certificate for a VAMF has been issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III.
- **Plasma Master File** (PMF) certification: this certificate provides detailed information on the characteristics of the human plasma used in a medicinal product.

The (Certificate) master file class is conditional and repeatable while the individual attributes of this class are to be repeated and completed as applicable.

(Certificate) master file Class	Description
Repeatable	Yes
Conformance	Conditional

5.5.4.1. File type

Tag	Description
User Guidance	The applicable type of master file should be specified. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/220000000070
Value(s)	As listed in Master File Type RMS list
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	Type
FHIR Path	DocumentReference.type (referenced from Ingredient.extension.masterFile)

Tag	Description
	Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

5.5.4.2. File code

The File code sub-class and it's attributes are mandatory and not repeatable.

(Certificate) master file Class	Description
Repeatable	No
Conformance	Mandatory

5.5.4.2.1. File identifier type

Tag	Description
User Guidance	The applicable certificate provided by the relevant Competent Authority following successful submission shall be specified in PMS. The file code shall always refer to the current version to the last submitted version.
Repeatable	No
Conformance	Mandatory
Data Type	CodableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000026028
Value(s)	The applicable value as listed in the Master File Identifier Type RMS list
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	system
FHIR Path	DocumentReference.identifier.system (referenced from Ingredient.extension.masterFile)

Example:

For ASMF: EU ASMF number, National ASMF number, Applicant part version number

5.5.4.2.2. File Identifier

Tag	Description
User Guidance	The applicable identifier as assigned by the relevant Competent Authority following successful submission shall be specified in PMS.
Repeatable	No
Conformance	Mandatory
Data Type	Identifier
RMS URI/URL	Not applicable
Value(s)	The relevant identifier as assigned shall be specified

Tag	Description
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	value
FHIR Path	DocumentReference.identifier.value (referenced from Ingredient.extension.masterFile)

5.5.4.3. Submission date

Tag	Description
User Guidance	The date when the certificate was submitted to the relevant Competent Authority shall be specified.
Repeatable	No
Conformance	Based on the following terms specified in 5.5.4.1: • Conditional: – CEP – ASMF – VAMPF – PMF • Not applicable: – CEP TSE
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	submissionDate
FHIR Path	DocumentReference.extension.submissionDate Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

5.5.4.4. Date of last update

Tag	Description
User Guidance	The date when the certificate was updated most recently shall be specified where applicable.
Repeatable	No
Conformance	Based on the following terms specified in 5.5.4.1: • Mandatory:

Tag	Description
	– CEP – ASMF – VAMPF – PMF • Not applicable: – CEP TSE
Data Type	dateTime
RMS URI/URL	Not applicable
Value(s)	A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM).
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	dateOfUpdate
FHIR Path	DocumentReference.extension.dateOfUpdate Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

5.5.4.5. Manufacturer

Tag	Description
User Guidance	The reference to the relevant Manufacturer of the selected substance shall be selected from on the list of manufacturers recorded in section 5.4. Manufacturer. This data field shall be specified in case of the following certificates type: CEP, ASMF, VAMF certificates.
Repeatable	Yes
Conformance	Conditional
Data Type	Reference
RMS URI/URL	Not applicable
Value(s)	Reference to the relevant ActivityDefinition resource describing the manufacturing business operation.
ISO Element Name	Not applicable
ISO Path	Not applicable
FHIR Element Name	subject
FHIR Path	DocumentReference.extension.manufacturingBusinessOperation Note: Please refer to Chapter VI – SPOR API Technical Specification for the details of the extension URL.

6. Pharmaceutical product

Each authorised medicinal product shall contain at least one pharmaceutical product.

The technical concept of a "pharmaceutical product", refers to the qualitative and quantitative composition of a medicinal product in the pharmaceutical form, approved for administration to the patient, in line with the regulated product information.

A medicinal product may contain one or more "pharmaceutical product(s)" (e.g., a kit containing vaginal tablets 500 mg and a vaginal cream 10% or a kit containing a combination of norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate tablets). In these instances, a pharmaceutical product section is to be completed for each "pharmaceutical product".

Where applicable, the technical concept of a "pharmaceutical product" can also include information on a medical device if it is an "integral part" of the medicinal product and supports the pharmacological/metabolic/immunological action of the medicinal product, for example the scaffolding or net for a cell therapy medicinal product in accordance with Regulation (EC) No 1394/2007.

The administrable pharmaceutical form refers to the pharmaceutical form for administration to the patient, after any necessary transformation of the "manufactured" pharmaceutical form has been carried out. This concept is illustrated in the following examples.

If a product undergoes several transformations before it is given to the patient, intermediate forms that are not given to the patient will not be captured in the data. Only the final form(s) that are given to the patient should be included in the pharmaceutical product data.

Example(s):

Example 1:

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

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

In this case the medicinal product needs to undergo the necessary transformation prior to the administration to the patient and the pharmaceutical form is as follows:

Administrable dose form	Solution for Injection
Strength	20mg/mL
Unit of Presentation	Vial

Example 2:

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

- Tablet

In this case the medicinal product does not need to undergo any transformation prior to the administration to the patient and the administrable dose form equals the manufactured dose form. The pharmaceutical form is as follows:

Administrable dose form	Tablet

Strength	500 mg / unit
Unit of Presentation	Tablet

Each pharmaceutical product shall contain information on:

- Active ingredient(s) - active ingredient substance name(s) and its/their amounts(s) can be found in Module 3.2.P.1 – Description and Composition of the Drug Product. This information is also reflected in *section 2. Qualitative and Quantitative Composition* of the corresponding SmPC;
- Excipient(s) - excipient substance name(s) and their amount(s) can be found in Module 3.2.P.1 – Description and Composition of the Drug Product. This information is also reflected in *section 6.1 List of excipients* of the corresponding SmPC. In case that Module 3.2.P.1 have additional granularity on the components of an individual excipient, the information on the SmPC should be taken as a reference, corresponding with the highest level of the excipient described in 3.2.P.1, provided this "multi-components Excipient" is registered in SMS.
- In some instances, pharmaceutical product can also contain adjuvants. Adjuvant substance name(s) and its/their amount(s) can be found in Module 3.2.P.1 – Description and Composition of the Drug Product. This information is also reflected in *section 2. Qualitative and Quantitative Composition* (or in *section 6.1 List of excipients*) of the corresponding SmPC;
- The ingredient(s) of a manufactured item or of the pharmaceutical product shall be specified based on the Resource *Ingredient* as outlined below.

