TECHNICAL SPECIFICATION

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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

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(E)

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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).

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).

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.

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[1]).

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.
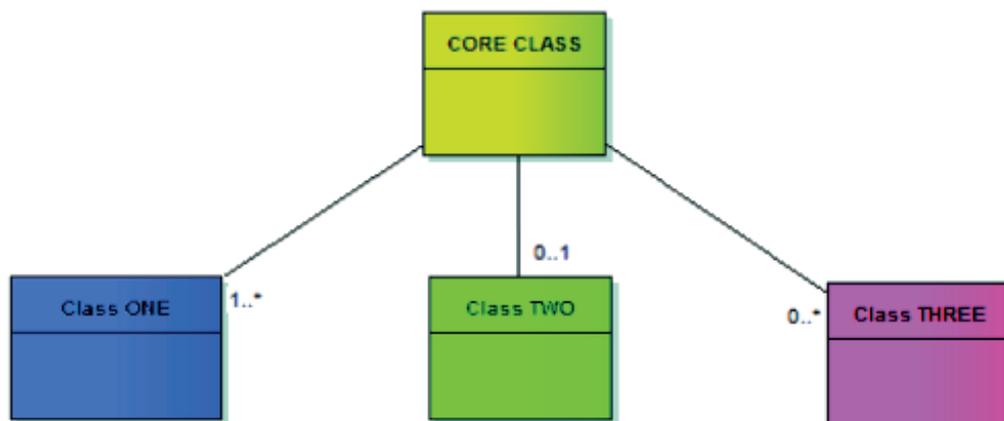
Figure 2 — Example conceptual overview diagram

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.
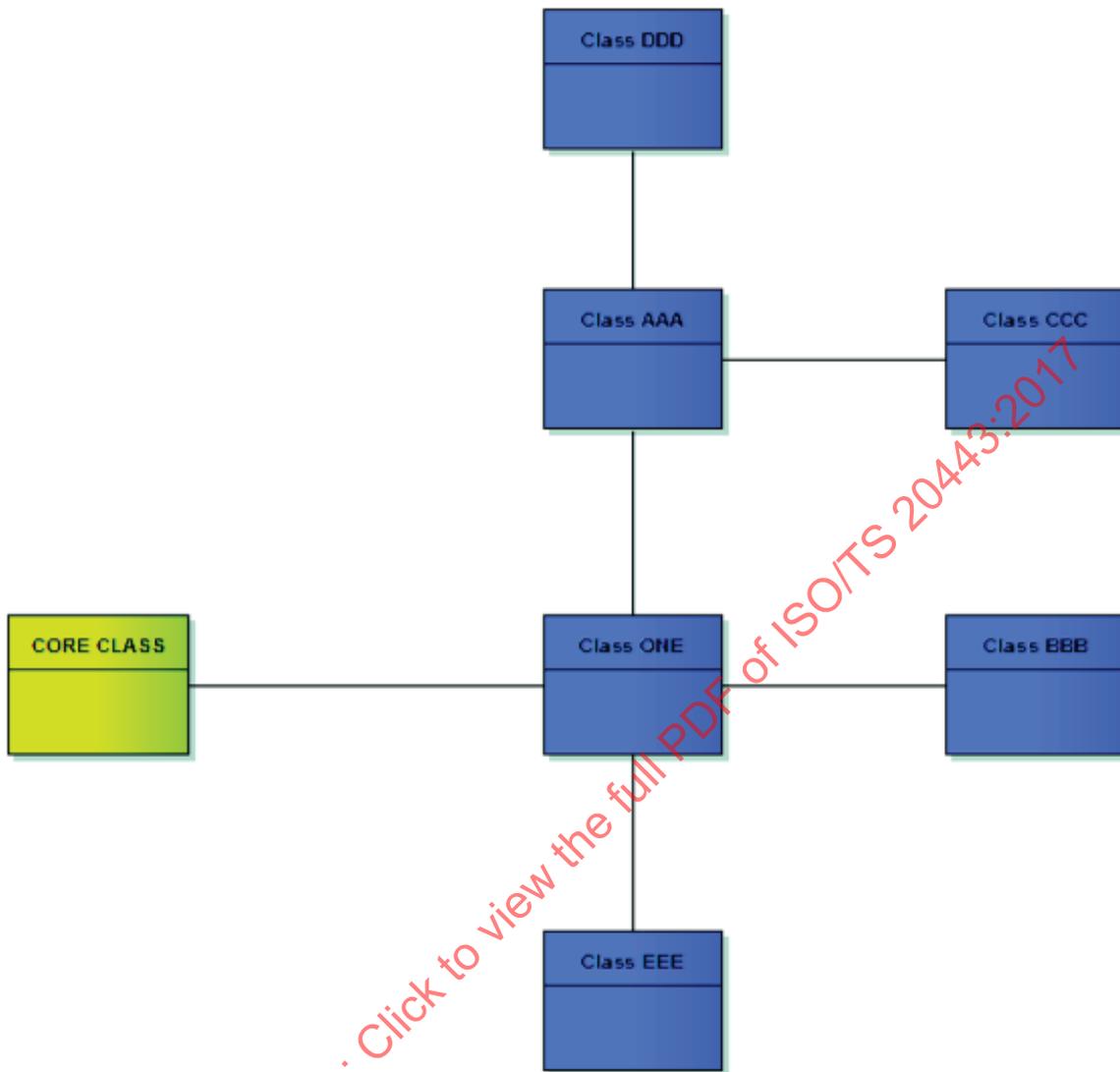
Figure 3 — Example section high-level diagram

