



BSI Standards Publication

**Health informatics – Identification of medicinal products – Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO/TS 20443:2017)**

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## National foreword

This Published Document is the UK implementation of CEN ISO/TS 20443:2018. It is identical to ISO/TS 20443:2017.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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|------|---------------|

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English Version

Health informatics - Identification of medicinal products -  
Implementation guidelines for ISO 11615 data elements  
and structures for the unique identification and exchange  
of regulated medicinal product information (ISO/TS  
20443:2017)

Informatique de santé - Identification des médicaments  
- Lignes directrices pour l'implémentation des  
éléments de données et structures ISO 11615 pour  
l'identification unique et l'échange d'informations  
réglementées sur les médicaments (ISO/TS  
20443:2017)

Medizinische Informatik - Identifikation von  
Arzneimitteln - Datenelemente und -strukturen zur  
Identifikation von Arzneimitteln für den Austausch von  
behördlich genehmigten Arzneimittelinformationen  
(ISO/TS 20443:2017)

This Technical Specification (CEN/TS) was approved by CEN on 13 May 2018 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## European foreword

This document (CEN ISO/TS 20443:2018) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

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## Endorsement notice

The text of ISO/TS 20443:2017 has been approved by CEN as CEN ISO/TS 20443:2018 without any modification.

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## Foreword

ISO (the International Organization for Standardisation) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

## Introduction

This document is a guide for implementing ISO 11615, one of the five ISO IDMP standards. The five ISO standards and four ISO Technical Specifications, when used together, provide the basis for exchanging data elements that will support the unique and unambiguous identification of Medicinal Products. The primary purpose for this document is to provide technical guidance to software implementers. Short descriptions of business rationale are also included, where relevant, to provide context. Thus, this document focuses on business and technical considerations for implementation that will construct and parse well-formed, transmittable IDMP messages. Following transmission of required data elements, unique identifiers are to be produced in conformance with the standards to support applications where it is necessary to reliably identify and trace regulated biopharmaceutical products. However, this document does not include extensive information on creation or maintenance of identifier repositories. Reference is made to regional guidance/implementation guides to support practical implementation within a given region/jurisdiction. The development of an ISO technical report for identifying core principles for the maintenance of identifiers and terms for ISO IDMP is to be developed and referenced for applicable ISO IDMP standards and corresponding technical specifications.

### Purpose

To meet the primary objectives of the regulation of medicines (pharmacovigilance) it is necessary to reliably exchange Medicinal Product information in a robust and consistent manner. The data elements and message specifications described in this document support, at a minimum, the following interactions within the following scope:

- regulator to regulator;
- biopharmaceutical company to regulator;
- sponsor of clinical trials to regulator;
- regulator to other stakeholders;
- regulator to worldwide-maintained data sources.

Unique identifiers produced in conformance with this document are aimed at supporting applications where it is necessary to reliably identify and trace the use of Medicinal Products.

In the context of exchange of regulatory information, the purpose of this document is twofold:

- to specify data elements, structures and relationships between the data elements which are required to uniquely identify Medicinal Products for human use;
- to specify definitions of terms for all data elements required to uniquely identify Medicinal Products for human use.

# Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11615 data elements and structures for the unique identification and exchange of regulated medicinal product information

## 1 Scope

This document defines concepts and describes data elements and their structural relationships, which are required for the unique identification and the detailed description of Medicinal Products.

Taken together, all ISO IDMP standards (ISO 11615, ISO 11616, ISO 11238, ISO 11239 and ISO 11240) define, characterise, and uniquely identify regulated Medicinal Products for human use from approval, to post-marketing and renewal or withdrawal from the market, where applicable.

Furthermore, to support successful information exchange in relation to the unique identification and characterisation of Medicinal Products, the normative use of HL7 common product model (CPM) and structured product labeling (SPL) messaging is described. References to the use of other relevant standards for Medicinal Product information are included in this document to support successful information exchange.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO/IEC 5218, *Information technology — Codes for the representation of human sexes*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11238, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated information on substances*

ISO 11239, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

ISO 11240, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of units of measurement*

ISO 11615, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated Medicinal Product information*

ISO 11616, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

ISO/TS 20440, *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*

HL7 Reference Information Model (RIM).

HL7 Version 3 Standard, Common Clinical Product Model

HL7 Version 3 Standard, Common Product Model CMETs

HL7 Version 3 Standard, Regulated Product Submission

HL7 Version 3 Standard, Structured Product Labeling

## 3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

## 4 Message exchange

### 4.1 General

HL7 messaging standards are widely implemented globally. The HL7 V3 messaging standard deals with a static model of healthcare information as viewed within the scope of HL7 standards development activities. ISO recognises HL7 as an accredited partner organisation for mutually issuing standards. The first mutually published standard was ISO/HL7 21731:2006.

HL7 V3 was developed to address the complex requirements of health information technology. The HL7 Reference Information Model (RIM) is the cornerstone of V3 and the essential model from which all HL7 messages are derived. The RIM defines data content needed in a specific context and provides an explicit representation of the semantic and lexical connections that exist between the information carried in the elements of a message. V3 seeks to develop specifications that facilitate interoperability between systems. The HL7 model-driven methodology is used to develop consensus-based standards for healthcare system interoperability and information exchange. HL7 V3 messages are based on an XML encoding syntax.

The ISO IDMP standards were designed to specify the necessary data elements and associated standards to be used for unique identifiers. These were developed as an integral part of the IDMP consensus requirements and are consistent with the HL7 Common Product Model (CPM). The IDMP data elements represent a subset of those in the CPM. The normative use of HL7 standards will facilitate the integration of IDMP into the broader healthcare community.

### 4.2 Message exchange format

In the context of this document, the normative message exchange format to be utilised as reference in transactions is HL7 Structured Product Labeling (SPL). SPL is a standard message exchange format based on Clinical Document Architecture (CDA) and the HL7 Reference Information Model (RIM). Various solutions for creating SPL files exist and range from basic software tools to comprehensive information management systems. SPL instances (code snippets) are provided throughout to illustrate the representation of an IDMP concept within the HL7 SPL message exchange format. Technical conformance criteria for SPL messages will not be addressed in this document and shall be left to regional guidance/implementation per their respective requirements. A reference to the most up to date HL7 CPM and SPL reference as a resource for IDMP implementation is accessible on the HL7 website<sup>1)</sup>.

### 4.3 Controlled vocabularies

There are many terms in use to describe basic concepts in the regulatory, pharmaceutical and healthcare standards development domain for different purposes and in different contexts. The terms and definitions described in this document apply to the concepts, which are required to uniquely identify, characterise, and exchange regulated Medicinal Products and associated information. A long-term goal for IDMP is to promote the development of controlled vocabularies for worldwide application, with transitional measures envisioned to accommodate regional requirements. Regional guidance/implementation guides shall be developed to support practical implementation within a given region/jurisdiction. The development of a technical report for identifying core principles for the maintenance of identifiers and terms for ISO IDMP shall be developed and referenced for applicable ISO IDMP standards and corresponding technical specifications upon completion.

NOTE Harmonisation by regions to adopt identical controlled vocabularies for IDMP implementation is out of the scope of this document, but is being facilitated by external activities outside of ISO. It is anticipated that this will be revisited as an in scope activity within ISO IDMP as the standard is adopted worldwide over time.

## 5 Conformance terminology and context as it relates to the ISO IDMP standards and corresponding technical specifications

- **Mandatory:** Defining elements **necessary** for the unique identification of Medicinal Products per the ISO IDMP standards/technical specifications.
- **Conditional:** Conditional applies to the “*within category*” data elements, as applicable, when there are alternative data sources for a given data element(s) to identify a medicinal/pharmaceutical product. Regional implementation of the ISO IDMP standards/technical specifications may elevate the conditional conformance categories to “**mandatory**” per regional requirements.
- **Optional:** When listed at the category level (e.g. specified substance), optional corresponds to ISO categories or data elements that are not absolutely necessary for the **unique** identification of medicinal/pharmaceutical products according to the ISO IDMP standards/technical specifications. Regional implementation of the ISO IDMP standards/technical specifications may elevate the optional conformance categories to “**mandatory**” or “**conditional**” per regional requirements.

## 6 Maintenance of IDMP data elements and IDMP identifiers

### 6.1 General

Creation, maintenance, and publication of the actual IDMP identifiers are envisioned as a distributed process where each participating regulatory authority would establish and maintain the identifiers utilised in their respective regions. Over the longer term, a list of certain identifiers for global use may be developed and agreed via a federated approach, and associated with the regulatory process in each respective region. It is anticipated that IDMP maintenance requirements will mature and evolve over time and IDMP scope and use cases expand.

### 6.2 Translation and language

With the specific exception of Medicinal Product name information (see [A.2.13](#)), there is no description of the translation of information described in ISO 11615. It was acknowledged that, for global implementation, translation of the information will be required and will occur according to regional implementation guidelines as applicable.

The requirement for translation is determined by a region. An international body may or may not require documents translated in some or all languages of its member nationalities. In addition, a country with multiple sizable sub-populations using multiple languages may or may not require translations into more than one of these languages. The IDMP standards do not set such requirements. The multilingual make-up of many regions are supported by HL7 CPM and SPL for multilingual contexts

and international exchange of IDMP data. [Annex J](#) specifies how SPL is to be utilised in support of multilingual requirements.

## 7 Why standardisation of identification of Medicinal Products is needed

Medicines regulatory authorities and pharmaceutical industry engage in an intensive information exchange during drug development, drug evaluation and approval phase and the post-authorisation phase. The standardisation of Medicinal Product information is regarded as one of the key elements of this information flow.

However, regulators in the various regions have established their own procedures and applications with standards that differ in data format, content, language, and applied terminology (e.g. different terminology is used for describing substances, routes of administration, pharmaceutical dose forms, pharmaceutical products, and Medicinal Products).

Due to the lack of a common and harmonised approach, both regulators and pharmaceutical industry are confronted with the following issues:

- no possibility to exchange Medicinal Product information between medicines regulatory authorities and pharmaceutical industry in a structured and efficient way;
- difficulties in ensuring data consistency and in evaluating and comparing Medicinal Product-related information across the regions due to the lack of harmonised definitions of terminologies and data sets, which impairs pharmacovigilance and electronic prescription/dispensing activities, especially across borders;
- for the pharmaceutical industry, major administrative burdens and duplication of efforts requiring substantial human and financial resources to comply with and handle different regional requirements;
- lack of consistency in the use of terminology in the healthcare community.

The objectives of the IDMP are to address the issues outlined above by developing harmonised standards that build on the regulatory, scientific, and technical processes already established and to support the population and maintenance of existing systems/applications with fully reliable regulatory Medicinal Product information.

Harmonised standards will support external stakeholders in developing “off-the-shelf” interoperable tools in conformance with international standards. International standards will also help maximise forward compatibility of data and minimise the complexities of backward compatibility.

## 8 General considerations

### 8.1 Overview

This document is intended to accompany, but not replace, ISO 11615 or HL7 CPM/SPL standards.

To satisfy the requirements as described in this document, the following identifiers shall be specified as described in this document for the unique identification of Medicinal Products:

- Medicinal Product Identifier (MPID),
- Medicinal Product Package Identifier (PCID);
- Medicinal Product Batch Identifier (BAID 1), allocated to a specific batch of a Medicinal Product, which appears on the outer packaging of the Medicinal Product;
- Medicinal Product Batch Identifier (BAID 2), allocated to a specific batch of a Medicinal Product, which appears on the immediate packaging, where this is not the outer packaging;

- expiration date;
- serialisation-package level identification of a packaged Medicinal Product (including the particular package configuration). Serial numbers should be numeric (numbers) or alphanumeric (include letters and/or numbers) and should have no more than 20 characters (letters and/or numbers).

NOTE 1 Serialisation requirements are given in regional guidance.

NOTE 2 In addition, there is an association with Pharmaceutical Product Identifiers (PhPIDs) as defined in ISO 11616 and ISO/TS 20451.

NOTE 3 Reference made to ISO 11615 for description/context of BAID 1 and BAID 2.