Note: The contents of the document [i.e., Module 1.2 – Electronic Application form (eAF), Relevant sections in Module 3 – Quality, Summary of Product Characteristics (SmPC)] supporting the regulatory process shall be aligned, where applicable, to ensure the discrepancies between the documents are minimized. The content should enhance the quality of the product data reported in Product Management Service (PMS). This requirement applies to new medicinal products single entry in PMS.

Based on the above principle. the SmPC as authorized/to be authorized is the main referring document for data entry purposes.

However, for medicinal product entry already available in PMS, following the data load from XEVMPD to PMS database (existing product data), whenever the common contents of each of the above supporting documentation are not aligned, the information available in the relevant sections in Module 3 can be used to harmonize the values in PMS. This requirement applies provided data confidentiality is ensured and if no additional complexity is added to the data entry in PMS. For additional information, refer to section 1.3.1 of EU IG Chapter 8 – Practical example.

Note: Further information referring to existing product data will be made available in the EU IG Chapter 9 - Process for submitting existing data on medicinal products authorised for human use. This chapter is under development and it will be made available at later stage.

The full information on Pharmaceutical Product as presented in the FHIR *Resource AdministrableProductDefinition* is shown below. In the context of the Iteration 1 of the PMS implementation, the elements included in the red rectangle below are in scope and should be provided according to the rules and guidance described in this section:

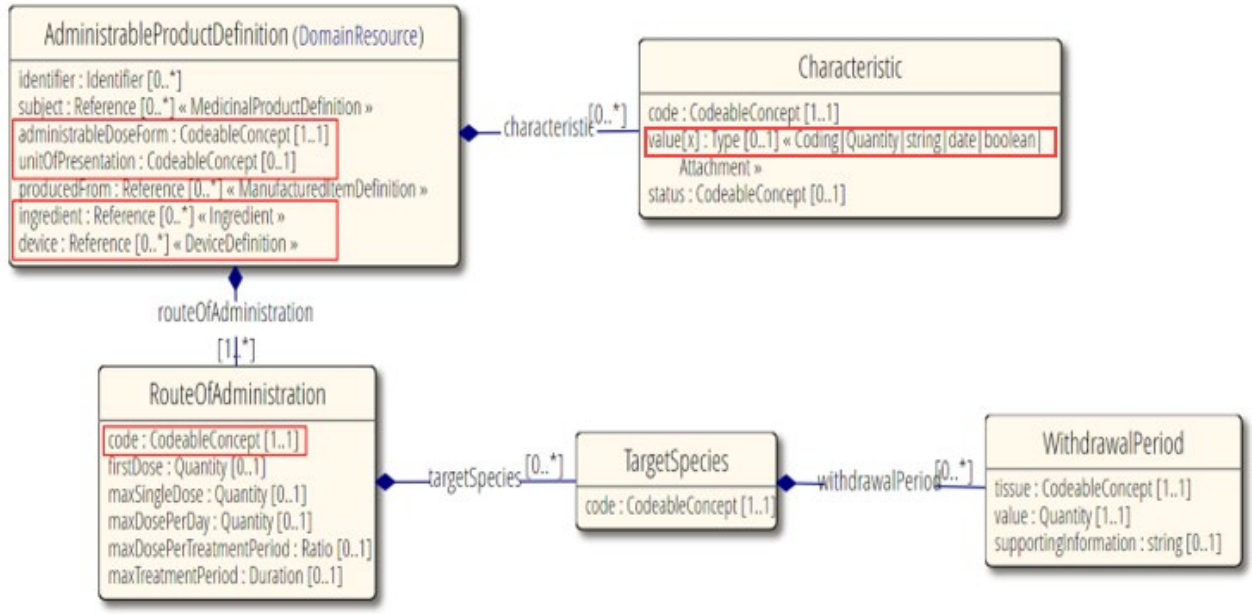


Figure 32: Resource AdministrableProductDefinition (Source: http://www.hl7.org/fhir)

The Pharmaceutical product class is mandatory and repeatable while the individual attributes of this class are not repeatable (with the exception of the ingredient and device data elements class) and shall be populated as applicable.

Pharmaceutical product Class	Description
Repeatable	Yes
Conformance	Mandatory

6.1. Pharmaceutical product description

The description of pharmaceutical product shall be provided whenever the medicinal product contains more than one pharmaceutical product in order to allow differentiation in the database.

The provision of pharmaceutical product description is not needed for medicinal products with a single pharmaceutical product.

In medicinal products containing more than one pharmaceutical product (e.g., contraceptive having different strengths and fixed dose combination as part of the same medicinal product), differentiation of manufacturing items is not easily visualised with the information provided in the rest of individual data fields (in certain cases it can only be differentiated on specific characteristics of substances including the qualitative and quantitative composition of the pharmaceutical product).

Information on pharmaceutical product description is free text and should be provided in the form of: "Physical Characteristics" + "Unit of presentation".

Physical Characteristics of the pharmaceutical product item includes colour or shape among others which allow differentiation from remaining pharmaceutical products.

Tag	Description
User Guidance	The high-level description of pharmaceutical product shall be provided whenever the medicinal product contains more than one pharmaceutical product (e.g., different types of tablets in the same package).

Tag	Description
	Information on pharmaceutical item description is free text and should be provided in the form of: "Physical Characteristics" + "Unit of presentation". **Products authorised through MRP/DCP/NP routes** • The pharmaceutical product description is to be provided in English or in the local language(s) of authorisation, or optionally in all of them. **Products authorised through the centralised procedure** The pharmaceutical product description is to be provided in English.
Repeatable	Yes
Conformance	Conditional
Data Type	Markdown
RMS URI/URL	Not applicable
Value(s)	Free text or markdown text for rich content
ISO Element name	Not Applicable
ISO Path	Not Applicable
FHIR Element name	Text
FHIR Path	AdministrableProductDefinition.property.valueCodeableConcept.text

Example(s):

Dark yellow film-coated tablet to differentiate from Medium red film-coated tablet

6.1.1. Language

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

Tag	Description
User Guidance	The language of the pharmaceutical product description, as approved by the regulatory authority and indicated in the corresponding regulatory document(s) shall be specified as a term ID. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000072057
Value(s)	As indicated in the Language RMS list
ISO Element Name	Not Applicable
ISO Path	Not Applicable
FHIR Element Name	language
FHIR Path	AdministrableProductDefinition.property.valueCodeableConcept.text.extension.language