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.
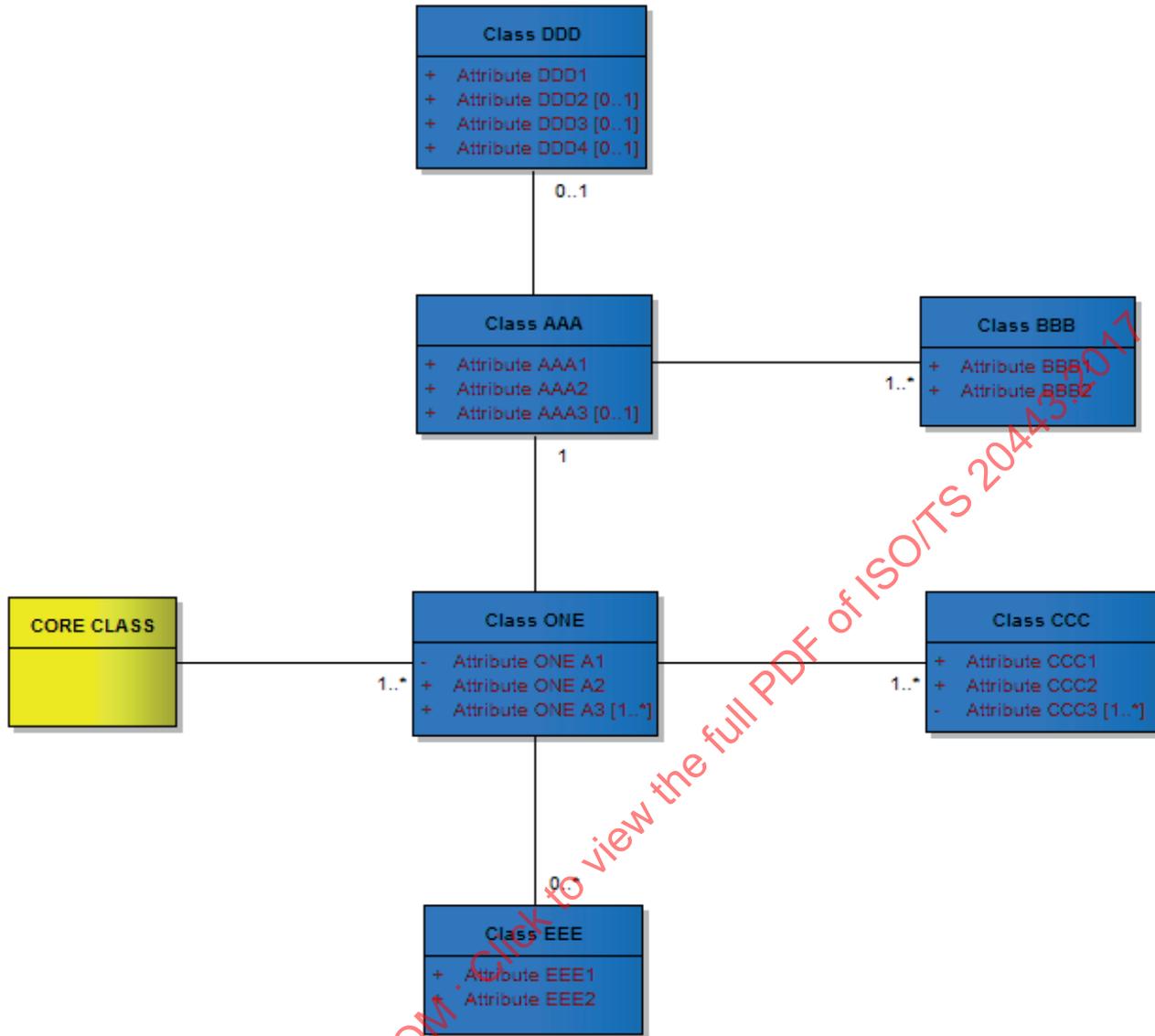
Figure 4 — Example detailed description diagram