## 8.2 General considerations related to the description of the information modelling principles and practices

### 8.2.1 Overview

The information modelling in this document uses the Unified Modelling Language (UML), which is maintained by the Object Management Group (OMG).

UML may say the same thing in several different ways, and there are different styles and patterns that may be followed. The use of UML in this document utilises classes, attributes and basic association relationships only. Some constructs (such as stereotypes and complex relationships) have been explicitly avoided for the reason cited above. In addition, colour has been used in the diagrams to help visualise groups of associated entities together with one another (see [Figure 1](#)).

[Figure 1](#) explains the represented approach for this document.



Figure 1 — Legends for colour coding of model classes

### 8.2.2 Conceptual overview diagrams

The conceptual overview diagram provides a framework with which to view the more detailed descriptions of information (see [Figure 2](#)).

The Medicinal Product and investigational Medicinal Product overarching models (see [Figure 5](#) and [Figure 7](#)) show a single representative class from each particular information section, related to the core concept (either the Medicinal Product or the Investigational Medicinal Product).

Basic cardinalities between the Medicinal Product or the Investigational Medicinal Product and these core classes are shown, but none of the detailed entities, relationships or attributes is described.

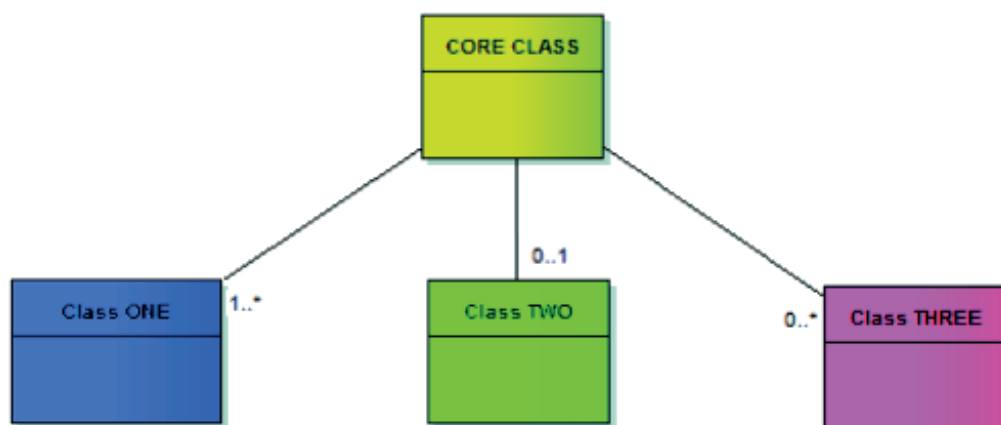


Figure 2 — Example conceptual overview diagram

### 8.2.3 Section high-level diagrams

The high-level diagrams provided at the start of each section of information show all the classes required to describe the information for that section and the conceptual relationships between those classes, with the starting point always as the (Investigational) Medicinal Product.

No attributes and no detailed cardinalities are shown in these conceptual diagrams, as again their primary purpose is to provide a framework with which to view the more detailed descriptions of information that follow in the detailed description diagrams.

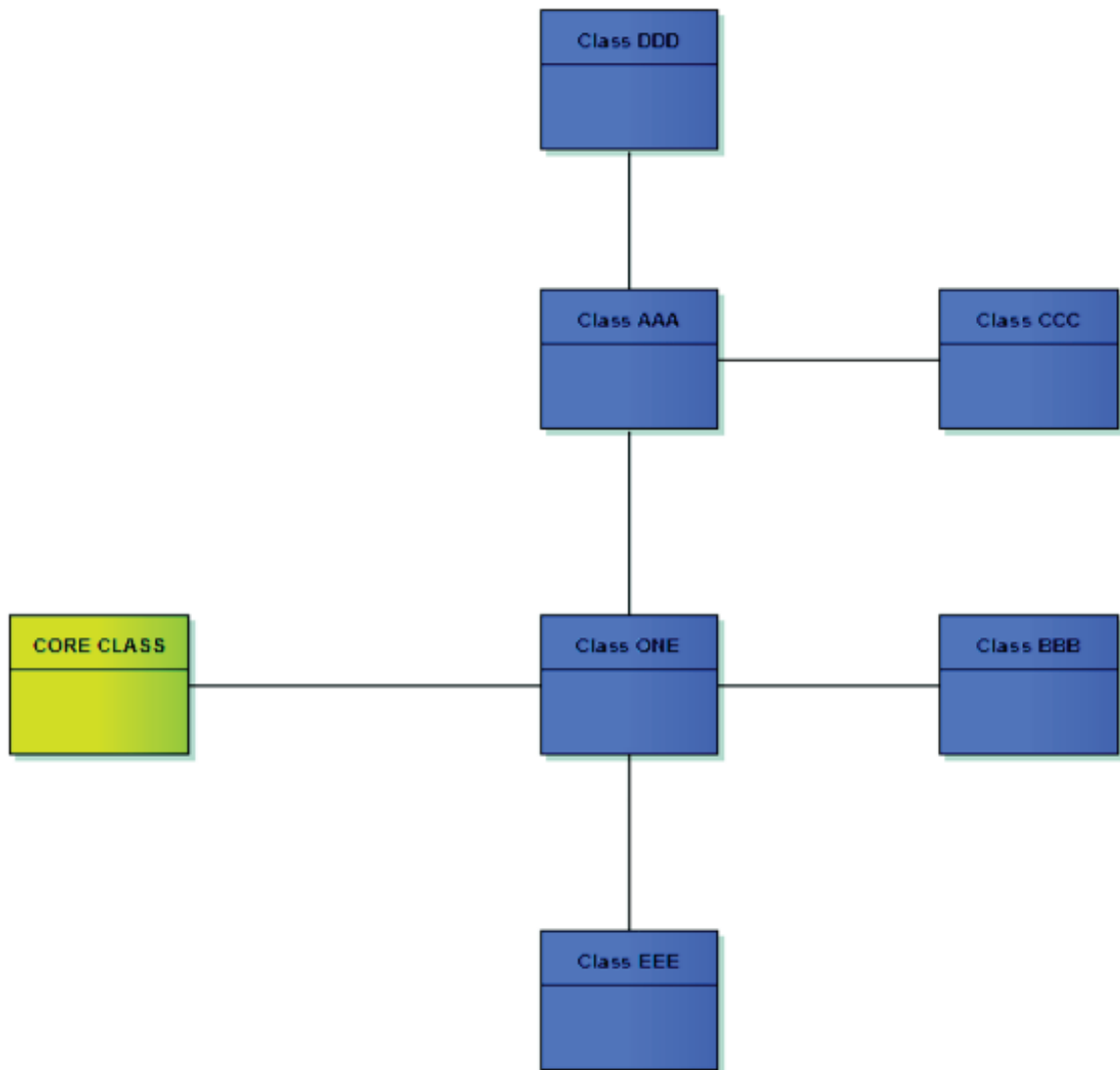


Figure 3 — Example section high-level diagram

#### 8.2.4 Detailed description diagrams

The detailed description diagrams for each section show all the classes and all the attributes required to describe the information for that section, and the detail of the conceptual relationships between those classes.

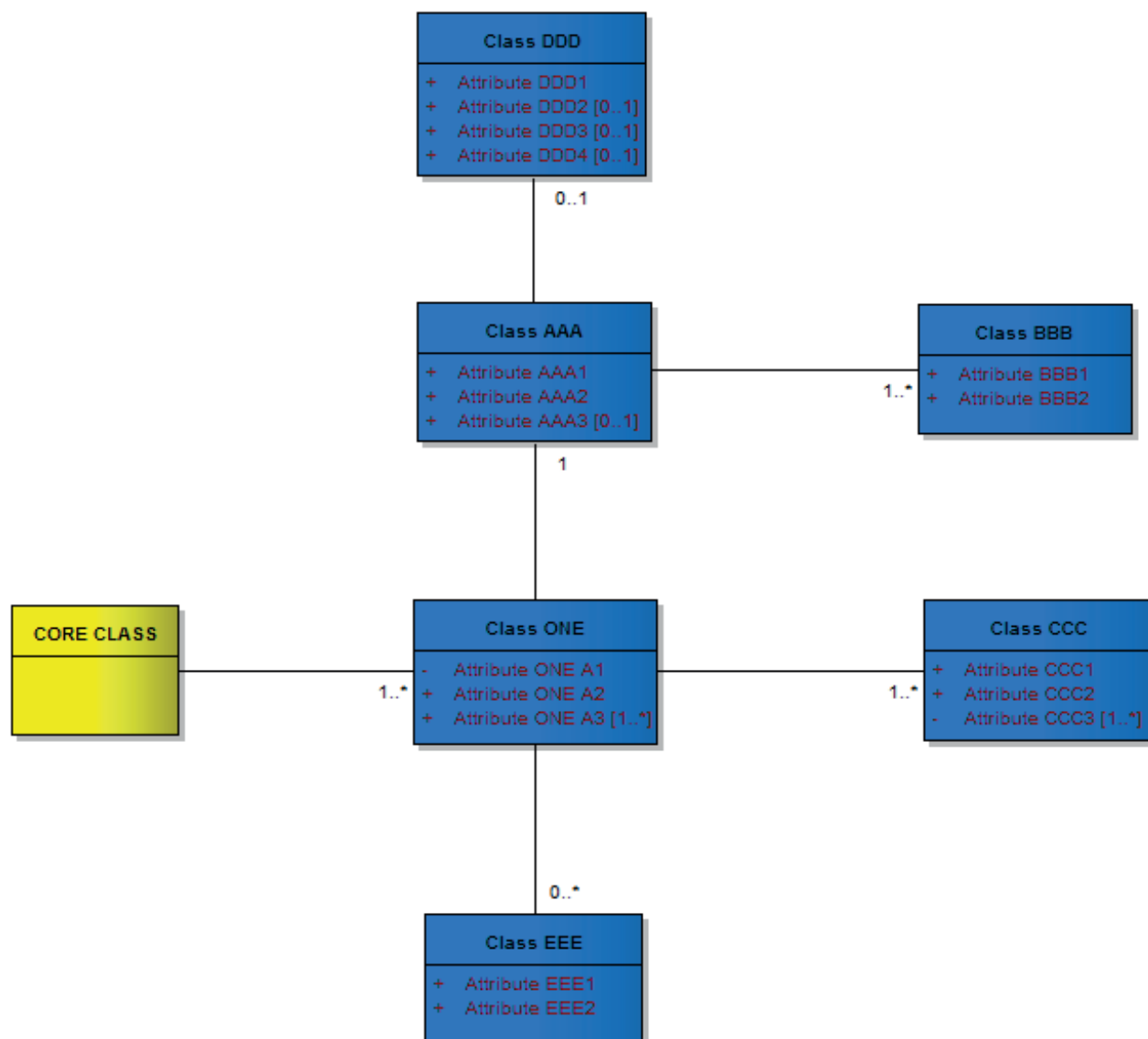


Figure 4 — Example detailed description diagram

### 8.2.5 Relationships between classes

Relationships between classes are described in the context of the (Investigational) Medicinal Product, and are described simply as associations, with no further qualification as to the role or type of the association, in order to keep the model simple.

Cardinalities on relationships are given in a single direction only: the direction with the (Investigational) Medicinal Product always as the direct or indirect source entity. The rationale for this is that the scope of this document is to describe the (Investigational) Medicinal Product and its associated information; therefore, having the (Investigational) Medicinal Product always as the source entity brings clarification and avoids describing complex many-to-many cardinalities that might occur in a reverse direction from an entity towards the (Investigational) Medicinal Product.

A cardinality of “1” is synonymous with a cardinality of “1..1”.

A cardinality of “1” between entities is reflected in the text as the information for that entity shall be specified, and that only one set of the entity information shall be given.

A cardinality of “1..\*” between entities is reflected in the text as the information for that entity shall be specified, and that one or more sets of the entity information shall be given.

A cardinality of “0..1” between entities is reflected in the text as the information for that entity can be specified, and that one set of the entity information can be given.