6.2. Administrable dose form

Tag	Description
User Guidance	The administrable dose form corresponds with the dose form intended for administration to the patient, after any necessary transformation of the manufactured dose form has been carried out. This information shall be provided in line with the information indicated in Section 3. *Pharmaceutical form* of the corresponding SmPC. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000000004
Value(s)	Listed in the Pharmaceutical Dose Form RMS list
ISO Element name	Administrable Dose Form
ISO Path	/MedicinalProduct/PharmaceuticalProduct/AdministrableDoseForm
FHIR Element name	administrableDoseForm
FHIR Path	AdministrableProductDefinition.administrableDoseForm

Example(s):

Tablets, Solution for injection, Capsule

6.3. Unit of presentation

Tag	Description
User Guidance	The unit of presentation describing the unit in which a "pharmaceutical product" is administered to describe the strength or quantity. The unit of presentation shall be specified as a term ID. The value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	No
Conformance	Conditional
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/200000000014
Value(s)	As listed in the Units of Presentation RMS list
ISO Element name	Unit of Presentation
ISO Path	/MedicinalProduct/PharmaceuticalProduct/UnitOfPresentation
FHIR Element name	unitOfPresentation
FHIR Path	AdministrableProductDefinition.unitOfPresentation

Example(s):

- units of presentation: puff, actuation, patch, tablet, vial

6.4. Ingredient

The ingredient(s) of the pharmaceutical product shall be selected from the previously recorded list of ingredients based on the *Resource Ingredient* as outlined in section 5. Ingredient

The Ingredient class is mandatory. For further information related to the technical details and business rules please refer to section 5. Ingredient. This value is an attribute within Pharmaceutical Product domain.

Tag	Description
User Guidance	The reference to the ingredient(s) of the pharmaceutical product shall be selected from the list of ingredients recorded in section 5. Ingredient.
Repeatable	Yes
Conformance	Mandatory
Data Type	Reference
RMS URI/URL	Not applicable
Value(s)	Structured data elements referencing the included ingredients in the manufactured item
ISO Element Name	Ingredient
ISO Path	For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Ingredient
FHIR Element name	Ingredient
FHIR Path	AdministrableProductDefinition.ingredient

6.5. Device

A medical device may support the pharmacological/metabolic/immunological action of the medicinal product (e.g., collagen scaffold). These types of devices are considered part of the pharmaceutical product administered to the patient and should be recorded as part of the pharmaceutical product.

Any other device co-packaged (e.g., spoon, syringe) or integral (e.g., pre-filled pen) with the medicinal product shall be recorded as part of the packaged medicinal product with the attributes described in section **4.10. Medical device**.

When applicable, the information shall be provided as described in section **4.10. Medical device.** The applicable value(s) shall be selected from the term ID as listed in the Referentials Management Service (RMS).

Example(s):

collagen scaffold

Tag	Description
User Guidance	The reference to the medical device(s) which is part of the administered pharmaceutical product shall be selected from the list of medical device(s) recorded in section 4.10 Medical device.
Repeatable	Yes
Conformance	Conditional
Data Type	Reference
RMS URI/URL	Not applicable

Tag	Description
Value(s)	Structured data element referencing the included device in the pharmaceutical form
ISO Element Name	Device
ISO Path	For the Pharmaceutical product, the ISO path is: /MedicinalProduct/PharmaceuticalProduct/Device
FHIR Element name	Device
FHIR Path	AdministrableProductDefinition.device

6.6. Route of administration

Tag	Description
User Guidance	The route of administration of the pharmaceutical form shall be specified in accordance with *Section 4.2. Posology and method of administration* of the SmPC as Term ID. Administration route section describes the route(s) of administration i.e., the path by which the medicinal product (described as technical concept of a "pharmaceutical product") is taken into or makes contact with the body. The applicable value shall be selected from the term ID as listed in the applicable Referentials Management Service (RMS) list.
Repeatable	Yes
Conformance	Mandatory
Data Type	CodeableConcept
RMS URI/URL	https://spor.ema.europa.eu/v1/lists/100000073345
Value(s)	As listed in Routes and Methods of Administration RMS List
ISO Element name	Route of Administration
ISO Path	/MedicinalProduct/PharmaceuticalProduct/RouteOfAdministration/RouteOfAdministration
FHIR Element name	Code
FHIR Path	AdministrableProductDefinition.routeOfAdministration.code

Example(s):

Oral use, intravenous use, oromucosal use, ocular use

7. Annex I - PMS ID, MPIDs and PCIDs relationship during lifecycle of medicinal products – Examples

This annex provides a description of the relationship and evolution of identifiers from the first submission and during the lifecycle of medicinal products. For more information, please refer to Introduction Section of Chapter 2: Data elements for the electronic submission of information on medicinal products for human use.

7.1. MPIDs/PCIDs examples CAPs*

Action [i]	Procedure number[ii]	Version [iii]	Content of change	Medicinal product[iv]	Package	MAH name/ID[v]	PMS ID[vi]	MPID[vii]	Marketing Authorisation number (Medicinal Product Level)[viii]	PCID[ix]	Marketing Authorisation number (Package Medicinal Product Level)[x]
Submission	EMA/H/C/000123/0000	v1	Initial submission; MPID is generated	Product A, 50mg, <active substance>, Tablet, MAH A, EU	Blister (alu) 1 tablet Blister (alu) 5 tablets	MAH A/ 100000396	00012654	EU-100000396-00010000	EU/1/98/077 (root number)	EU-100000396-00010000-0001 EU-100000396-00010000-0002	EU/1/98/077/001 EU/1/98/077/002
Type 1A variation	EMA/H/C/000123/IA/0001	v2	change of admin data	no change	no change	no change	no change	no change	no change	no change	no change
Type II variation	EMA/H/C/000123/II/0002	v3	change of manufacturer	no change	no change	no change	no change	no change	no change	no change	no change