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 -->
```
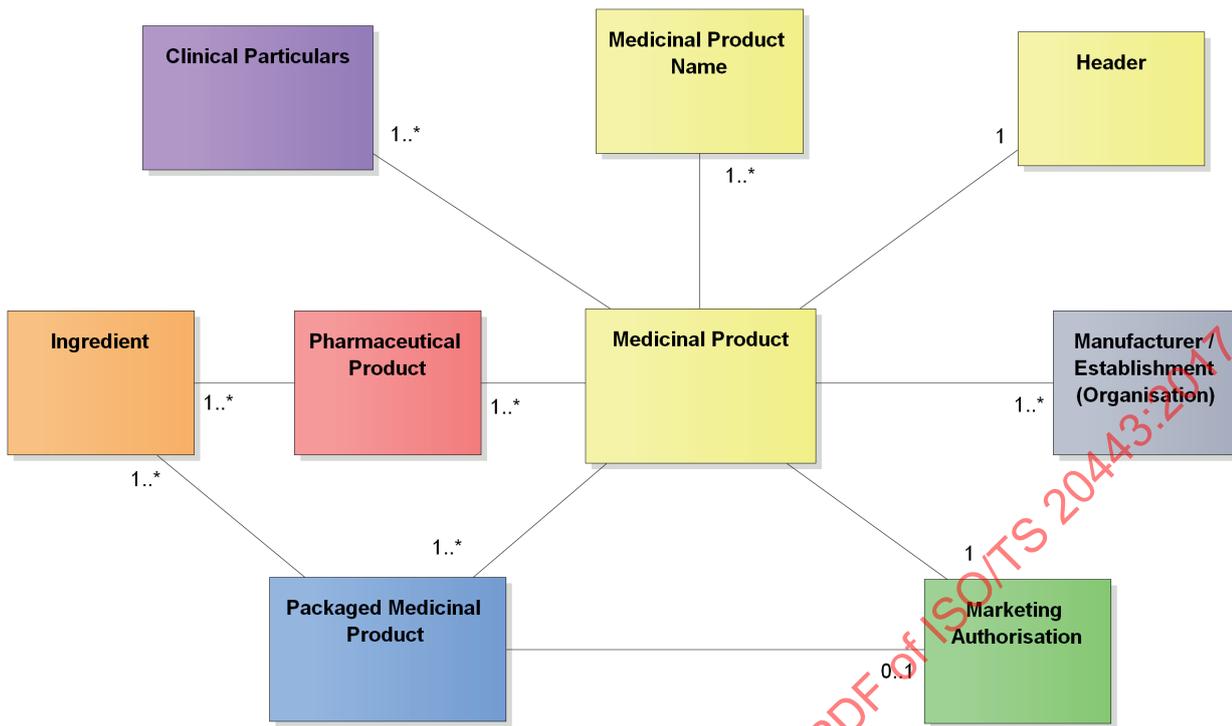
9.7   Packaged Medicinal Product

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.
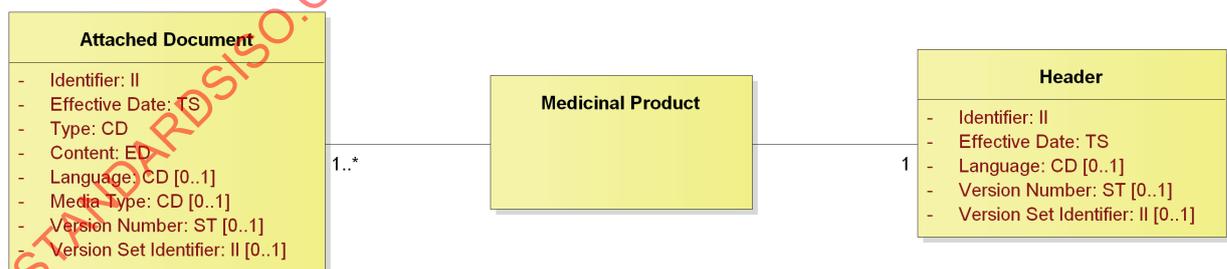
Figure 6 — Header/version for Medicinal Product

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" .../>
```
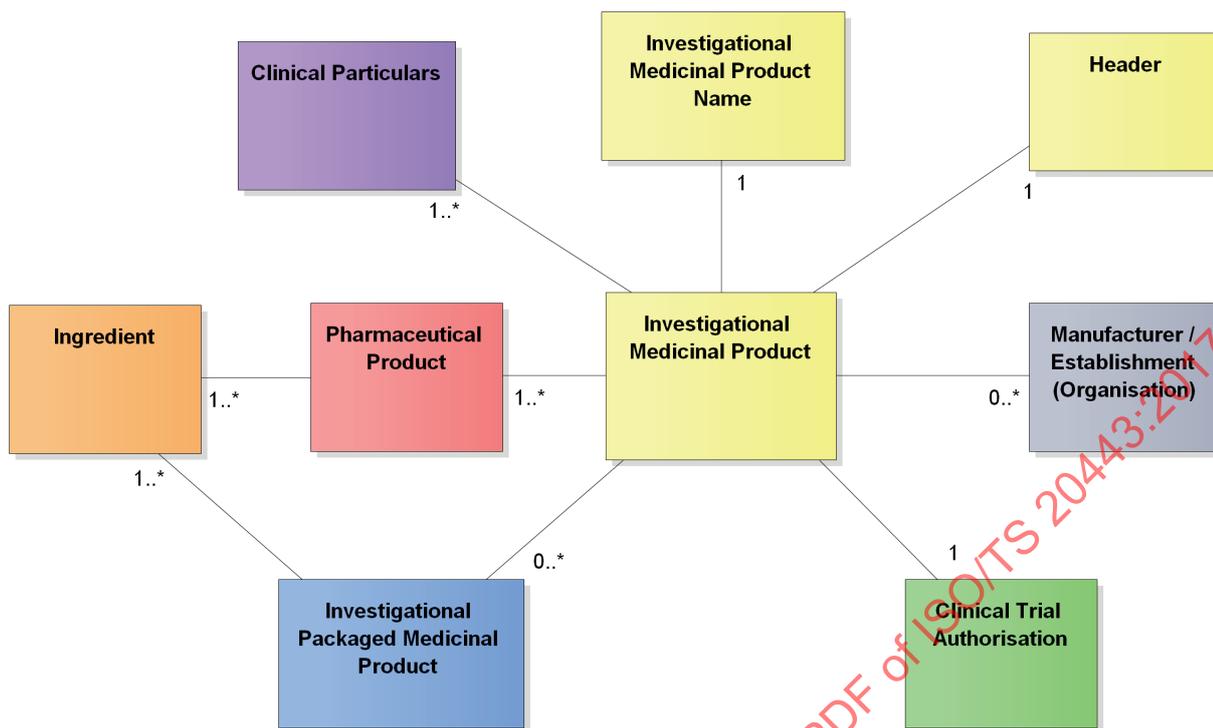
10.8 Investigational Packaged Medicinal Product