A cardinality of “0..\*” between entities is reflected in the text as the information for that entity can be specified, and that one or more sets of the entity information can be given.

Some optional attributes can be elevated to mandatory if some conditions are met. Please see [Clause 5](#).

See ISO 21090 for more information on composition of attributes. A datatype for the data in each attribute is not specified directly in the model. However, the text description for each attribute indicates the form in which data should be specified.

### 8.2.6 Attributes of classes

Attributes of a class are described using an attribute name in the model. The definition, description and example values for the attribute are given in the text following the model diagram.

An attribute showing no explicit cardinality means that the attribute shall be valued with one value (this is the equivalent to [1]).

An attribute showing a cardinality of [1..\*] means that the attribute shall be valued with one or more values.

An attribute showing a cardinality of [0..1] means that the attribute can be valued with one value.

An attribute showing a cardinality of [0..\*] means that the attribute can be valued with one or more values.

### 8.2.7 Generalised classes and patterns

There is one use of a generalised class in the diagrams whereby the pattern for a set of information is described once, but applied for use for several classes. For simplicity, this has not been described by using the formal UML generalisation/specialisation relationships, but by using a specialised class name.

The detailed representation of an “Organisation”, its “Contact Persons” and its “Other Locations” is described in [Annex G](#). Wherever information of type “Organisation” with its “Contact Person(s)” and/or “Other Locations” is required, as for example in the class “Manufacturer/Establishment (Organisation)” or the “Medicines Regulatory Agency (Organisation)” class, the “(Organisation)” in the class name indicates that the information shall be described as per the generalised “Organisation” class.

There is also one generalised pattern used several times in the diagrams whereby generic classes provide the ability to describe something using (unspecified) classification, nomenclature or identification systems. To do this at the conceptual level, the model shows a class with two attributes: the first to identify the system itself (a classification, nomenclature or identification system), and the second to describe the applicable term or value from that system.

## 9 Information for an authorised Medicinal Product

### 9.1 General

The main concepts modelled in [Figure 3](#) and described below should apply in order to identify and characterise an authorised Medicinal Product which itself is identified by the MPID/PCID.

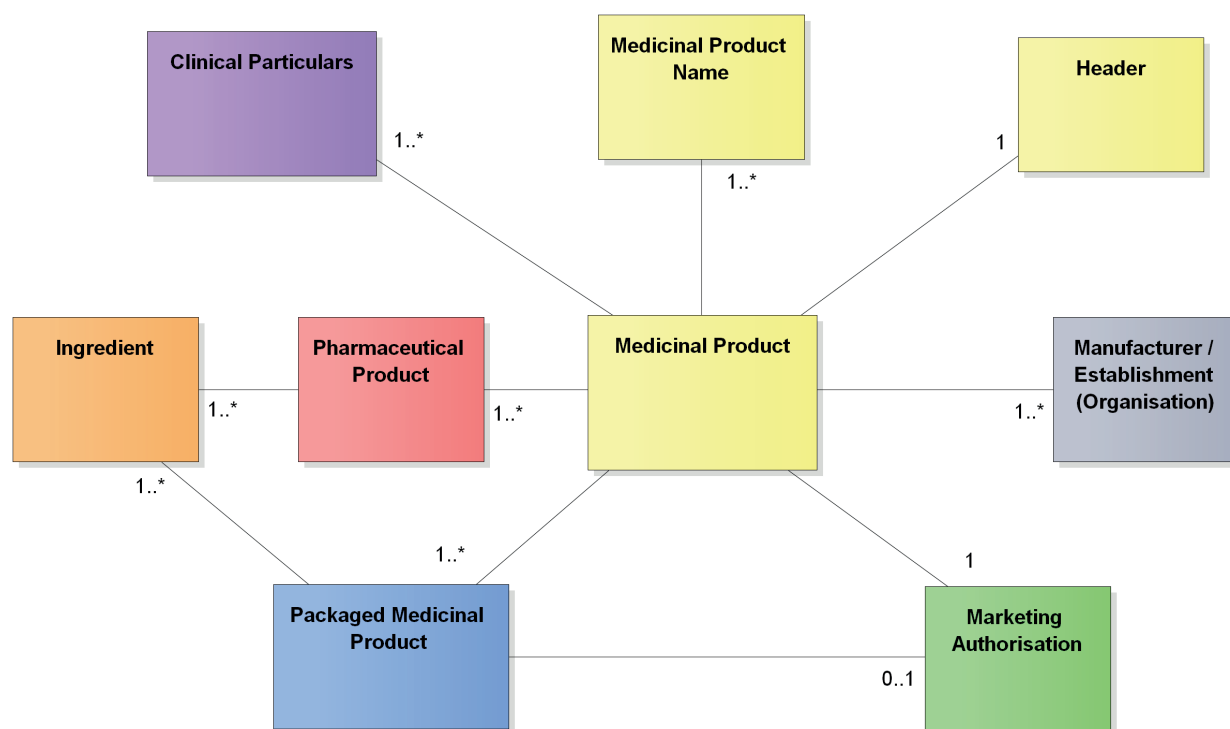


Figure 5 — Medicinal Product overarching model

```

<!-- SPL header -->
<document>
<!-- Version -->
<author>
  <assignedEntity>
    <representedOrganisation>
      <!-- Manufacturer/Establishment (Organisation) -->
      ...
    </representedOrganisation>
  </assignedEntity>
</author>
<component><structuredBody><component><section>...
<subject>
  <!-- CPM body -->
  <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product -->
    <code code="MPID" codeSystem="MPID Code System OID"/>
    <name><!-- Medicinal Product Name --></name>
    ...
    <asSpecialisedKind><!-- Pharmaceutical Product -->
    <generalisedMaterialKind>
      <code code="PhPID" codeSystem="PhPID Code System OID" .../>
    </generalisedMaterialKind>
    </asSpecialisedKind>
    ...
    <asContent><!-- Packaged Medicinal Product --></asContent>
  </manufacturedProduct>
  <subjectOf>
    <approval><!-- Marketing Authorisation --></approval>
  </subjectOf>
  <consumedIn><!-- Clinical Particulars --></consumedIn>

```

## 9.2 Medicinal Product

This subclause specifies the MPID together with the information that uniquely identifies and characterises a Medicinal Product as authorised by a medicines regulatory agency in a defined region.

```
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct><!-- Medicinal Product -->
  <code code="MPID" codeSystem="MPID Code System OID"/>
```

## 9.3 Header

This subclause specifies the versioning of the core identifiers related to a Medicinal Product in a region, as well as the characteristics associated with the Medicinal Product and the documentation that supports the versioning.

## 9.4 Medicinal Product name

This subclause specifies the name of the Medicinal Product as authorised by a medicines regulatory agency in a defined region, together with an analysis of the name into various parts.

```
<!-- SPL header -->
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct><!-- Medicinal Product -->
  <name><!-- Medicinal Product Name --></name>
```

## 9.5 Manufacturer/establishment (organisation)

This subclause specifies the characteristics of the manufacturing process and other associated operations and their authorisations as issued by a medicines regulatory agency, which grants permission to a manufacturer or an establishment to undertake manufacturing and other associated operations related to a Medicinal Product in a region.

```
<!-- SPL header -->
<document>
<!-- Version -->
<author>
  <assignedEntity>
    <representedOrganisation>
      <!-- Manufacturer/Establishment (Organisation) -->
    </representedOrganisation>
  </assignedEntity>
</author>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
  <manufacturedProduct><!-- Medicinal Product -->
```

## 9.6 Marketing authorisation

This subclause specifies the information about the marketing authorisation as issued by a medicines regulatory agency, which grants permission to a pharmaceutical company to place a Medicinal Product on the market in a region.

NOTE 1 Marketing authorisation holder and labeller are considered synonymous.

NOTE 2 Marketing authorisation, in the context of ISO IDMP, refers to the regulatory procedure (granting authorisation) versus marketing authorisation as “actual” placement on the market.

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
    <subject>
      <!-- CPM body -->
      <manufacturedProduct>
        <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
      <subjectOf>
        <approval><!-- Marketing Authorisation -->
```

## 9.7 Packaged Medicinal Product

This subclause specifies information about the packaging and container(s) of a Medicinal Product and any associated device(s) which is an integral part or provided in combination with a Medicinal Product, as supplied by the manufacturer for sale and distribution. It also specifies the ingredient information for the manufactured item(s).

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
    <subject>
      <!-- CPM body -->
      <manufacturedProduct>
        <manufacturedProduct><!-- Medicinal Product -->
          <asContent><!-- Packaged Medicinal Product --></asContent>
          <asPartOfAssembly>
            <wholeProduct>
              <part><!-- associated device(s) used in combination --></part>
            </wholeProduct>
          </asPartOfAssembly>
        <part><!-- associated device(s) which are an integral part --></part>
```

## 9.8 Pharmaceutical Product

This subclause specifies information about the Medicinal Product in the dose form approved for administration to the patient in line with the regulated product information. It also includes the reference to the associated PhPID set(s) and the ingredient(s) for the pharmaceutical product. Where applicable, the pharmaceutical product can also include information on a medical device, if it is an integral part of the Medicinal Product (e.g. scaffolding or net for a cell therapy Medicinal Product).

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
      <productOf>
        <reconstitution>
          <consumable>
            <adminstrableMaterial>
              <administrableProduct>
                <asSpecialisedKind><!-- Pharmaceutical Product -->
                <generalisedMaterialKind>
                  <code code="PhPID" codeSystem="PhPID Code System OID" .
```

9.9 Ingredient

This subclause specifies information on all the active ingredients, adjuvants and excipients present in the Medicinal Products.

9.10 Clinical particulars

This subclause specifies information about the clinical particulars of the Medicinal Product as described in line with the regulated product information.

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
      <consumedIn><!-- Clinical Particulars --></consumedIn>
```

The “document that supports the versioning” is the MPID/PCID-SPL document itself and its version tracking information is contained in the document header.

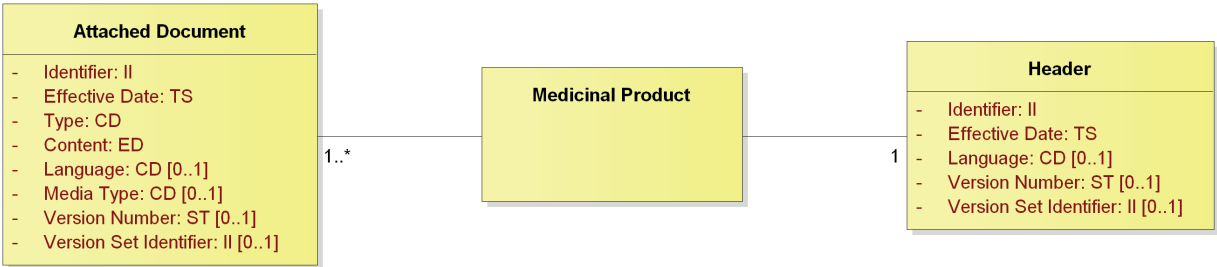


Figure 6 — Header/version for Medicinal Product

10 Investigational Medicinal Product Identifier (IMPID)

10.1 Conceptual overview of the information for an Investigational Medicinal Product

In addition to the primary identifiers described above, the main concepts modelled in [Figure 5](#) and described in the text below shall apply in order to identify and characterise an investigational Medicinal Product which is identified by the IMPID.