Action [i]	Procedure number[ii]	Version [iii]	Content of change	Medicinal product[iv]	Package	MAH name/ID[v]	PMS ID[vi]	MPID[vii]	Marketing Authorisation number (Medicinal Product Level)[viii]	PCID[ix]	Marketing Authorisation number (Package Medicinal Product Level)[x]
Transfer	EMA/H/C/000123/T/0003	v4	change of MAH	Product A, 50mg, <active substance>, Tablet, **MAH B**, EU	no change	**MAH B/ 100000955**	no change	EU-**100000955**-00010000	no change	EU-**100000955**-00010000-0001 EU-**100000955**-00010000-0002	no change
Type 1A variation	EMA/H/C/000123/IA/0004	v5	change of admin data	no change	no change	no change	no change	no change	no change	no change	no change
Extension of therapeutic indication	EMA/H/C/000123/II/0005	v6	Introduction of new therapeutic indication	no change	no change	no change	no change	EU-100000955-**00020046**	no change	EU-100000955-**00020046**-0001 EU-100000955-**00020046**-0002	no change
Type 1A variation	EMA/H/C/000123/IA/0006	v7	change of admin data	no change	no change	no change	no change	no change	no change	no change	no change
Transfer	EMA/H/C/000123/T/0007	v8	change of MAH	Product A, 50mg, <active	no change	**MAH C/ 100014078**	no change	EU-**100014078**-00020046	no change	EU-**100014078**-00020046-	no change

Action [i]	Procedure number[ii]	Version [iii]	Content of change	Medicinal product[iv]	Package	MAH name/ID[v]	PMS ID[vi]	MPID[vii]	Marketing Authorisation number (Medicinal Product Level)[viii]	PCID[ix]	Marketing Authorisation number (Package Medicinal Product Level)[x]
				substance>, Tablet, **MAH C**, EU						0001 EU-**100014078**-00020046-0002	
Type II variation	EMA/H/C/000123/II/0008	v9	Change of legal status	Product A, 50mg, <active substance>, Tablet, MAH C, EU	no change	no change	no change	no change	no change	no change	no change
Type IB variation	EMA/H/C/000123/IB/0009	v10	Addition of pack size	Product A, 50mg, <active substance>, Tablet, MAH C, EU	Blister (alu) 1 tablet Blister (alu) 5 tablets **Blister (alu) 20 tablets**	no change	no change	no change	no change	EU-100014078-00020046-0001 EU-100014078-00020046-0002 **EU-100014078-00020046-0003**	EU/1/98/077/001 EU/1/98/077/002 **EU/1/98/077/003**
Type 1A variation	EMA/H/C/000123/IA/0010	v11	change of admin data	Product A, 50mg,	no change	no change	no change	no change	no change	no change	no change

Action [i]	Procedure number[ii]	Version [iii]	Content of change	Medicinal product[iv]	Package	MAH name/ID[v]	PMS ID[vi]	MPID[vii]	Marketing Authorisation number (Medicinal Product Level)[viii]	PCID[ix]	Marketing Authorisation number (Package Medicinal Product Level)[x]
				<active substance>, Tablet, MAH C, EU							
Type IB variation	EMA/H/C/000123/II/0011	v10	change of packaging	Product A, 50mg, <active substance>, Tablet, MAH C, EU	Blister (alu) 1 tablet Blister (alu) 5 tablets **Bottle (glass) 20 tablets**	no change	no change	no change	no change	EU-100014078-00020046-0001 EU-100014078-00020046-0002 ~~**EU 100014078 -0002-0003**~~ **EU-100014078-0002-0004**	no change

7.2. MPIDs/PCIDs examples MRP/DCP*

Action[i]	Procedure number[ii]	Version[iii]	Content	Medicinal product[iv]	Package	MAH name/ID[v]	PMS ID[vi]	MPID[vii]	Marketing Authorisation number (Medicinal Product Level)[viii]	PCID[ix]	Marketing Authorisation number (Package Medicinal Product Level)[x]
Submission in Sweden	FR/H/0121/03	v1	initial submission via MRP; MPID is generated	Product S, 120 mg, <active substance>, film-coated tablet, MAH D, SE	Blister (plast, alu) 100 tablets Blister (plast, alu) 200 tablets	MAH D/ 100000999 (SE)	00001997	SE-100000999-00000001	13650	SE-100000999-00000001-0001 SE-100000999-00000001-0002	Not applicable - Blank
Type I variation	FR/H/0121/03	v2	change of shelf life	no change	no change	no change	no change	no change	no change	no change	Not applicable - Blank
Type II variation	FR/H/0121/03	v3	change of SmPC, change in section 4.8 (adverse reactions)	no change	no change	no change	no change	no change	no change	no change	Not applicable - Blank
Transfer	FR/H/0121/03	v4	change of MAH	Product S, 120 mg, <active substance>, film-coated tablet, **MAH E**, SE	no change	**MAH E / 100001563 (SE)**	no change	SE-**100001563-00000001**	no change	SE-**100001563-00000001**-0001 SE-**100001563-00000001**-0002	Not applicable - Blank
Type IA variation	FR/H/0121/03	v5	change of admin data	no change	no change	no change	no change	no change	no change	no change	Not applicable - Blank
Type IB variation	FR/H/0121/03	v6	Change of product name	**Product S01**, 120 mg, <active substance>, film-coated	no change	no change	no change	SE-100001563-**00000002**	no change	SE-100001563-**00000002**-0001 SE-100001563-	Not applicable - Blank

Action[i]	Procedure number[ii]	Version[iii]	Content	Medicinal product[iv]	Package	MAH name/ID[v]	PMS ID[vi]	MPID[vii]	Marketing Authorisation number (Medicinal Product Level)[viii]	PCID[ix]	Marketing Authorisation number (Package Medicinal Product Level)[x]
				tablet, MAH E, SE						**00000002**-0002	
Type II variation	FR/H/0121/03	v7	Any change to indication	no change	no change	no change	no change	SE-100001563-**00000003**	no change	SE-100001563-**00000003**-0001 SE-100001563-**00000003**-0002	Not applicable - Blank
Type IA variation	FR/H/0121/03	v8	Change of admin data	no change	no change	no change	no change	no change	no change	no change	Not applicable - Blank
Transfer	FR/H/0121/03	v9	Change of MAH	Product S01, 120 mg, <active substance>, film-coated tablet, **MAH G**, SE	no change	**MAH G / 100001745 (SE)**	change no	SE-**100001745-00000003**	no change	SE-**100001745-0000003**-0001 SE-**100001745-00000003**-0002	Not applicable - Blank
Change of legal status	FR/H/0121/03	v10	Change of legal status	no change	Blister (plast, alu) 100 tablets Blister (plast, alu) 200 tablets **Blister (plast, alu) 10 tablets (OTC)**	no change	no change	no change	no change	SE-100001745-0000-003-0001 SE-100001745-00000003-0002 **SE-100001745-00000003-0003**	Not applicable - Blank

Action[i]	Procedure number[ii]	Version[iii]	Content	Medicinal product[iv]	Package	MAH name/ID[v]	PMS ID[vi]	MPID[vii]	Marketing Authorisation number (Medicinal Product Level)[viii]	PCID[ix]	Marketing Authorisation number (Package Medicinal Product Level)[x]
Administrative change	**IT/H/0805/02**	v11	Change of RMS	no change	no change	no change	no change	no change	no change	no change	Not applicable - Blank

8. Annex II - Common/European Union (EU) and national data set

This section provides a comprehensive list of the different resources, classes and related attributes defined in the Product Management Service (PMS) database. The below tables illustrate how the different data elements and related product data values apply based on the different EU regulatory authorization procedural context.