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
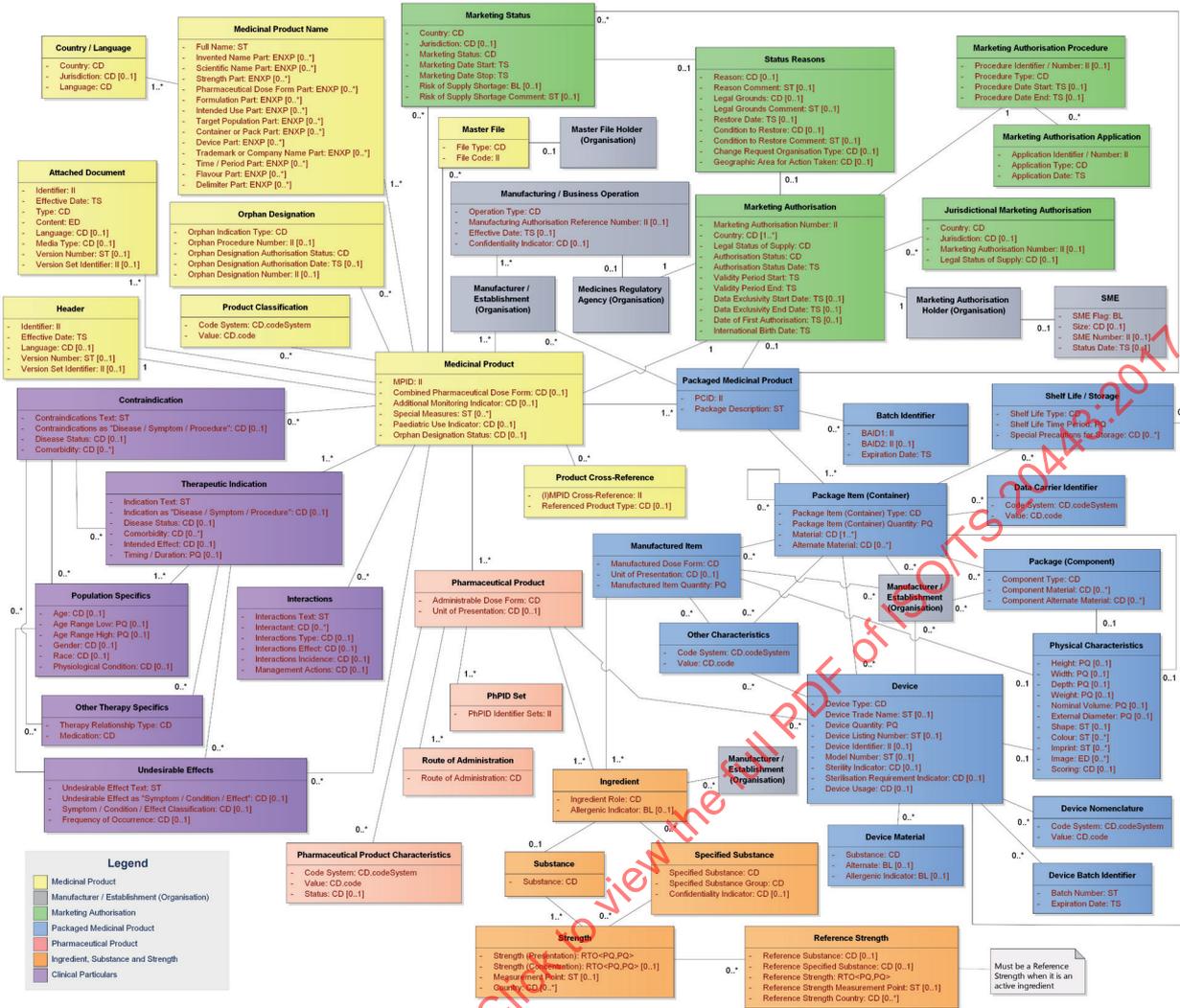
Figure 9 — Authorised Medicinal Products high level detailed diagram (full model)
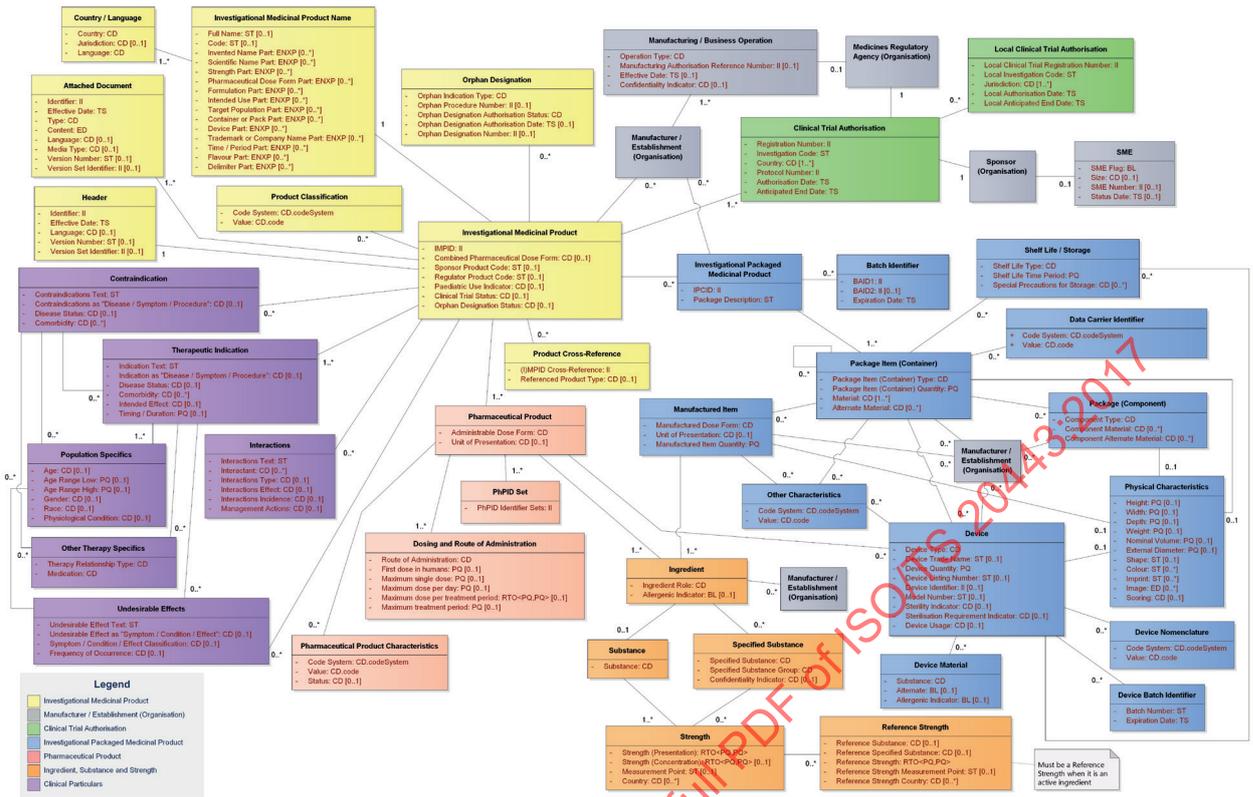
Figure 10 — Investigational Medicinal Products detailed diagram (full model)