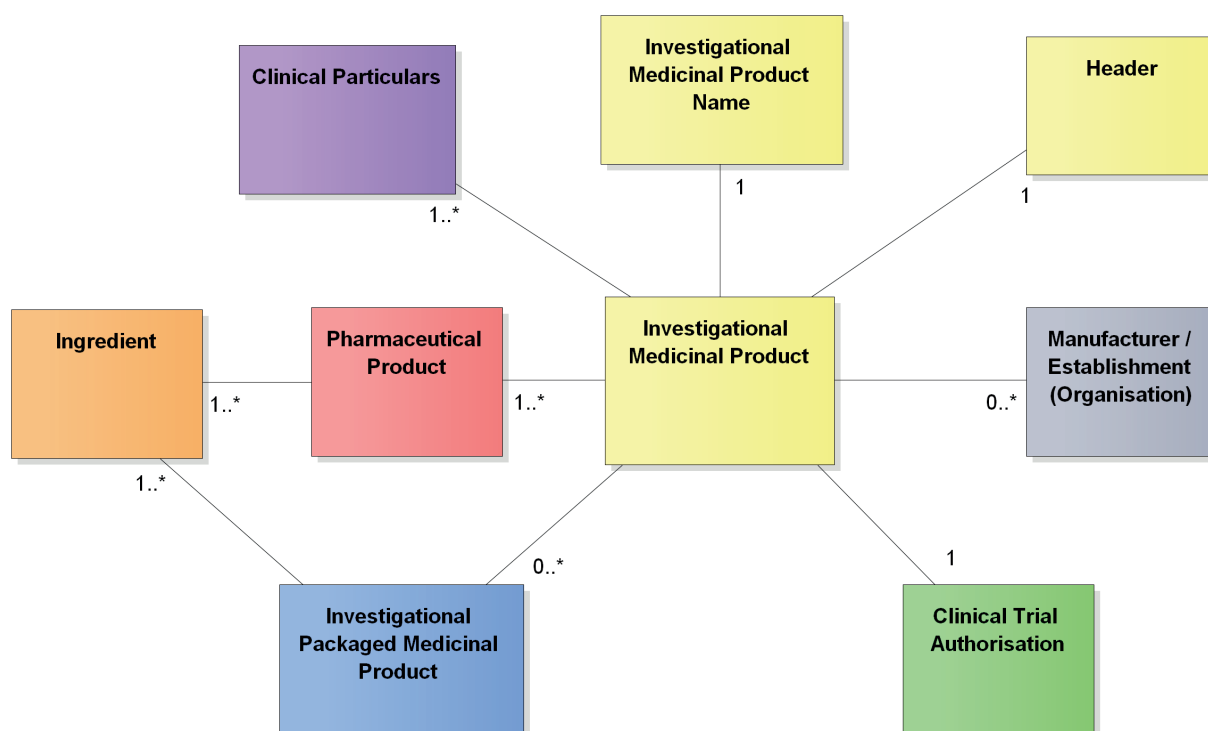


Figure 7 — Investigational Medicinal Product overarching model

```

<!-- SPL header -->
<document>
<!-- Version -->
<author>
  <assignedEntity>
    <representedOrganisation>
      <!-- Manufacturer/Establishment (Organisation) -->
    </representedOrganisation>
  </assignedEntity>
</author>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
  <manufacturedProduct><!-- Investigational Medicinal Product -->
    <code code="IMPID" codeSystem="IMPID Code System OID"/>
    <name><!-- Investigational Medicinal Product Name --></name>
    ...
    <asSpecialisedKind><!-- Pharmaceutical Product -->
      <generalisedMaterialKind>
        <code code="PhPID" codeSystem="PhPID Code System OID" .../>
      </generalisedMaterialKind>
    </asSpecialisedKind>
    ...
    <asContent><!-- Investigational Packaged Medicinal Product --></asContent>
  </manufacturedProduct>
  <subjectOf>
    <approval><!-- Clinical Trial Authorisation --></approval>
  </subjectOf>
  <consumedIn><!-- Clinical Particulars --><consumedIn>

```

## 10.2 Investigational Medicinal Product

This subclause specifies the IMPID together with the information that uniquely identifies and characterises an investigational Medicinal Product as authorised for investigation in a clinical trial by a medicines regulatory agency in a region.

```
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct><!-- Investigational Medicinal Product -->
<code code="IMPID" codeSystem="IMPID Code System OID"/>
```

## 10.3 Clinical trial authorisation

This subclause specifies the information about the clinical trial authorisation as issued by a medicines regulatory agency, which grants permission to a sponsor to place an investigational Medicinal Product into trial in a specific region.

NOTE Clinical trial authorisation holder and sponsor are considered synonymous.

```
<!-- SPL header -->
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct>
<!-- Investigational Medicinal Product -->
</manufacturedProduct>
<subjectOf>
<approval><!-- Clinical Trial Authorisation -->
```

## 10.4 Investigational Medicinal Product name

This subclause specifies the name of the Investigational Medicinal Product as given by a sponsor, together with an analysis of the name into various parts.

```
<!-- SPL header -->
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct><!-- Medicinal Product -->
<name><!-- Investigational Medicinal Product Name --></name>
```

## 10.5 Header

This subclause specifies the versioning of the core identifiers related to a Medicinal Product in a region, as well as the characteristics associated with the Medicinal Product and the documentation that supports the versioning.

## 10.6 Manufacturer/establishment (organisation)

This subclause specifies characteristics about the manufacturing and other associated operations and their authorisations as issued by a medicines regulatory agency, which grants permission to a

manufacturer/establishment to undertake manufacturing and other associated operations related to an investigational Medicinal Product in a specific region.

```
<!-- SPL header -->
<document>
  <!-- Version -->
  <author>
    <assignedEntity>
      <representedOrganisation>
        <!-- Manufacturer/Establishment (Organisation) -->
      </representedOrganisation>
    </assignedEntity>
  </author>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct><!-- Investigational Medicinal Product -->
```

## 10.7 Pharmaceutical product

This subclause specifies information about the investigational Medicinal Product in the dose form and route of administration(s) to be studied in line with the trial protocol. It also includes reference to the associated PhPID(s) and the ingredient(s) for the pharmaceutical product. Where applicable, the pharmaceutical product can also include information on a medical device, if it is an integral part of the investigational Medicinal Product.

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct><!-- Investigational Medicinal Product -->
      <asSpecialisedKind><!-- Pharmaceutical Product -->
      <generalisedMaterialKind>
        <code code="PhPID" codeSystem="PhPID Code System OID" .../>
```

## 10.8 Investigational Packaged Medicinal Product

This subclause specifies the information about the packaging and container(s) of an Investigational Medicinal Product and any associated device(s), which are an integral part or provided in combination with the investigational Medicinal Product, as supplied for a clinical trial. It also specifies the ingredient information for the manufactured item(s).

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct><!-- Investigational Medicinal Product -->
      <asContent><!-- Packaged Medicinal Product --></asContent>
      <asPartOfAssembly>
        <wholeProduct>
          <part><!-- associated device(s) used in combination --></part>
        </wholeProduct>
      </asPartOfAssembly>
      <part><!-- associated device(s) which are an integral part --></part>
```

10.9 Ingredient

This subclause specifies information on all the active ingredients, adjuvants and excipients present in the Medicinal Products.

10.10 Clinical particulars

This subclause specifies information about the clinical particulars of the Investigational Medicinal Product in line with the study protocol and the investigator’s brochure.

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...

  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct>
        <!-- Investigational Medicinal Product -->
      </manufacturedProduct>
    </consumedIn><!-- Clinical Particulars --></consumedIn>
```

The “document that supports the versioning” is the IMPID/SPL document itself and its version tracking information is contained in the document header.

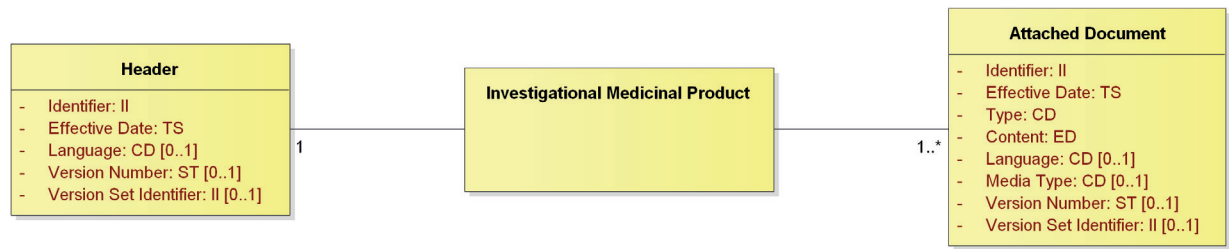


Figure 8 — Header/version for Investigational Medicinal Product

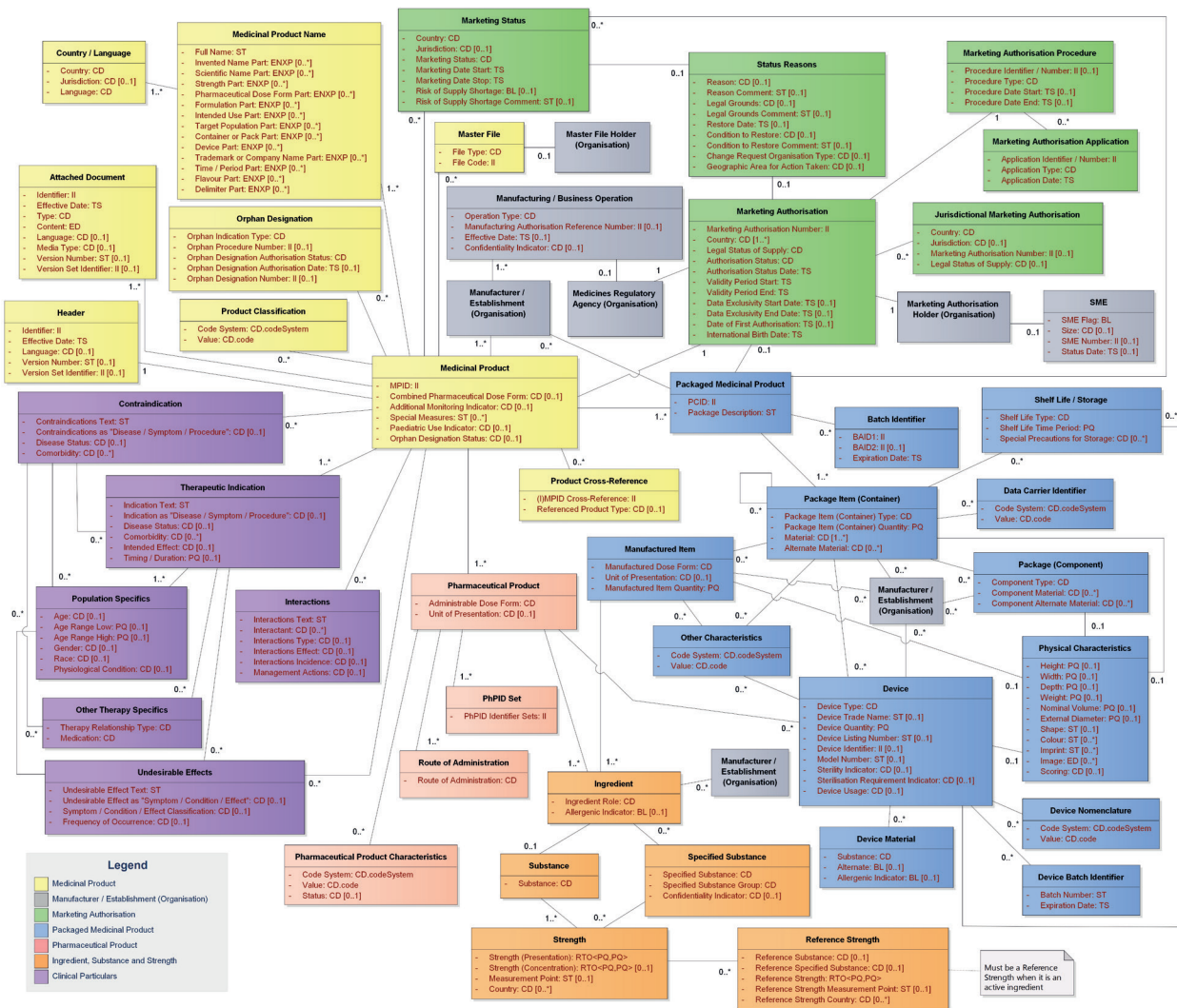


Figure 9 — Authorised Medicinal Products high level detailed diagram (full model)

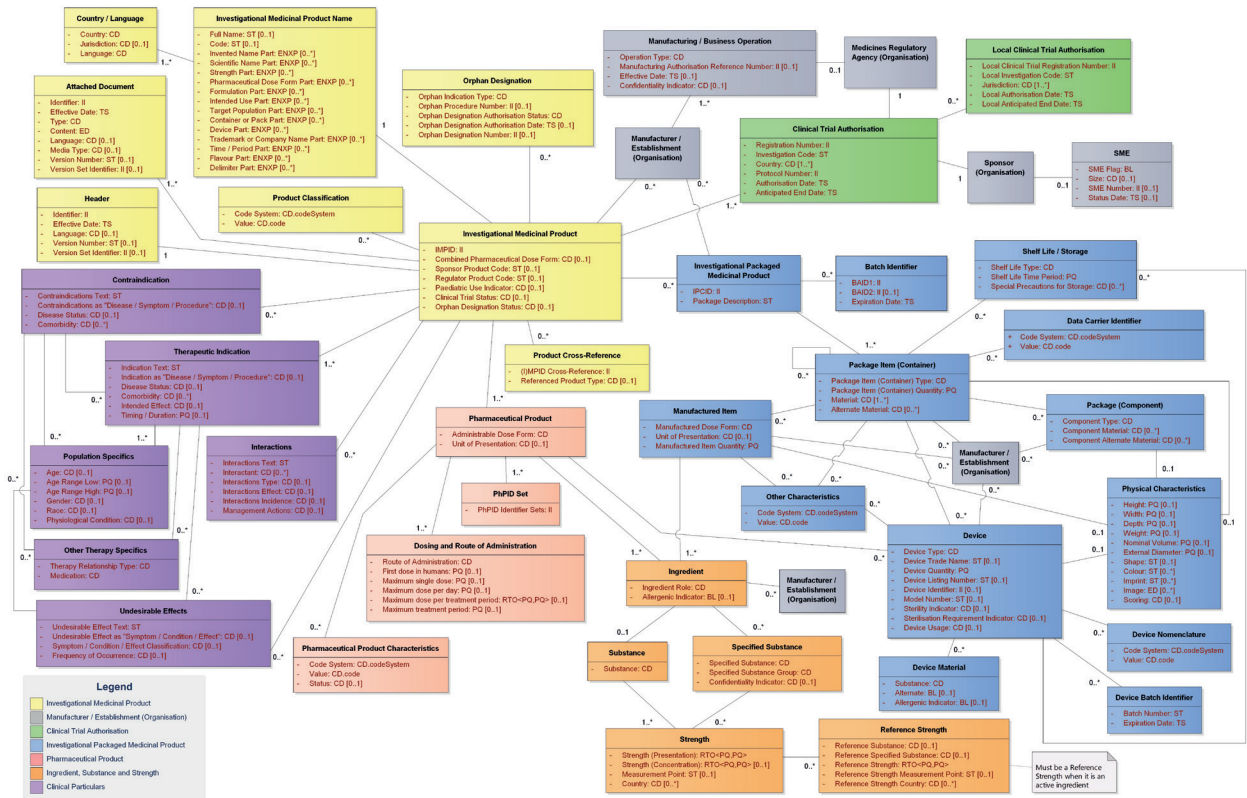


Figure 10 — Investigational Medicinal Products detailed diagram (full model)

## Annex A (normative)

### Medicinal Product

#### A.1 General

This annex specifies the MPID together with the information that uniquely identifies and characterises a Medicinal Product as authorised by a medicines regulatory agency in a region.

A Medicinal Product has a Medicinal Product name, may be applicable in one or more country/language combinations. During its life cycle, a Medicinal Product (MPID) has one or more versions based on its associated information and characteristics, which can change over time. One or more Medicinal Product classifications can be applied to the Medicinal Product.

NOTE A Medicinal Product may have more than one proprietary/non-proprietary name across regions. Multiple languages may also be applicable.