Term	Centralised Procedure (CAP) context	Mutual Recognition Procedure (MRP) /Decentralized Procedure (DCP) context
European Union (EU)	The same value(s) is applicable across all EU Member States. The value shall not differ across the EU Member States. This term is applicable to medicinal products authorised/to be authorised under Centralised Procedure(s).	This term is not applicable to medicinal products authorised/to be authorised under non-Centralised Procedure(s). The term Common shall apply.
Common	This term is not applicable to medicinal products authorised/to be authorised under Centralised Procedure(s). The term European Union shall apply.	The same value(s) is applicable across all Member State(s) related to the specific non-CAP regulatory authorisation procedure (MRP/DCP). This term is applicable to medicinal products authorised/to be authorised under non-Centralised Procedure(s).
National	The different value(s) based on the National requirements is applicable to each individual Member State(s).	The different value based on the National requirements is applicable to each individual Member State(s) related to the specific non-CAP regulatory authorisation procedure (MRP/DCP) National procedure.
EU & National	At least one (or the) common value(s) is applicable across the EU Member States. Additionally, based on National legal requirement a separate value shall also apply. Based on EEA agreements a separate value shall apply to Iceland, Liechtenstein and Norway [Article 57(2) of Regulation (EC) No. 726/2004)].	This term is not applicable to medicinal products authorised/to be authorised under non-Centralised Procedure(s). This term Common & National shall apply.

	This term is applicable to medicinal products authorised/to be authorised under Centralised Procedure(s).	
Common & National	This term is not applicable to medicinal products authorised/to be authorised under Centralised Procedure(s). The term EU & National shall apply.	At least one (or the) common value(s) is applicable across the EU Member States involved in the specific non-CAP regulatory authorisation procedure (MRP/DCP). Additionally, based on National legal requirement a separate value shall also apply. This term is applicable to medicinal products authorised/to be authorised under non-Centralised Procedure(s).

Legend for repeatable fields:

≠ - Referring to repeatable data attribute as a class

‡ - Referring to repeatable data attribute as a data element

Additional demarcations

* - Marking linked classes of data elements

• - Marking data elements subjects to RMS lists

Item	Resource Definition Level	PMS EU IG Ref.	PMS data element name	Conformance	Applicable values in the context of CAPs: EU or EU & National	Applicable values in the context of non-CAPs (MRPs, DCPs, NPs): Common when across all MS or National
1	**0**	**0**	**Provenance•**	**Mandatory**	-	-
2		0	Reason•	Mandatory	Not applicable (Technical)	Not applicable (Technical)
3		0	Target	Mandatory	Not applicable (Technical)	Not applicable (Technical)
4		0	Recorded	Mandatory	Not applicable (Technical)	Not applicable (Technical)
5		0	Sender	Mandatory	Not applicable (Technical)	Not applicable (Technical)
6	**1**	**1.**	**Medicinal product**	**Mandatory**	**-**	-

Item	Resource Definition Level	PMS EU IG Ref.	PMS data element name	Conformance	Applicable values in the context of CAPs: EU or EU & National	Applicable values in the context of non-CAPs (MRPs, DCPs, NPs): Common when across all MS or National
7		1.1.	Product Management Service Identifier (PMS ID)	Not applicable/Mandatory	EU & National (IS, LI, NO) [6]	(Dependent on the respective regulatory authorisation type)
8		1.2.	Medicinal Product Identifier (MPID)	Not applicable	EU & National (IS, LI, NO) [7]	(Dependent on the respective regulatory authorisation type)
9		1.3.	Domain•	Mandatory	EU	Common
10		1.4.	Type•	Mandatory	EU	Common
11		1.5.	(Authorised) pharmaceutical form•‡	Mandatory	EU	Common
12		1.6.	Combined pharmaceutical dose form•	Conditional	EU	Common
13		1.7.	Legal status of supply•	Mandatory	EU	Common
14		1.8.	Additional monitoring indicator	Mandatory	EU	Common
15		**1.9.**	**Orphan Designation[8]≠**	**Conditional**	**-**	-
16		1.9.1.	Regulatory authorisation type•	Mandatory	EU	Common & National
17		1.9.2.	Orphan designation status•	Mandatory	EU	Not applicable
18		1.9.3.	Orphan designation number	Mandatory	EU	Not applicable
19		1.9.4.	Orphan designation status date	Mandatory	EU	Not applicable
20		1.9.5.	Market exclusivity start date	Mandatory	EU	Not applicable
21		**1.10.**	**Paediatric use indicator**	**Mandatory**	**EU**	Common & National
22		**1.11.**	**Full indication text‡**	**Mandatory/ Optional**	**EU & National**	National
23		1.11.1.	Language•	Mandatory	EU & National	National
24		1.12.	EURD ID	Conditional	EU	Common

[6] Please refer to the section 1.1. PMS ID of this Chapter for further details. When referring to "EU & National" we are referring to the "country" entities European Union (EU, IS, LI, NO.
[7] Please refer to the section 1.2 MPID of this Chapter for further details. When referring to "EU & National" we are referring to the "country" entities European Union (EU, IS, LI, NO.
[8] Orphan designation only applicable to EU as authorizations for IS, LI and NO are national authorisations from the corresponding regulatory authorities.