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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>
```

A.2.2   MPID

User guidance	This is the MPID for the Medicinal Product, which always needs to be specified.
	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.
	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:
	— country code segment (ISO 3166-1 alpha-2 code elements);
	— marketing authorisation holder (Organisation Identifier) code segment;
	— Medicinal Product code segment (Unique Medicinal Product Identifier).
	Any change of the values related to these three code segments should result in the assignment of a new MPID.
Conformance	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

User guidance	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 manu-factured 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.
	NOTE This element consists of a "Display Name" and "Code" as represented in the XML instance below.
Conformance	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"/>
```

A.2.4   Additional monitoring indicator

User guidance	If the Medicinal Product is subject to additional monitoring, it shall be specified. The term and the term identifier shall be specified.
Conformance	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

User guidance	If the Medicinal Product is subject to paediatric use, it shall be specified. The term and the term identifier shall be specified.
Conformance	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

User guidance	The class should capture information necessary after identifying the product authorised in a region is qualified to be treated as an orphan drug.
Conformance	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

User guidance	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.
Conformance	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

User guidance	The type of the orphan indication should be captured.
Conformance	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

User guidance	Procedure number for the orphan designation authorisation application.
Conformance	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

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

        <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)"/> ...
       </approval>
      </subjectOf>
```

A.2.8.4 Orphan designation authorisation date

User guidance	Date issued by the authorities for orphan designation. This element is required if a positive decision on the orphan designation is issued.
Conformance	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"/>
```

A.2.8.5 Orphan designation number

User guidance	Number issued by the authorities for orphan designation.
Conformance	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

User guidance	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.
	The classification system can be specified using an appropriate identification system. The term and term identifier shall be specified.
	The individual value that applies to the Medicinal Product shall be specified using a term and a term identifier from the classification system.
Conformance	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

User guidance	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.
Conformance	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

User guidance	The value of the classification.
Conformance	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

User guidance	This class is used to identify any type of master file related to the Medicinal Product.
Conformance	Conditional

EXAMPLE   The Pharmacovigilance System Master File (PSMF).

A.2.10.1 File type

User guidance	This attribute is to define which kind of master file is indicated.
	EXAMPLE Pharmacovigilance System Master File.
Conformance	Mandatory

A.2.10.2 File code

User guidance	This attribute is the identifier/code assigned to the master file as applicable.
Conformance	Mandatory

A.2.11 Master file holder (organisation)

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

A.2.12 Product cross-reference

User guidance	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 sublcause. 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.
Conformance	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

User guidance	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.
	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.
	A cross reference to the MPID of the authorised Medicinal Product shall be included for reference purposes.
	NOTE There may be occasions where more than one MPID is cross-referenced, if an IMPID is representing a new therapeutic regimen.
Conformance	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

User guidance	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.
Conformance	Conditional

A.2.13 Medicinal product name

User guidance	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.
	A Medicinal Product may have more than one proprietary/non-proprietary name across jurisdictions. Multiple languages may also be applicable per jurisdictional requirements.
	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).
	Other characteristics of the name can refer to strength, pharmaceutical form, intended usage or an administration device, etc.
	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.
	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).

| | 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:
Full Name: "Drug XYZ Precisehaler 200 mg"
Pharmaceutical Dose Form Part: "Precisehaler"
Strength Part: "200 mg"

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

EXAMPLE B   Full Medicinal Product name not represented within the name parts:

Full Name: "Drug XYZ Precisehaler 200 mg"
Pharmaceutical Dose Form Part: "Precision inhaler"
Strength Part: "200 milligrams"

<!–first the full name on its own –>
<name>Drug XYZ Precisehaler 200 mg</name>
<!–secondly all the name parts, on their own –>
<name use = "SRCH">
    <suffix qualifier="FRM"> Precision inhaler</suffix>
    <suffix qualifier="STR"> 200 mg</suffix>
</name>

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".