```
<!-- SPL header -->
<document>
  <!-- Version -->
  <component><structuredBody><component><section>...
    <subject>
      <!-- CPM body -->
      <manufacturedProduct>
        <manufacturedProduct><!-- Medicinal Product -->
        <code code="MPID" codeSystem="MPID Code System OID"/>
        <name><!-- Medicinal Product Name --></name>
        ...
      <asSpecialisedKind><!-- Product Classification -->
        <generalisedMaterialKind>
          <code code="Classification Code"
            codeSystem="Classification Code System OID" .../>
        </generalisedMaterialKind>
      </asSpecialisedKind>
```

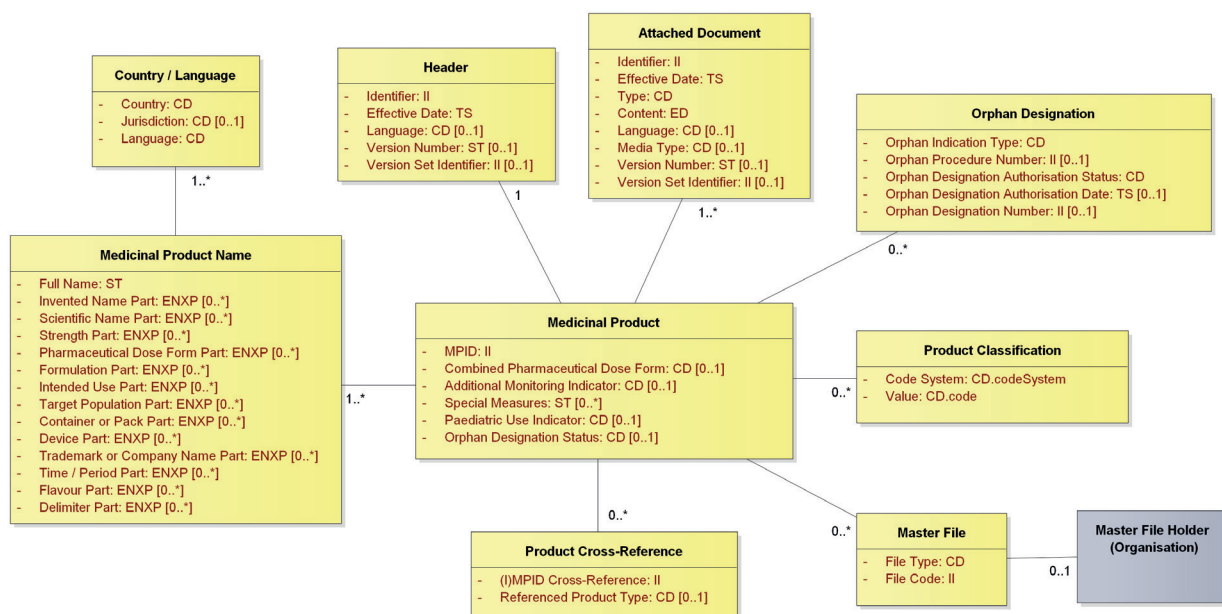


Figure A.1 — Medicinal product detailed description diagram

```

<!-- SPL header -->
<document>
  <!-- Header and Regulated Document -->
  <id root="Document (version) Identifier UUID"/>
  <code code="Document Type code" codeSystem="document type code system OID"
    displayName="document type name"/>
  <effectiveTime value="document (version) effective date"/>
  <setId root="document version-set identifier UUID"/>
  <versionNumber value="version number"/>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct><!-- Medicinal Product -->
        <code code="MPID" codeSystem="MPID Code System OID"/>
        <name><!-- Medicinal Product Name --></name>
        <formCode code="Combined Pharmaceutical Dose Form code"
          codeSystem="form code system" displayName="form name"/>
        <asSpecialisedKind><!-- Product Classification -->
          <generalisedMaterialKind>
            <code code="Classification System Value (Code)"
              codeSystem="Classification System OID" .../>
          </generalisedMaterialKind>
        </asSpecialisedKind>
      </manufacturedProduct>
    </subjectOf>
    <policy><!-- Additional Monitoring Indicator / Special Measures --></policy>
  
```

NOTE A Universal Unique Identifier (UUID) is a 128-bit number used to uniquely identify some object or entity.

## A.2 Medicinal Product

### A.2.1 General

This represents the Medicinal Product and its attributes as authorised by a medicines regulatory agency in a region and has the following attributes.

## A.2.2 MPID

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | <p>This is the MPID for the Medicinal Product, which always needs to be specified.</p> <p>For each authorised Medicinal Product, a unique MPID shall be assigned. The MPID should be allocated supplementary to any existing authorisation number as ascribed by a medicines regulatory agency in a region.</p> <p>The MPID should use a common segment pattern related to a Medicinal Product, which when each segment is valued should define a specific MPID concept. The pattern is:</p> <ul style="list-style-type: none"> <li>— country code segment (ISO 3166-1 alpha-2 code elements);</li> <li>— marketing authorisation holder (Organisation Identifier) code segment;</li> <li>— Medicinal Product code segment (Unique Medicinal Product Identifier).</li> </ul> <p>Any change of the values related to these three code segments should result in the assignment of a new MPID.</p> |
| <b>Conformance</b>   | Mandatory                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

```

<!-- SPL header -->
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct><!-- Medicinal Product -->
<code code="MPID" codeSystem="MPID Code System OID"/>

```

## A.2.3 Combined pharmaceutical dose form

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | <p>The combined pharmaceutical dose form is a single term to describe two or more manufactured items that are intended to be combined in a specific way, to produce a single pharmaceutical product. It includes information on the manufactured dose form of each manufactured item and the administrable dose form of the pharmaceutical product. If the Medicinal Product requires description of a combined pharmaceutical dose form, it can be specified here using a term and a term identifier as defined in ISO 11239 and ISO/TS 20440 and the resulting terminology shall be specified.</p> <p>NOTE This element consists of a "Display Name" and "Code" as represented in the XML instance below.</p> |
| <b>Conformance</b>   | Conditional                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

```

<!-- SPL header -->
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct><!-- Medicinal Product -->
<code code="MPID" codeSystem="MPID Code System OID"/>
<formCode code="Combined Pharmaceutical Dose Form code"
codeSystem="form code system" displayName="form name"/>

```

```

<!-- SPL header -->
<document>
<component><structuredBody><component><section>...
  <subject>

    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct><!-- Medicinal Product -->
        <code code="MPID#1" codeSystem="MPID Code System OID"/>
        <formCode code="Dose Form code"
          codeSystem="form code system" displayName="KIT"/>
        <part><!--(i) a powder for solution for injection-->
          <partProduct>
            <formCode code="Dose Form code" codeSystem="form code system OID"
              displayName="POWDER FOR SOLUTION FOR INJECTION"/>
          </partProduct>
        </part>
        <part><!--(ii) solvent for solution for injection -->
          <partProduct>
            <formCode code="Dose Form code" codeSystem="form code system OID"
              displayName="SOLVENT FOR SOLUTION FOR INJECTION"/>
          </partProduct>
        </part>
      </manufacturedProduct>
    </manufacturedProduct>
  </subject>

```

Once the Medicinal Product containing the two manufactured items has been fully specified, a term code for combined dose form shall be specified, representing the dose forms of the manufactured items prior to preparation. The pharmaceutical product that is prepared (reconstituted) from the two manufactured items), can be specified as follows.