Item	Resource Definition Level	PMS EU IG Ref.	PMS data element name	Conformance	Applicable values in the context of CAPs: EU or EU & National	Applicable values in the context of non-CAPs (MRPs, DCPs, NPs): Common when across all MS or National
25		**1.13.**	**Product classification**	**Mandatory**	-	-
26		1.13.1.	xEVMPD product type information•	Mandatory	EU	Common
27		1.13.2.	Legal basis•	Mandatory	EU	Common
28		1.13.3.	ATC code(s)•	Mandatory	EU	Common
29		1.13.3.1.	ATC code(s) - Flag	Conditional	EU	Common
30		1.13.4.	Medicinal product category•‡	Mandatory	EU	Common
31		1.13.5.	Genetically Modified Organisms (GMOs)	Mandatory	EU	Common
32		**1.14.**	**Medicinal product name≠**	**Mandatory**	-	-
33		1.14.1.	Full name‡	Mandatory	EU & National	National
34		1.14.2.	Country/Language	Mandatory	EU & National	National
35		1.14.2.1.	Country•	Mandatory	EU & National	National
36		1.14.2.2.	Language•	Mandatory	EU & National	National
37		1.14.3.	(Medicinal product name) name part(s)≠	Mandatory	EU & National	Common & National
38		1.14.3.1.	Name part type•	Mandatory	EU & National	Common
39		1.14.3.2.	Name part text ‡	Mandatory	EU & National	Common & National
40		1.14.3.3.1.	Invented name part	Conditional	EU & National	Common
41		1.14.3.3.2.	Scientific part	Conditional	EU & National	National
42		1.14.3.3.3.	Strength part	Conditional	EU & National	Common
43		1.14.3.3.4.	Pharmaceutical dose form part	Conditional	EU & National	National
44		1.14.3.3.5.	Formulation part	Conditional	EU & National	National
45		1.14.3.3.6.	Intended use part	Conditional	EU & National	National
46		1.14.3.3.7.	Target population part	Conditional	EU & National	National
47		1.14.3.3.8.	Container or pack part	Conditional	EU & National	National
48		1.14.3.3.9.	Device part	Conditional	EU & National	National

Item	Resource Definition Level	PMS EU IG Ref.	PMS data element name	Conformance	Applicable values in the context of CAPs: EU or EU & National	Applicable values in the context of non-CAPs (MRPs, DCPs, NPs): Common when across all MS or National
49		1.14.3.3.10.	Trademark or company name part	Conditional	EU & National	National
50		1.14.3.3.11.	Time/period part	Conditional	EU & National	National
51		1.14.3.3.12.	Flavour part	Conditional	EU & National	National
52		1.14.3.3.13.	Delimiter part	Conditional	EU & National	National
53		**1.15.**	**(Pharmacovigilance) master file**	**Mandatory**	**-**	-
54		1.15.1.	File type•	Mandatory	EU	Common
55		1.15.2.	File code	Mandatory	EU	Common
56		**1.16.**	**Contact (QPPV)**	**Mandatory**	**-**	-
57		1.16.1.	Identifier	Mandatory	EU	Common
58		1.16.2.	Role•	Mandatory	EU	Common
59		**1.17.**	**Pharmacovigilance enquiry information≠**	**Mandatory**	**-**	-
60		1.17.1.	Email address	Mandatory	EU	Common
61		1.17.2.	Phone number	Mandatory	EU	Common
62		1.17.3.	Role•	Mandatory	EU	Common
63		**1.18.**	**Attached document≠**	**Mandatory**	**-**	-
64		1.18.1.	Master (Attached document) Identifier	Conditional	EU	National
65		1.18.1.1.	Identifier value	Mandatory	EU	National
66		1.18.1.2	Identifier system•	Mandatory	EU	National
67		1.18.2.	Alternative (Attached document) Identifier‡	Optional	EU & National	National
68		1.18.2.1.	Identifier value	Mandatory	EU & National	National
69		1.18.2.2.	Identifier system•	Mandatory	EU & National	National
70		1.18.3.	(Attached document) Type•	Mandatory	EU & National	National

Item	Resource Definition Level	PMS EU IG Ref.	PMS data element name	Conformance	Applicable values in the context of CAPs: EU or EU & National	Applicable values in the context of non-CAPs (MRPs, DCPs, NPs): Common when across all MS or National
71		1.18.4.	(Attached document) Effective date	Conditional	EU & National	National
72		1.18.5.	(Attached document) Language•≠	Mandatory	EU & National	National
73		1.18.6.	URL value	Mandatory	EU & National	National
74		1.18.7	(Attached document) Status	Mandatory	EU & National	National
75		**1.19.**	**Product cross-reference≠**	**Conditional**	**-**	**-**
76		1.19.1.	Product cross-reference type•	Mandatory	EU & National	Common
77		1.19.2.	Product cross-reference resource identifier	Mandatory	EU & National	Common
78		**1.20.**	**Manufacturing business operation≠**	**Mandatory**	**-**	**-**
79		1.20.1.	Manufacturer*	Mandatory	EU	Common & National
80		1.20.2.	Operation type•	Mandatory	EU	Common & National
81		1.20.3.	Manufacturing operation start date	Conditional	EU	Common & National
82		1.20.4.	Manufacturing operation end date	Conditional	EU	Common & National
83		1.20.5.	Confidentiality indicator•	Mandatory	EU	Common & National
84		1.20.6.	Manufacturing authorisation reference number	Conditional	EU	Common & National
85		1.20.7.	Effective date	Conditional	EU	Common & National
86		1.20.8.	(Manufacturing business operation) Medicines Regulatory Agency Organisation	Mandatory (ORG ID); Conditional (LOC ID)	EU	Common & National
87	**2**	**2.**	**Marketing authorisation information**	**Mandatory**	**-**	-
88		2.1.	Regulatory authorisation type•	Mandatory	EU	Common
89		2.2.	Marketing authorisation number	Conditional	EU	National

Item	Resource Definition Level	PMS EU IG Ref.	PMS data element name	Conformance	Applicable values in the context of CAPs: EU or EU & National	Applicable values in the context of non-CAPs (MRPs, DCPs, NPs): Common when across all MS or National
90		2.3.	Country•	Mandatory	EU & National (IS, LI, NO)	National
91		2.4.	Authorisation status•	Mandatory	EU & National (IS, LI, NO)	National
92		2.5.	Authorisation status date	Conditional	EU & National (IS, LI, NO)	National
93		2.6.	Date of first authorisation	Mandatory	EU & National (IS, LI, NO)	National
94		2.7.	International birth date	Mandatory	EU	Common
95		2.8.	Marketing authorisation holder (organisation)	Mandatory	EU	National
96		2.9.	(Marketing authorisation) Regulator	Mandatory/ Conditional	EU	National
97		**2.10.**	**Marketing authorisation procedure[9]**	**Mandatory/ Optional[10]***	**-**	-
98		2.10.1.	Procedure Identifier	Conditional	EU	Common
99		2.10.2.	Procedure type – Medicines approval system•	Mandatory	EU	Common
100		2.10.3.	Procedure start date	Conditional	EU	Common
101		2.10.4.	Procedure end date	Conditional	EU	Common
102		2.10.5.	Regulatory application	Conditional	EU	Common & National
103		2.10.5.1.	Regulatory application identifier/Number	Conditional	EU	Common & National
104		2.10.5.2.	Regulatory application type•	Mandatory	EU	Common & National

[9] Please refer to the section 2.10 in this Chapter for further details. When referring to "EU & National" we are referring to the "country" entities European Union (EU, IS, LI, NO.
[10] "Mandatory" conformance designated for medicinal products authorized in EU/EEA and "Optional" for medicinal products outside this region. For further details please refer to the corresponding section in Chapter 2 for further details.