Regional guidance/implementation shall determine the applicable Medicinal Product name representation to be utilised per their requirements. |
| **Conformance** | Mandatory |

A.2.13.1 Full name

User guidance	The complete Medicinal Product name as approved by the medicines regulatory agency in a jurisdiction shall be specified as text.
Conformance	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

User guidance	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.
Conformance	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

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

User guidance	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 Annex F. The use of decimal points shall be accommodated, if required.
Conformance	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

User guidance	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 Annex E and Annex C, respectively.
Conformance	Conditional

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

A.2.13.6 Formulation part

User guidance	The formulation, if reflected in the Medicinal Product name, shall be specified as text, where applicable.
Conformance	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

User guidance	The intended use, if reflected in the Medicinal Product name, shall be specified as text, where applicable.
Conformance	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

User guidance	The target population, if reflected in the Medicinal Product name, shall be specified as text, where applicable.
Conformance	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

User guidance	The container or pack, if reflected in the Medicinal Product name, shall be specified as text, where applicable.
Conformance	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

User guidance	The device, if reflected in the Medicinal Product name, shall be specified as text, where applicable.
Conformance	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

User guidance	The trademark, if reflected in the Medicinal Product name, shall be specified as text, where applicable.
Conformance	Conditional

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

A.2.13.12 Time/period part

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

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

A.2.13.13 Flavour part

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

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

A.2.13.14 Delimiter part

User guidance	A delimiter separates one composite in a segment from another, or separates one sub-composite from another.
Conformance	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

User guidance	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.
Conformance	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

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

A.2.14.2 Jurisdiction

User guidance	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.
Conformance	Conditional

ISO/TS 20443:2017(E)

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

User guidance	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.
Conformance	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).

User guidance	Any document(s) officially submitted to a medicines regulatory agency in support of the regulatory process shall be specified as a regulated document.
	The characteristics of an authorised Medicinal Product shall be versioned within a regulated document, as applicable.
	NOTE 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.
Conformance	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>
   </manufacturedProduct>
```

Medical product information is itself delivered inside the attached document.

A.2.15.1 Identifier

User guidance	A document corresponding to a particular regulatory use case/instance (e.g. SmPC).
Conformance	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

User guidance	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.
	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).
Conformance	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

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

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

A.2.15.4 Version number

User guidance	An identifier for the version or a version number can be provided in text.
Conformance	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

User guidance	A unique identifier for the version or a version number can be provided (e.g. GUID).
Conformance	Conditional

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

A.2.16 Attached document

User guidance	The reference to any regulatory use case where an attached document is utilised/ warranted for Medicinal Product information shall be specified.
Conformance	Mandatory

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

A.2.16.1 Identifier

User guidance	A unique identifier (e.g. GUID) for the version of an attached document to a regulated document (Header) specific to a particular product or other regulatory instance.
Conformance	Mandatory

HL7 SPL files are regulated documents when they are utilised as part of the regulatory submission process. For example, MPID/PCID information would be contained in a regulated document. That SPL file may also have other information, which may just be inside human readable text. Versioning shall occur at the header/regulated document level with other associated attached documents as applicable (primary vs. secondary).

If the product is also the subject of other documents and is to be referenced, then the structure is as follows:

```
<!-- SPL header -->
<document><!-- (this) Header -->
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
   </manufacturedProduct>
   <subjectOf2>
    <document><!-- Attached Document -->
     <id root="Regulated Document Identifier UUID"/> <!-- or non UUID in the extension with a nullFlavor root -->
     <code code="Regulated Document Type code" codeSystem="document type code system OID"
         displayName="document type name"/>
     <text mediaType="text/plain">Attached Document Content</text>
     <effectiveTime><low value="Attached Document effective date"/></effectiveTime>
     <languageCode code="Attached Document language" codeSystem="language code system OID"
         displayName="language name"/>
     <setId root="Code System OID" extension="Attached Document version set identifier"/>
     <versionNumber>Attached Document version number</versionNumber>
    </document>
   </subjectOf2>
```

A.2.16.2 Effective date

User guidance	The date specified in the attached document by which the corresponding updates indicated within a submission become active/operational shall be specified. Complete dates consisting of day, month and year shall be specified using the ISO 8601 date format.
	NOTE ISO 8601 can accommodate year and month should day of the month not be known (i.e. YYYY-MM). Refer to regional guidance for date requirements.
Conformance	Mandatory

```
<!-- SPL header -->
<document><!-- (this) Header -->
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
   </manufacturedProduct>
   <subjectOf2>
    <document><!-- Attached Document -->
      <id root="Attached Document Identifier UUID"/> <!-- or non UUID in the extension with a nullFlavor root -->
      <code code="Regulated Document Type code" codeSystem="document type code system OID"
          displayName="document type name"/>
      <text mediaType="text/plain">Attached Document Content</text>
      <effectiveTime><low value="Attached Document effective date"/></effectiveTime>
      <setId root="Code System OID" extension="Attached Document version set identifier"/>
      <versionNumber>Attached Document version number</versionNumber>
    </document>
   </subjectOf2>
```

A.2.16.3 Type

User guidance	A secondary regulated document corresponding to a regulatory use case/instance within a primary regulated document (e.g. Patient Information Leaflet associated with an SPC).
	The type of attached document that is supporting a version increment shall be specified. The term and term identifier shall be specified.
Conformance	Mandatory

```
<!-- SPL header -->
<document><!-- (this) Header -->
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
   </manufacturedProduct>
   <subjectOf2>
    <document><!-- Attached Document -->
      <id root="Attached Document Identifier UUID"/> <!-- or non UUID in the extension with a nullFlavor root -->
      <code code="Regulated Document Type code" codeSystem="document type code system OID"
          displayName="document type name"/>
```

A.2.16.4 Content

User guidance	The content corresponding the attached document type.
Conformance	Mandatory