```

<subject>
<!-- CPM body -->
<manufacturedProduct>
  <manufacturedProduct><!-- Pharmaceutical Product -->
    <formCode code="Dose Form code" codeSystem="form code system OID"
      displayName="POWDER AND SOLVENT FOR SOLUTION FOR INJECTION"/>
    <asSpecialisedKind><!-- Pharmaceutical Product -->
      <generalisedMaterialKind>
        <code code="PhPID" codeSystem="PhPID Code System OID" .../>
      </generalisedMaterialKind>
    </asSpecialisedKind>
  </manufacturedProduct>
<productOf>
  <reconstitution>
    <consumable>
      <manufacturedProduct>
        <code code="MPID#1" codeSystem="MPID Code System OID"/>
      </manufacturedProduct>
    </consumable>
  </reconstitution>
</productOf>

```

#### A.2.4 Additional monitoring indicator

|                      |                                                                                                                                           |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | If the Medicinal Product is subject to additional monitoring, it shall be specified. The term and the term identifier shall be specified. |
| <b>Conformance</b>   | Conditional                                                                                                                               |

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
    <subject>
      <!-- CPM body -->
      <manufacturedProduct>
        <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
        <subjectOf>
          <policy>
            <code code="Additional Monitoring Indicator" codeSystem="code system OID"
              displayName="Additional Monitoring name"/>
          </policy>
```

Example for “black triangle monitoring”:

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
    <subject>
      <!-- CPM body -->
      <manufacturedProduct>
        <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
        <subjectOf>
          <policy>
            <code code="Code for 'black triangle monitoring'" codeSystem="code system OID"
              displayName="BLACK TRIANGLE MONITORING"/>
          </policy>
```

A.2.5 Special measures

|               |                                                                                       |
|---------------|---------------------------------------------------------------------------------------|
| User guidance | If the Medicinal Product is subject specific special measures, it shall be specified. |
| Conformance   | Conditional                                                                           |

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
    <subject>
      <!-- CPM body -->
      <manufacturedProduct>
        <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
        <subjectOf>
          <policy><!-- Special measures is an uncoded string, so can use an "uncoded" code and the displayName -->
            <code nullFlavor="OTH" codeSystem="code system OID"
              displayName="Special Measures"/>
          </policy>
```

Example, for “post-authorisation studies required”:

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
      <subjectOf>
        <policy>
          <code code="Code for 'post-authorisation studies required'"
            codeSystem="code system OID"
            displayName="POST-AUTHORISATION STUDIES REQUIRED"/>
        </policy>
```

## A.2.6 Paediatric use indicator

|                      |                                                                                                                                    |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | If the Medicinal Product is subject to paediatric use, it shall be specified. The term and the term identifier shall be specified. |
| <b>Conformance</b>   | Conditional                                                                                                                        |

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
      <subjectOf>
        <policy>
          <code code="Paediatric Use Indicator" codeSystem="code system OID"
            displayName="Paediatric Use"/>
        </policy>
```

## A.2.7 Orphan designation status

|                      |                                                                                                                                                   |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The class should capture information necessary after identifying the product authorised in a region is qualified to be treated as an orphan drug. |
| <b>Conformance</b>   | Optional                                                                                                                                          |

Category is optional with conformance within the category applicable to regions who shall implement orphan designation.

```
<!-- SPL header -->
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct>
<!-- Medicinal Product -->
</manufacturedProduct>
<consumedIn><!-- Clinical Particulars -->
<substanceAdministration1>
<reason classCode="Orphan Indication Type"><!-- Indication --></reason>
<subjectOf>
<approval><!-- Orphan Designation -->
<id extension="Orphan designation number"
root="Orphan designation number system OID"/>
<code code="Orphan designation procedure number (code)"
codeSystem="Orphan designation procedure code system OID"
displayName="Orphan designation procedure display text"/>
<statusCode code="Orphan designation status"/>
<effectiveTime value="Orphan designation authorisation date"/>
</approval>
</subjectOf>
```

## A.2.8 Orphan designation

|                      |                                                                                                                                                                                                                                        |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The class is utilised to identify whether a product authorised in a region is qualified to be treated as an orphan drug (i.e. product includes an orphan designated indication). There could be multiple orphan designations per MPID. |
| <b>Conformance</b>   | Conditional                                                                                                                                                                                                                            |

An orphan drug designation is against a specific indication because the same existing product may serve as a potential treatment against an indication with hardly any other treatment options. The orphan drug designation is located in the clinical particulars.

```
<!-- SPL header -->
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct>
<!-- Medicinal Product -->
</manufacturedProduct>
<consumedIn>
<substanceAdministration1>
<reason typeCode="Orphan Indication Type"><!-- Indication --></reason>
<precondition><!-- Population Specifics --></precondition>
<subjectOf>
<approval><!-- Orphan Designation --></approval>
</subjectOf>
```

### A.2.8.1 Orphan indication type

|                      |                                                       |
|----------------------|-------------------------------------------------------|
| <b>User guidance</b> | The type of the orphan indication should be captured. |
| <b>Conformance</b>   | Mandatory                                             |

```

<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct>
        <!-- Medicinal Product -->
      </manufacturedProduct>
    <consumedIn><!-- Clinical Particulars -->
    <substanceAdministration1>
      <reason classCode="Orphan Indication Type Code"><!-- Indication --></reason>
      <precondition><!-- Population Specifics --></precondition>
      <subjectOf>
        <approval><!-- Orphan Designation -->
          <id extension="Orphan designation number"
            root="Orphan designation number system OID"/>
          <code code="Orphan designation procedure number (code)"
            codeSystem="Orphan designation procedure code system OID"
            displayName="Orphan designation procedure display text"/>
        </approval>
      </subjectOf>

```

NOTE Orphan indication type codes are: PRYLX – prophylaxis, TREAT – treatment, DIAG – diagnostic.

#### A.2.8.2 Orphan procedure number

|                      |                                                                        |
|----------------------|------------------------------------------------------------------------|
| <b>User guidance</b> | Procedure number for the orphan designation authorisation application. |
| <b>Conformance</b>   | Conditional                                                            |

```

<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct>
        <!-- Medicinal Product -->
      </manufacturedProduct>
    <consumedIn><!-- Clinical Particulars -->
    <substanceAdministration1>
      <reason classCode="Orphan Indication Type Code"><!-- Indication --></reason>
      <precondition><!-- Population Specifics --></precondition>
      <subjectOf>
        <approval><!-- Orphan Designation -->
          <id extension="Orphan designation number"
            root="Orphan designation number system OID"/>
          <code code="Orphan designation procedure number (code)"
            codeSystem="Orphan designation procedure code system OID"
            displayName="Orphan designation procedure display text"/>
        </approval>
      </subjectOf>

```

#### A.2.8.3 Orphan designation authorisation status

|                      |                                                                                                                                        |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The element is required for orphan medicines and initial MA/post-authorisation processes (Granted, Pending, Expired, Withdrawn, etc.). |
| <b>Conformance</b>   | Mandatory                                                                                                                              |

```

<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct>
        <!-- Medicinal Product -->
      </manufacturedProduct>
    <consumedIn>
      <substanceAdministration1>
        <reason classCode="Orphan Indication Type"><!-- Indication --></reason>
        <subjectOf>
          <approval><!-- Orphan Designation -->
            <id extension="Orphan designation number" root="Orphan designation number system OID"/>
            <code code="Orphan designation procedure number (code)"
              codeSystem="Orphan designation procedure code system OID"
              displayName="Orphan designation procedure display text"/>
          </approval>
          <subjectOf>
            <characteristic>
              <code code="Orphan designation status Characteristic Code" codeSystem="Code System (OID)"/>
              <value xsi:type="CV" code="Orphan designation status" codeSystem="Code System (OID)"/> ...
            </subjectOf>
          </subjectOf>
        </subjectOf>
      </subjectOf>
    </consumedIn>
  </subject>
</component>
</structuredBody>
</document>

```

#### A.2.8.4 Orphan designation authorisation date

|                      |                                                                                                                                             |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | Date issued by the authorities for orphan designation. This element is required if a positive decision on the orphan designation is issued. |
| <b>Conformance</b>   | Conditional                                                                                                                                 |

```

<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct>
        <!-- Medicinal Product -->
      </manufacturedProduct>
    <consumedIn><!-- Clinical Particulars -->
      <substanceAdministration1>
        <reason classCode="Orphan Indication Type"><!-- Indication --></reason>
        <precondition><!-- Population Specifics --></precondition>
        <subjectOf>
          <approval><!-- Orphan Designation -->
            <id extension="Orphan designation number"
              root="Orphan designation number system OID"/>
            <code code="Orphan designation procedure number (code)"
              codeSystem="Orphan designation procedure code system OID"
              displayName="Orphan designation procedure display text"/>
          </approval>
        </subjectOf>
      </consumedIn>
    </subject>
  </component>
</structuredBody>
</document>

```

#### A.2.8.5 Orphan designation number

|                      |                                                          |
|----------------------|----------------------------------------------------------|
| <b>User guidance</b> | Number issued by the authorities for orphan designation. |
| <b>Conformance</b>   | Conditional                                              |

```

<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct>
        <!-- Medicinal Product -->
      </manufacturedProduct>
    <consumedIn><!-- Clinical Particulars -->
    <substanceAdministration1>
      <reason classCode="Orphan Indication Type"><!-- Indication --></reason>
      <precondition><!-- Population Specifics --></precondition>
    <subjectOf>
      <approval><!-- Orphan Designation -->
      <id extension="Orphan designation number"
        root="Orphan designation number system OID"/>

```

## A.2.9 Product classification

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | <p>The Medicinal Product can be classified according to various classification systems, which may be regional, jurisdictional or international. The various classifications of the product can be specified in this subclause.</p> <p>The classification system can be specified using an appropriate identification system. The term and term identifier shall be specified.</p> <p>The individual value that applies to the Medicinal Product shall be specified using a term and a term identifier from the classification system.</p> |
| <b>Conformance</b>   | Optional                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

| Classification system name                                      | OID                        |
|-----------------------------------------------------------------|----------------------------|
| WHO Anatomical Therapeutic Chemical (ATC) Classification System | 2.16.840.1.113883.6.73     |
| WHO National Drug File - Reference Terminology (NDF-RT)         | 2.16.840.1.113883.3.26.1.5 |

```

<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
  <subject>
    <!-- CPM body -->
    <manufacturedProduct>
      <manufacturedProduct><!-- Medicinal Product -->
      <asSpecialisedKind><!-- Product Classification -->
      <generalisedMaterialKind>
        <code code="Classification Value (Code)"
          codeSystem="Classification System OID" .../>

```

```

<!-- SPL header -->
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct><!-- Medicinal Product -->
<asSpecialisedKind><!-- Product Classification WHO ATC -->
<generalisedMaterialKind>
<code code="J07BB02" displayName="Metformin"
codeSystem="2.16.840.1.113883.6.73"/>
</generalisedMaterialKind>
</asSpecialisedKind>
<asSpecialisedKind><!-- Product Classification NDF-RT -->
<generalisedMaterialKind>
<code code="N0000000072" displayName="14-alpha Demethylase Inhibitor"
codeSystem="2.16.840.1.113883.3.26.1.5"/>

```

### A.2.9.1 Code system

|                      |                                                                                                                                                                               |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | This refers to the system used for the classification of the Medicinal Product. It may include global classification (e.g. WHO ATC Code) as well as regional classifications. |
| <b>Conformance</b>   | Mandatory                                                                                                                                                                     |

```

<!-- SPL header -->
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct><!-- Medicinal Product -->
<asSpecialisedKind><!-- Product Classification -->
<generalisedMaterialKind>
<code code="Classification Value (Code)"
codeSystem="Classification System OID" .../>

```

### A.2.9.2 Value

|                      |                                  |
|----------------------|----------------------------------|
| <b>User guidance</b> | The value of the classification. |
| <b>Conformance</b>   | Mandatory                        |

```

<!-- SPL header -->
<document>
<component><structuredBody><component><section>...
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct><!-- Medicinal Product -->
<asSpecialisedKind><!-- Product Classification -->
<generalisedMaterialKind>
<code code="Classification Value (Code)"
displayName="Classification Value (Display Name)"
codeSystem="Classification System OID" .../>

```

**A.2.10 Master file**

|                      |                                                                                          |
|----------------------|------------------------------------------------------------------------------------------|
| <b>User guidance</b> | This class is used to identify any type of master file related to the Medicinal Product. |
| <b>Conformance</b>   | Conditional                                                                              |

EXAMPLE The Pharmacovigilance System Master File (PSMF).