Item	Resource Definition Level	PMS EU IG Ref.	PMS data element name	Conformance	Applicable values in the context of CAPs: EU or EU & National	Applicable values in the context of non-CAPs (MRPs, DCPs, NPs): Common when across all MS or National
105		2.10.5.3.	Regulatory application end date	Conditional	EU	Common & National
106	**3**	**3.**	**Therapeutic (product) indication**≠	**Mandatory**	-	-
107		3.1.	Indication as "Disease/Symptom/Procedure"•	Mandatory	EU	Common & National
108		3.2.	Co-morbidity‡•	Conditional	EU	Common & National
109		3.3.	Intended effect‡•	Mandatory	EU	Common & National
110	**4**	**4.**	**Packaged medicinal product**≠	**Mandatory**	-	-
111		4.1.	Packaged medicinal product Identifier (PCID)	Not applicable	EU & National	National
112		4.2.	Package description‡	Mandatory	EU	National
113		4.2.1.	Language•	Mandatory	EU & National	National
114		4.3.	Manufacturer‡	Conditional	EU	Common & National
115		4.4	Pack size‡	Mandatory	EU	National
116		4.4.1.	Quantity operator•	Mandatory	EU	National
117		4.5.	Legal status of supply•	Conditional	EU	National
118		**4.6.**	**Marketing status**≠	**Mandatory**	**-**	-
119		4.6.1.	Country•	Mandatory	National	National
120		4.6.2.	Marketing status•	Mandatory	National	National
121		4.6.3.	(Marketing status) start date	Conditional	National	National
122		4.6.4.	(Marketing status) end date	Conditional	National	National
123		4.6.5.	Risk of supply shortage	Conditional	National	National
124		4.6.6.	Risk of supply shortage comment	Conditional	National	National
125		4.6.7.	Status Reason	Conditional	National	National
126		4.6.7.1	Reason•	Mandatory	National	National
127		4.6.7.2.	Restore date	Optional	National	National

Item	Resource Definition Level	PMS EU IG Ref.	PMS data element name	Conformance	Applicable values in the context of CAPs: EU or EU & National	Applicable values in the context of non-CAPs (MRPs, DCPs, NPs): Common when across all MS or National
128		**4.7.**	**Marketing authorisation (Package level)**	**Mandatory**	**-**	**-**
129		4.7.1.	Regulatory authorisation type•	Conditional	EU	Common & National
130		4.7.2.	Marketing authorisation number (Package level)	Conditional	EU	National
131		4.7.3.	Country•	Mandatory	EU	National
132		4.7.4.	Authorisation status•	Mandatory	EU	National
133		4.7.5.	Authorisation status date (Package level)	Conditional	EU	National
134		**4.8.**	**Package item (container)**	**Mandatory**	**-**	-
135		4.8.1.	Package item (container) type•	Mandatory	EU	Common & National
136		4.8.2.	Package item reference(s)‡	Conditional	EU	Common & National
137		4.8.3.	Manufactured item reference(s) ‡	Conditional	EU	Common & National
138		4.8.4.	Device reference(s)‡	Conditional	EU	Common & National
139		4.8.5.	Package item (container) quantity	Conditional	EU	Common & National
140		4.8.5.1.	Quantity operator•	Mandatory	EU	Common & National
141		4.8.6.	Data carrier identifier ≠	Optional	National	National
142		4.8.6.1.	Identifier value	Mandatory	National	National
143		4.8.6.2.	Identifier system•	Mandatory	National	National
144		4.8.7.	Material•‡	Mandatory	EU	Common & National
145		**4.9.**	**Package (component)** ≠	**Mandatory**	**-**	-
146		4.9.1.	Component type•	Mandatory	EU	Common & National
147		4.9.2.	Component material‡	Conditional	EU	Common & National
148		**4.10.**	**Medical Device*** ≠	**Conditional**	**-**	-
149		4.10.1.	Type of combination product – Drug/ Device; Biological/ Device•	Mandatory	EU	Common & National

Item	Resource Definition Level	PMS EU IG Ref.	PMS data element name	Conformance	Applicable values in the context of CAPs: EU or EU & National	Applicable values in the context of non-CAPs (MRPs, DCPs, NPs): Common when across all MS or National
150		4.10.2.	Medical Device type•	Mandatory	EU	Common & National
151		4.10.3.	Medical Device identifier	Conditional	EU	Common & National
152		4.10.4.	Medical Device trade name	Conditional	EU & National	Common & National
153		4.10.5.	Medical Device quantity	Mandatory/Not applicable	EU	Common & National
154		4.10.5.1	Quantity operator•	Mandatory	EU	Common & National
155		4.10.6.	Medical device description≠	Mandatory	EU	Common & National
156		4.10.6.1	Language•	Mandatory	EU	Common & National
157		4.10.7.	Medical device description of intended purpose≠	Mandatory	EU	Common & National
158		4.10.7.1.	Language•	Mandatory	EU	Common & National
159		4.10.8.	Medical device classification•	Mandatory/Not applicable	EU	Common & National
		4.10.9.	Medical device manufacturer‡	Mandatory	EU	Common & National
160		**4.11.**	**Manufactured item≠**	**Mandatory**	**-**	-
161		4.11.1.	Unit of presentation•	Mandatory	EU	Common & National
162		4.11.2.	Manufactured item quantity	Conditional	EU	Common & National
163		4.11.2.1.	Quantity operator•	Mandatory	EU	Common & National
164		4.11.3.	Manufactured dose form•	Mandatory	EU	Common & National
165		4.11.4.	Ingredient*≠	Mandatory	EU	Common & National
166		4.11.5.	Manufactured item description‡	Conditional	EU	Common & National
167		4.11.5.1.	Language•	Mandatory	EU & National	National
168		4.12.	**Shelf life/ Storage≠**	Conditional	EU	Common & National
169		4.12.1.	Shelf life type•	Mandatory	EU	Common & National
170		4.12.2.	Shelf life time period and units•	Mandatory	EU	Common & National
171		4.12.3.	Special precautions for storage‡•	Mandatory	EU	Common & National