```
<!-- SPL header -->
<document><!-- (this) Header -->
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
   </manufacturedProduct>
   <subjectOf2>
    <document><!-- Attached Document -->
     <id root="Attached Document Identifier UUID"/> <!-- or non UUID in the extension with a nullFlavor root -->
     <code code="Regulated Document Type code" codeSystem="document type code system OID"
         displayName="document type name"/>
     <text mediaType="text/plain">Attached Document Content</text>
```

A.2.16.5 Language

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

```
<!-- SPL header -->
<document><!-- (this) Header -->
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
   </manufacturedProduct>
   <subjectOf2>
    <document><!-- Attached Document -->
     <id root="Attached Document Identifier UUID"/> <!-- or non UUID in the extension with a nullFlavor root -->
     <code code="Regulated Document Type code" codeSystem="document type code system OID"
         displayName="document type name"/>
     <text mediaType="text/plain">Attached Document Content</text>
     <effectiveTime><low value="Attached Document effective date"/></effectiveTime>
     <languageCode code="Regulated Document language" codeSystem="language code system OID"
         displayName="language name"/>
```

A.2.16.6 Media type

User guidance	The graphic media type specified within an attached document (e.g. JPEG).
Conformance	Conditional

```
<!-- SPL header -->
<document><!-- (this) Header -->
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
   </manufacturedProduct>
   <subjectOf2>
    <document><!-- Attached Document -->
     <id root="Attached Document Identifier UUID"/> <!-- or non UUID in the extension with a nullFlavor root -->
     <code code="Regulated Document Type code" codeSystem="document type code system OID"
         displayName="document type name"/>
     <text mediaType="Attached document media type">Attached Document Content</text>
```

A.2.16.7 Version Number

User guidance	A whole number for the version of a regulated document (header) can be provided in text.
Conformance	Conditional

```
<!--  SPL header -->
<document><!-- (this) Header -->
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
   </manufacturedProduct>
   <subjectOf2>
    <document><!-- Attached Document -->
     <id root="Attached Document Identifier UUID"/> <!-- or non UUID in the extension with a nullFlavor root -->
     <code code="Regulated Document Type code" codeSystem="document type code system OID"
          displayName="document type name"/>
     <text mediaType="text/plain">Attached Document Content</text>
     <effectiveTime><low value="Attached Document effective date"/></effectiveTime>
     <setId root="Code System OID" extension="Attached Document version set identifier"/>
     <versionNumber>Attached Document version number</versionNumber>
    </document>
   </subjectOf2>
```

A.2.16.8 Version set identifier

User guidance	A unique identifier (e.g. GUID) for the version of a regulated document (header) specific to a particular product or other regulatory instance.
Conformance	Conditional

```
<!-- SPL header -->
<document><!-- (this) Header -->
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
   </manufacturedProduct>
   <subjectOf2>
    <document><!-- Attached Document -->
     <id root="Attached Document Identifier UUID"/> <!-- or non UUID in the extension with a nullFlavor root -->
     <code code="Regulated Document Type code" codeSystem="document type code system OID"
          displayName="document type name"/>
     <text mediaType="text/plain">Attached Document Content</text>
     <effectiveTime><low value="Attached Document date"/></effectiveTime>
     <setId root="Code System OID" extension="Attached Document version set identifier"/>
    </document>
   </subjectOf2>
```

Annex B
(normative)

Marketing authorisation

B.1   General

This annex specifies the marketing authorisation information for a Medicinal Product.

The marketing authorisation is issued by the appropriate regulatory medicines authority in a region/jurisdiction. An authorisation is required before a Medicinal Product is placed on the market. For some categories of Medicinal Products (e.g. "grandfather" drugs) exemptions may be applicable. For these type of medicines, the same principles of information provision as for authorised Medicinal Products shall be applied as outlined in this annex. Where no formal marketing authorisation holder is established, the distributor shall be specified.

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

     <approval><!-- Marketing Authorisation / Procedure -->
      <author>
       <territorialAuthority>
        <territory>...</territory>
        <governingAgency>
         <!-- Medicines Regulatory Agency -->
        </governingAgency>
       </territorialAuthority>
      </author>

      <holder><!-- Marketing Authorisation Holder --></holder>
      <sourceOf typeCode="FLFS">
       <approval><!-- Marketing Authorisation Application --></approval>
      </sourceOf>
     </approval>
    </subjectOf>
    <subjectOf>
     <marketingAct><!-- Marketing Status --></marketingAct>
    </subjectOf>
```

A Medicinal Product has a marketing authorisation (applicable to "grandfather products" as this status would be considered an authorisation).

This marketing authorisation is issued by a medicines regulatory agency to an organisation referred to as marketing authorisation holder. Within the marketing authorisation holder, there can be a named individual who is responsible for the pharmacovigilance activities associated with that Medicinal Product (e.g. Qualified Person Responsible for Pharmacovigilance within the EU).

An initial marketing authorisation, renewal, variation to and revocation of a marketing authorisation is managed on the basis of a marketing authorisation procedure, which itself is supported by a marketing authorisation application.

During the lifetime of a Medicinal Product, its marketing authorisation is likely to have had a variety of changes. Therefore, the status of a marketing authorisation will change over time, which has to be recorded accordingly.