**A.2.10.1 File type**

|                      |                                                                                                                      |
|----------------------|----------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | This attribute is to define which kind of master file is indicated.<br>EXAMPLE Pharmacovigilance System Master File. |
| <b>Conformance</b>   | Mandatory                                                                                                            |

**A.2.10.2 File code**

|                      |                                                                                  |
|----------------------|----------------------------------------------------------------------------------|
| <b>User guidance</b> | This attribute is the identifier/code assigned to the master file as applicable. |
| <b>Conformance</b>   | Mandatory                                                                        |

**A.2.11 Master file holder (organisation)**

|                      |                                                                                       |
|----------------------|---------------------------------------------------------------------------------------|
| <b>User guidance</b> | This attribute is to define the organisation/entity responsible for a master file(s). |
| <b>Conformance</b>   | Conditional                                                                           |

**A.2.12 Product cross-reference**

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | Where an authorised Medicinal Product is subject to investigation in a clinical trial but is used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, it shall be specified as an Investigational Medicinal Product based on the characteristics described in this subclause. In addition, an authorised Medicinal Product subject to an investigation in a clinical trial in its authorised form shall be specified per its assigned MPID. Furthermore, an authorised Medicinal Product may be cross-referenced to another authorised Medicinal Product. |
| <b>Conformance</b>   | Conditional                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

```
<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct><!-- Medicinal Product -->
<asEquivalentEntity classCode="EQUIV">
<code code="Code meaning 'Cross Referenced Product'"
codeSystem="Code System (OID)"/>
<definingMaterialKind>
<code code="MPID" codeSystem="MPID System (OID)"/>
```

## A.2.12.1 (I)MPID cross-reference

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | <p>There can be a cross-reference between the MPID(s) of the authorised Medicinal Product(s) and the related IMPID(s) of an investigational Medicinal Product(s) assigned during the development phase and clinical investigation of that Medicinal Product. In addition, there may be references between authorised Medicinal Products and associated corresponding identifiers. The related Medicinal Products, and investigational Medicinal Products can be specified with their corresponding identifiers.</p> <p>Where an authorised Medicinal Product is subject to investigation in a clinical trial but is used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, it shall be specified as an Investigational Medicinal Product based on the characteristics described in this subclause.</p> <p>A cross reference to the MPID of the authorised Medicinal Product shall be included for reference purposes.</p> <p>NOTE There may be occasions where more than one MPID is cross-referenced, if an IMPID is representing a new therapeutic regimen.</p> |
| <b>Conformance</b>   | Mandatory                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

```

<subject>
<!-- CPM body -->
<manufacturedProduct>
<manufacturedProduct><!-- Medicinal Product -->
<asEquivalentEntity classCode="EQUIV">
  <code code="Code meaning 'Investigational Predecessor/Prototype Product'"
    codeSystem="Code System (OID)"/>
  <definingMaterialKind>
    <code code="IMPID" codeSystem="IMPID System (OID)"/>

```

## A.2.12.2 Referenced product type

|                      |                                                                                                                                                                                                                                                                                       |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | Reference product is a Medicinal Product that is not yet authorised in a region or is a Medicinal Product authorised within a region but utilised in a different manner (e.g. unauthorised indication) for investigational purposes. Can also be reference from generic to innovator. |
| <b>Conformance</b>   | Conditional                                                                                                                                                                                                                                                                           |

### A.2.13 Medicinal product name

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | <p>The Medicinal Product Name is one of the defining characteristics of a Medicinal Product and its MPID. There may be more than one Medicinal Product Name for a Medicinal Product instance.</p> <p>A Medicinal Product may have more than one proprietary/non-proprietary name across jurisdictions. Multiple languages may also be applicable per jurisdictional requirements.</p> <p>The convention applied for naming a Medicinal Product can differ between medicines regulatory agencies within regions. As a general principle, a marketing authorisation is granted to a single marketing authorisation holder who is responsible for placing the Medicinal Product on the market. The marketing authorisation contains the name of the Medicinal Product, which can refer to, for example, a single invented name or a scientific name [when available, the International Non-Proprietary Name (INN) of the active substance(s)] accompanied by a trademark or other characteristics).</p> <p>Other characteristics of the name can refer to strength, pharmaceutical form, intended usage or an administration device, etc.</p> <p>In addition to the complete Medicinal Product name as authorised, an analysis of the name parts may be provided in a structured format. Depending on the jurisdiction, the Medicinal Product name may be specified in all official languages that apply.</p> <p>SPL represents name parts by marking out the parts within the full name. Each name part, when utilised, shall contain a string that appears in the full Medicinal Product name. The examples for each of the name parts in sections below assume such a usage (Example A). When a representation of the name parts shall not correspond to the full Medicinal Product name within a given region, a different SPL representation shall be utilised to accommodate this variance (Example B).</p> |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                    | <p>EXAMPLE A Single SPL name represents the full name and corresponding parts—two name parts in addition to the full name with both name part strings represented verbatim within the full name:</p> <p>Full Name: “Drug XYZ Precisehaler 200 mg”<br/> Pharmaceutical Dose Form Part: “Precisehaler”<br/> Strength Part: “200 mg”</p> <pre>&lt;name&gt;Drug XYZ &lt; suffix qualifier = "FRM" &gt; Precisehaler&lt;/suffix&gt; &lt;suffix qualifier="STR"&gt; 200 mg&lt;/suffix&gt;&lt;/name&gt;</pre> <p>EXAMPLE B Full Medicinal Product name not represented within the name parts:</p> <p>Full Name: “Drug XYZ Precisehaler 200 mg”<br/> Pharmaceutical Dose Form Part: “Precision inhaler”<br/> Strength Part: “200 milligrams”</p> <pre>&lt;!--first the full name on its own --&gt; &lt;name&gt;Drug XYZ Precisehaler 200 mg&lt;/name&gt; &lt;!--secondly all the name parts, on their own --&gt; &lt;name use = "SRCH"&gt;   &lt;suffix qualifier="FRM"&gt; Precision inhaler&lt;/suffix&gt;   &lt;suffix qualifier="STR"&gt; 200 mg&lt;/suffix&gt; &lt;/name&gt;</pre> <p>Example B shall also be used when the full Medicinal Product name is in the form “Drug XYZ (nameA 200 mg, nameB 25 mg)”, but the Strength Part is expected as a single string such as “200 mg, 25 mg”.</p> <p>Regional guidance/implementation shall determine the applicable Medicinal Product name representation to be utilised per their requirements.</p> |
| <b>Conformance</b> | Mandatory                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

#### A.2.13.1 Full name

|                      |                                                                                                                                  |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The complete Medicinal Product name as approved by the medicines regulatory agency in a jurisdiction shall be specified as text. |
| <b>Conformance</b>   | Mandatory                                                                                                                        |

```
<!-- SPL header -->
<document>
  <component><structuredBody><component><section>...
    <subject>
      <!-- CPM body -->
      <manufacturedProduct>
        <manufacturedProduct><!-- Medicinal Product -->
          <name><!-- Medicinal Product Name --></name>
```

The main brand name, or generic name is provided without name part tags. Additional name parts may be added as prefixes or suffixes to the main name. The suffixes may have the qualifier attribute to specify what the purpose of the name part is:

#### EXAMPLES:

```
<name>Hypostat<suffix> ER</suffix></name>
<name>Hypostat<suffix qualifier="FRM"> ER</suffix></name>
<name><prefix qualifier="POPUL">Children's </prefix>Tylenol</name>
```

The name part qualifiers are as follows.

| Code   | Qualifier meaning                                                      |
|--------|------------------------------------------------------------------------|
| CON    | Container name                                                         |
| DEV    | Device name                                                            |
| FLAV   | Flavour name, e.g. "mint"                                              |
| FORMUL | Formulation, e.g. "sugar free"                                         |
| FRM    | Form name, e.g. "capsil"                                               |
| POPUL  | Target population, e.g. "children's"                                   |
| SCI    | Scientific (generic) name                                              |
| STR    | Strength name, e.g. "extra strong"                                     |
| TIME   | For the period used in the name, e.g. flu shot for "2016/2017 season". |
| TMK    | Company name in name, e.g. the "Drug Co." in "Ranitidine Drug Co."     |
| USE    | Indication and use, e.g. "pain relief"                                 |

### A.2.13.2 Invented name part

|                      |                                                                                                                                                                                                        |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The invented name (i.e. trade name) of the Medicinal Product without e.g. the trademark or any other descriptors reflected in the Medicinal Product name shall be specified as text, where applicable. |
| <b>Conformance</b>   | Conditional                                                                                                                                                                                            |

The invented name part is provided without name part tags.

```
<name>Drug XYZ<suffix>®</suffix>
<suffix qualifier="FRM"> Precisehaler</suffix>
<suffix qualifier="STR"> 200 mg</suffix>
</name>
```

### A.2.13.3 Scientific name part

|                      |                                                                                                                                                 |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The scientific or common (i.e. generic) name of the Medicinal Product without any other descriptors can be specified as text, where applicable. |
| <b>Conformance</b>   | Conditional                                                                                                                                     |

EXAMPLE 1:

```
<name>Ben-u-ron
<suffix qualifier="SCI"> Paracetamol</suffix>
```

EXAMPLE 2:

```
<name>Irbesartan/Hydrochlorothiazide
<suffix qualifier="TMK"> Pharma KK</suffix>
</name>
```

## A.2.13.4 Strength part

|                      |                                                                                                                                                                                                                                                                                   |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The strength, if reflected in the Medicinal Product name, shall be specified as text, where applicable. This strength name part can differ from the concept of “strength” as described in <a href="#">Annex F</a> . The use of decimal points shall be accommodated, if required. |
| <b>Conformance</b>   | Conditional                                                                                                                                                                                                                                                                       |

**EXAMPLE** For the Medicinal Product Medicinal Product name “Drug K Forte (paracetamol 500 mg, dihydrocodeine tartrate 30 mg)”, the strength name parts are “Forte”, “500 mg”, and “30 mg”. This example demonstrates how to insert the special suffix tag <delimiter> which might span multiple suffixes.

```
<name>Drug K
<suffix qualifier="STR"> Forte</suffix>
<delimiter> (</delimiter>
<suffix qualifier="SCI"> Paracetamol</suffix>
<suffix qualifier="STR"> 500 mg</suffix>
<delimiter>, </delimiter>
<suffix qualifier="SCI"> dihydrocodeine tartrate</suffix>
<suffix qualifier="STR"> 30 mg</suffix>
<delimiter>)</delimiter>
</name>
```

## A.2.13.5 Pharmaceutical dose form part

|                      |                                                                                                                                                                                                                                                                                                                                        |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The pharmaceutical dose form, if reflected in the Medicinal Product name, should be specified as text, where applicable. This pharmaceutical dose form name part can differ from the concept of administrable dose form and manufactured dose form as described in <a href="#">Annex E</a> and <a href="#">Annex C</a> , respectively. |
| <b>Conformance</b>   | Conditional                                                                                                                                                                                                                                                                                                                            |

```
<name>Novo-DrugX
<suffix qualifier="FRM"> EASY TO SWALLOW CAPLETS</suffix>
</name>
```

## A.2.13.6 Formulation part

|                      |                                                                                                            |
|----------------------|------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The formulation, if reflected in the Medicinal Product name, shall be specified as text, where applicable. |
| <b>Conformance</b>   | Conditional                                                                                                |

```
<name>SpecialMed
<suffix qualifier="FORMUL"> Sugar Free</suffix>
<suffix qualifier="USE"> Cough</suffix>
<suffix qualifier="FRM"> Syrup</suffix>
</name>
```

## A.2.13.7 Intended use part

|                      |                                                                                                             |
|----------------------|-------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The intended use, if reflected in the Medicinal Product name, shall be specified as text, where applicable. |
| <b>Conformance</b>   | Conditional                                                                                                 |

```

<name>Drug-BI
<suffix qualifier="FRM"> Caplets</suffix>
<delimiter> - </delimiter>
<suffix qualifier="USE"> Heartburn Relief</suffix>
</name>

```

#### A.2.13.8 Target population part

|                      |                                                                                                                  |
|----------------------|------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The target population, if reflected in the Medicinal Product name, shall be specified as text, where applicable. |
| <b>Conformance</b>   | Conditional                                                                                                      |

```

<name>Broncho-Drug
<suffix qualifier="STR"> 3.5 mg</suffix>
<delimiter> -</delimiter>
<suffix qualifier="FRM"> capsules</suffix>
<suffix qualifier="POPUL"> for children</suffix>
</name>