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172	**5**	**5.**	**Ingredient*≠**	**Mandatory**	-	-
173		5.1.	Ingredient role•	Mandatory	EU	Common & National
174		5.2	Origin of the substance•	Optional	EU	Common
175		5.3.	Composition grouping description	Optional	EU	Common
176		5.4.	Manufacturer*‡	Conditional	EU	National
177		**5.5.**	**Substance**	**Mandatory**	-	-
178		**5.5.1.**	**Substance**	**Mandatory**	EU	Common & National
179		**5.5.2.**	**Substance strength (quantitative composition)**	**Conditional**	EU	Common & National
180		5.5.2.1.	Quantity operator•	Not applicable	EU	Common & National
181		5.5.2.2.	Strength (Presentation)	Conditional	EU	Common & National
182		5.5.2.2.1.	Quantity operator•	Mandatory	EU	Common & National
183		5.5.2.2.2.	Strength (Presentation single value or low limit) •	Mandatory	EU	Common & National
184		5.5.2.2.3.	Strength (Presentation high limit) •	Conditional	EU	Common & National
185		5.5.2.3.	Strength (Concentration)	Conditional	EU	Common & National
186		5.5.2.3.1.	Quantity operator•	Mandatory	EU	Common & National
187		5.5.2.3.2.	Strength (Concentration single value or low limit) •	Mandatory	EU	Common & National
188		5.5.2.3.3.	Strength (Concentration high limit) •	Conditional	EU	Common & National
189		**5.5.3.**	**Substance reference strength (quantitative composition)≠**	**Conditional**	**-**	**-**
190		5.5.3.1.	Reference substance	Mandatory	EU	Common & National
191		5.5.3.2.	Quantity operator•	Not applicable	EU	Common & National

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192		5.5.3.3.	Reference strength (Presentation)	Conditional	EU	Common & National
193		5.5.3.3.1.	Quantity operator•	Mandatory	EU	Common & National
194		5.5.3.3.2.	Reference strength (Presentation single value or low limit)•	Mandatory	EU	Common & National
195		5.5.3.3.3.	Reference strength (Presentation high limit)	Conditional	EU	Common & National
196		5.5.3.4.	Reference strength (Concentration)	Conditional	EU	Common & National
197		5.5.3.4.1.	Quantity operator•	Mandatory	EU	Common & National
198		5.5.3.4.2.	Reference strength (Concentration single value or low limit)•	Mandatory	EU	Common & National
199		5.5.3.4.3.	Reference strength (Concentration high limit)•	Conditional	EU	Common & National
200		**5.5.4.**	**(Certificate) master file**	Conditional	-	-
201		5.5.4.1.	File type•	Mandatory	EU	Common
202		5.5.4.2	File code	Mandatory	EU	Common
203		5.5.4.2.1.	File identifier type•	Mandatory	EU	Common
204		5.5.4.2.2.	File identifier	Mandatory	EU	Common
205		5.5.4.3	Submission date	Mandatory/Not applicable[11]	EU	Common
206		5.5.4.4	Date of last update	Conditional/ Not applicable	EU	Common
207		5.5.4.5.	Manufacturer	Conditional	EU	Common
208	**6**	**6.**	**Pharmaceutical product**≠	Mandatory	-	-

[11] "Conditional" conformance designated for any certificate as listed in the section 5.5.4. (Certificate) master file with the exception of the TSE certificate to which "Not applicable" conformance applies. For further details please refer to the corresponding section in Chapter 2 for further details.

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209		6.1.	Pharmaceutical product description‡	Conditional	EU	Common & National
210		6.1.1.	Language•	Mandatory	EU & National	National
211		6.2.	Administrable dose form•	Mandatory	EU	Common & National
212		6.3.	Unit of presentation•	Conditional	EU	Common & National
213		6.4.	Ingredient*≠	Mandatory	EU	Common & National
214		6.5.	Device*≠	Conditional	EU	Common & National
215		6.6.	Route of administration≠•	Mandatory	EU	Common & National

[i] **Action** refers to the type of change (usually as a consequence of a regulatory procedure) that results in an update on the product entry in Product Management System (PMS).
[ii] **Procedure number** refers to the number as given by the Regulator (NCA, EMA) at the time of submission of the regulatory procedure. This information is included as per section 2.10.5 - Regulatory application procedure of this document.
[iii] **Version** refers to the number given automatically by the system for each record submitted in Product Management System (PMS).
[iv] **Medicinal product** defined as in the Introduction of this document: Product name, Strength, active substance, pharmaceutical form and country.
[v] **MAH name/ID** refers to the Marketing Authorisation Holder and the ORG ID associated with it in the Organisations Management System (OMS).
[vi] **PMS ID** refers to the system generated ID uniquely assigned to a Medicinal Product level at the time of the first submission of the medicinal product information in Product Management System (PMS). This ID remains unchanged during the lifecycle of the product.
[vii] **MPID** refers to Medicinal Product Identifier as defined by ISO IDMP. This is further detailed in section Identifiers and defining characteristics of a medicinal product entry in PMS of this document.

[viii] **Marketing Authorisation number (Medicinal Product level)** refers to the authorisation number or equivalent identifier as granted by the European Commission or relevant Competent Authorities (Regulator) at the level of the Medicinal Product. In countries where MA numbers are assigned at Packaged Medicinal product level with a common root number across packages, the root number of the MAA must be provided. In countries where MA numbers are assigned at Package Medicinal product level with no common root number across packages, this field is to be left blank. This information is included as per section 2.2 – Marketing Authorisation Number.
[ix] **PCID** refers to Packaged Medicinal Product as defined by ISO IDMP. This is further detailed in section Identifiers and defining characteristics of a medicinal product entry in PMS of this document.
[x] **Marketing Authorisation number (Package Medicinal Product level)** refers to the authorisation number or equivalent identifier as granted by the European Commission or relevant Competent Authorities (Regulator) at the level of the Package Medicinal Product. This information is included as per section 4.7.2. – Marketing Authorisation Number.