```

#### A.2.13.9 Container or pack part

|                      |                                                                                                                  |
|----------------------|------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The container or pack, if reflected in the Medicinal Product name, shall be specified as text, where applicable. |
| <b>Conformance</b>   | Conditional                                                                                                      |

#### EXAMPLE 1

```

<name>LXA
<delimiter> - </delimiter>
<suffix qualifier="STR"> 10 mg/ ml</suffix>
<delimiter> -</delimiter>
<suffix qualifier="FRM"> Solution for injection</suffix>
<suffix qualifier="USE"> Subcutaneous use</suffix>
<delimiter> -</delimiter>
<suffix qualifier="CON"> Vial (glass) - 4 ml - 1 Vial</suffix>
</name>

```

#### EXAMPLE 2

```

<name>HeartDrug
<suffix qualifier="CON"> Titration Pack</suffix>
</name>

```

#### EXAMPLE 3

```

<name>BugVac
<suffix qualifier="CON"> Multidose Vial</suffix>
</name>

```

#### A.2.13.10 Device part

|                      |                                                                                                       |
|----------------------|-------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The device, if reflected in the Medicinal Product name, shall be specified as text, where applicable. |
| <b>Conformance</b>   | Conditional                                                                                           |

```
<name>LXA Drug XYZ<suffix>®</suffix>
<suffix qualifier="STR"> 200 mg</suffix>
<suffix qualifier="POPUL"> for adults</suffix>
</name>
```

#### A.2.13.11 Trademark or company name part

|                      |                                                                                                          |
|----------------------|----------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The trademark, if reflected in the Medicinal Product name, shall be specified as text, where applicable. |
| <b>Conformance</b>   | Conditional                                                                                              |

```
<name>Clopidrogel
<suffix qualifier="TMK"> Nimbopharm</suffix><suffix>®</suffix>
</name>
```

#### A.2.13.12 Time/period part

|                      |                                                                                                            |
|----------------------|------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The time/period, if reflected in the Medicinal Product name, shall be specified as text, where applicable. |
| <b>Conformance</b>   | Conditional                                                                                                |

```
<name>Drug-FLU
<suffix qualifier="TIME"> season 2016/2017</suffix>
</name>
```

#### A.2.13.13 Flavour part

|                      |                                                                                                                                              |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The flavour, if reflected in the Medicinal Product name, shall be specified as text, where applicable.<br>Example: Add example from standard |
| <b>Conformance</b>   | Conditional                                                                                                                                  |

```
<name>CoughCure
<suffix qualifier="FRM"> Linctus</suffix>
<suffix qualifier="FLV"> Orange Flavour</suffix>
</name>
```

#### A.2.13.14 Delimiter part

|                      |                                                                                                             |
|----------------------|-------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | A delimiter separates one composite in a segment from another, or separates one sub-composite from another. |
| <b>Conformance</b>   | Conditional                                                                                                 |

EXAMPLE Amoxan (Amoxicillin 500 mg and Clavulanic acid 125 mg) tablets.

```

<name>Amoxan
  <delimiter>(</delimiter>
  <suffix qualifier="SCI">Amoxicillin</suffix>
  <suffix qualifier="STR">500 mg</suffix>
  <delimiter>and</delimiter>
  <suffix qualifier="SCI">Clavulanic acid</suffix>
  <suffix qualifier="STR">125 mg</suffix>
  <delimiter>)</delimiter>
  <suffix qualifier="FRM">Tablets</suffix>
</name>

```

### A.2.14 Country/language

|                      |                                                                                                                                                                         |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The country and optionally the region where the Medicinal Product name of a Medicinal Product is authorised should be specified in the official language as applicable. |
| <b>Conformance</b>   | Mandatory                                                                                                                                                               |

To mark names as specifically country or jurisdiction dependent, use an asNamedEntity structure as shown in the next two examples below.

#### A.2.14.1 Country

|                      |                                                                                                                |
|----------------------|----------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The country where the Medicinal Product name is applicable should be described using ISO 3166-1 alpha-2 codes. |
| <b>Conformance</b>   | Mandatory                                                                                                      |

```

<manufacturedProduct>
  <name xml:lang="en">CoughCure</name>
  <asNamedEntity>
    <name xml:lang="en">CoughCure</name>
    <assigningTerritory>
      <code code="US" codeSystem="2.16.840.1.113883.5.28"/>
    </assigningTerritory>
  </asNamedEntity>
  <asNamedEntity>
    <name xml:lang="de">HustenFix</name>
    <assigningTerritory>
      <code code="DE" codeSystem="2.16.840.1.113883.5.28"/>
    </assigningTerritory>
  </asNamedEntity>
  <asNamedEntity>
    <name xml:lang="de">HusteFix</name>
    <assigningTerritory>
      <code code="AU" codeSystem="2.16.840.1.113883.5.28"/>
    </assigningTerritory>
  </asNamedEntity>
</manufacturedProduct>

```

#### A.2.14.2 Jurisdiction

|                      |                                                                                                                                                                                                                  |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The jurisdiction within the country where the Medicinal Product name is applicable can be described. The controlled term and the controlled term identifier shall be specified, when jurisdiction is applicable. |
| <b>Conformance</b>   | Conditional                                                                                                                                                                                                      |

A jurisdiction, being a territory within a country/region would be identically structured as country with the exception that the code and code system utilised shall represent the jurisdiction.

```
<manufacturedProduct>
  <name xml:lang="en">CoughCure</name>
  <asNamedEntity>
    <name xml:lang="en">CoughCure</name>
    <assigningTerritory>
      <code code="ON" codeSystem="jurisdiction code system OID"/>
      <name>Ontario </name>
    </assigningTerritory>
  </asNamedEntity>
```

### A.2.14.3 Language

|                      |                                                                                                                                                             |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The ISO 639-1 Language Code of the Medicinal Product Medicinal Product name as applicable in the specified country and the jurisdiction shall be specified. |
| <b>Conformance</b>   | Mandatory                                                                                                                                                   |

```
<name xml:lang="de">ISOORANGE Grippe/Erkältung Beutel</name>
<name xml:lang="fr">ISOORANGE Grippe/refroidissement sachets</name>
<name xml:lang="it">ISOORANGE Influenza/raffreddore bustine</name>
```

### A.2.15 Header

The characteristics of an authorised Medicinal Product as defined in ISO 11615 shall be versioned within a header, as applicable. For a given version, some characteristics of the Medicinal Product have changed but are not different to a sufficient extent to warrant the assignment of a new primary identifier as specified in ISO 11615:2017, Clause 10. However, the difference(s) are required to be recorded and tracked against the MPID/PCID.

Record to track against previous versions of a regulated document, regardless of whether the revisions warrant a new primary identifier (primary identifier reference shall be listed as an example of a change within a regulated document).

Regional guidance might contain additional criteria which may warrant a new version of a regulated document as it relates to the characteristics of a Medicinal Product.

**NOTE** Header version only corresponds to the tracking versions of a header as stated in the penultimate paragraph above. It is not related to the actual revisions that may be captured within a header (e.g. marketing status changes that may warrant a change to an MPID/PCID).

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | Any document(s) officially submitted to a medicines regulatory agency in support of the regulatory process shall be specified as a regulated document.<br><br>The characteristics of an authorised Medicinal Product shall be versioned within a regulated document, as applicable.<br><br><b>NOTE</b> For a given version, some characteristics of the Medicinal Product have changed but are not different to a sufficient extent to warrant the assignment of a new primary identifier as specified in ISO 11615:2017, Clause 10. However, the difference(s) are required to be recorded and tracked against the MPID/PCID. |
| <b>Conformance</b>   | Mandatory                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

```

<!-- SPL header -->
<document>
  <!-- Version and Header -->
  <id root="Header (version) Identifier UUID"/>
  <code code="Header Type code" codeSystem="document type code system OID"
    displayName="submission type name"/>
  <effectiveTime value="header (version) effective date"/>
  <setId root="header version-set identifier UUID"/>
  <versionNumber value="version number"/>
  <component><structuredBody><component><section>...
  <subject>
  <!-- CPM body -->
  <manufacturedProduct>
  <subjectOf>
    <document><!-- (other) Attached Document (reference) -->
    <id root="Attached Document Identifier UUID"/>
    <code code="Attached Document Type code" codeSystem="document type code
      system OID" displayName="attached document type name"/>
    <title language="en" mediaType="File type code">
      <!-- Attached Document name -->
      <reference value="File name"/>
    </title>
    <effectiveTime value="Attached Document effective date"/>
    <versionNumber value="version number"/>
  </document>
</subjectOf>

```

Medical product information is itself delivered inside the attached document.

#### A.2.15.1 Identifier

|                      |                                                                                    |
|----------------------|------------------------------------------------------------------------------------|
| <b>User guidance</b> | A document corresponding to a particular regulatory use case/instance (e.g. SmPC). |
| <b>Conformance</b>   | Mandatory                                                                          |

```

<!-- SPL header -->
<document>
  <!-- Version and Regulated Document -->
  <id root="Header (version) Identifier UUID"/>
  <code code="Header Type code" codeSystem="document type code system OID"
    displayName="submission type name"/>

```

```

<!-- SPL header -->
<document>
  <!-- Version and Regulated Document -->
  <id root="Header (version) Identifier UUID"/>
  <code code="Header Type code" codeSystem="submission type code system OID"
    displayName="HeaderRegulated Document type name"/>
  <effectiveTime value="HeaderRegulated Document (version) effective date"/>
  <setId root="Header version-set identifier UUID"/>
  <versionNumber value="version number"/>
  <component><structuredBody><component><section>...
  <subject>
  <!-- CPM body -->
  <manufacturedProduct>
  <manufacturedProduct><!-- Medicinal Product -->

```

## A.2.15.2 Effective date

|                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The date corresponding to a version of a header containing Medicinal Product information (e.g. elements related to the Summary of Product Characteristics, product labelling). A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.<br><br>NOTE Header version date corresponds to the tracking versions of a header. It does not correspond to the actual revisions or regulatory timelines that may be captured within a header (e.g. marketing status changes that may warrant a change to an MPID/PCID). |
| <b>Conformance</b>   | Mandatory                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

```
<!-- SPL header -->
<document>
  <effectiveTime value="Header version date"/>
```

NOTE The "ISO 8601 date format" is not one specific format but ISO 8601 has many variants. The HL7 dates are a subset of ISO 8601 in the format "YYYYMMDD" without dashes or other decorators; only this format is permitted.

## A.2.15.3 Language

|                      |                                                                                                                                  |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------|
| <b>User guidance</b> | The ISO 639-1 Language Code of attached document as applicable in the specified country and the jurisdiction shall be specified. |
| <b>Conformance</b>   | Conditional                                                                                                                      |

```
<!-- SPL header -->
<document>
  <languageCode code="language" codeSystem="oid"/>
```

## A.2.15.4 Version number

|                      |                                                                            |
|----------------------|----------------------------------------------------------------------------|
| <b>User guidance</b> | An identifier for the version or a version number can be provided in text. |
| <b>Conformance</b>   | Conditional                                                                |

```
<!-- SPL header -->
<document>
  <id root="Document (version) Identifier UUID"/>
  <setId root="document version-set identifier UUID"/>
  <versionNumber value="version number"/>
```

NOTE The colloquial notion of a single document which has multiple versions each different from the other does not exist in HL7. Each modification of a document is itself a new document. However, the document set, or, for additional clarity the "header version set" is recognised in HL7 and reflected in a "set id", which is a globally unique identifier for the entire set of versions of what might be considered "one document". Any change to a document produces a new document with a new document id, but with the same set id as the previous document and an increased version number. See [A.2.16.1](#).

## A.2.15.5 Version set identifier

|                      |                                                                                      |
|----------------------|--------------------------------------------------------------------------------------|
| <b>User guidance</b> | A unique identifier for the version or a version number can be provided (e.g. GUID). |
| <b>Conformance</b>   | Conditional                                                                          |