The marketing status describes when a Medicinal Product is actually put on the market or is no longer available in a country or jurisdiction. It also indicates the legal status of supply (e.g. prescription only).
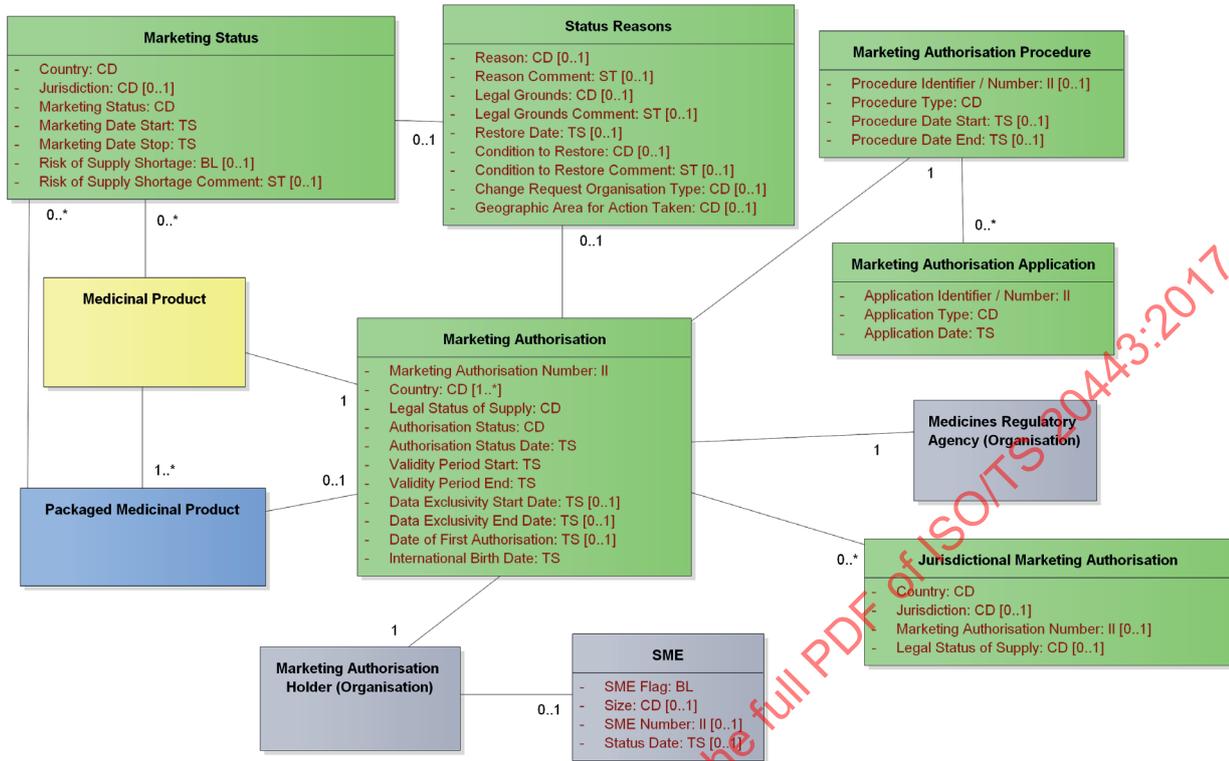
Figure B.1 — Marketing authorisation section detailed description diagram

NOTE   There may be circumstances where additional information on marketing status is specific to local provisions within a jurisdiction (e.g. provinces or territories).

Each Medicinal Product should have the relevant marketing authorisation information specified.

The marketing authorisation information should also be appropriately specified for a packaged Medicinal Product, where applicable (see below).

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

    <approval><!-- Marketing Authorisation -->
     <id extension="Marketing Authorisation Number"
      root="number system OID"/>

     <statusCode code="Authorisation Status"/>
     <effectiveTime xsi:type="IVL_TS">
      <low value="Validity Period Start Date"/>
      <high value="Validity Period End Date"/>
     </effectiveTime>

     <availabilityTime value="Authorisation Status Date"/>
     <author>
      <territorialAuthority>
       <territory>
        <code code="Country Code (ISO 2-alpha)"
           codeSystem="country code system OID"/>
       </territory>
       <governingAgency>
        <!-- Medicine's Regulatory Agency -->
       </governingAgency>
      </territorialAuthority>
     </author>

     <holder><!-- Marketing Authorisation Holder --></holder>
     <sourceOf typeCode="COMP">
      <approval><!-- Marketing Authorisation Procedure -->
       <id extension="Procedure Identifier / Number"
        root="number system OID"/>
       <code code="Procedure Type Code" displayName="Procedure Name"
         codeSystem="Procedure Type Code System OID"/>
       <activityTime xsi:type="IVL_TS">
        <low value="Procedure Date Start"/>
        <high value="Procedure Date End"/>

       </activityTime>
       <sourceOf typeCode="FLFS">
        <approval><!-- Marketing Authorisation Application -->
         <id extension="Application Identifier / Number"
          root="number system OID"/>
         <code code="Application Type Code"
           displayName="Application Type Name"
            codeSystem="Application Type Code System OID"/>
         <effectiveTime value="Application Date"/>
         <subjectOf>

          <document><!-- Associated Document --></document>
         </subjectOf>
        </approval>
       </sourceOf>
      </approval>
     </sourceOf>
     <pertinentInformation>
      <policy>
```

```
        <code code="Legal Status of Supply Code"
            codeSystem="Code System OID"/>
      </policy>
    </pertinentInformation>
  </approval>
 </subjectOf>
 <subjectOf>

  <marketingAct><!-- Marketing Status -->
   <statusCode code="Marketing Status Code"/>
   <effectiveTime xsi:type="IVL_TS">
    <low value="Marketing Date Start"/>
    <high value="Marketing Date Stop"/>
   </effectiveTime>
   <location>

    <role>
     <playingTerritory>
      <code code="Country / Jurisdiction Code"
          codeSystem="Country / Jurisdiction Code System"/>
      <name>Country / Jurisdiction Name</name>
     </playingTerritory>
    </role>

   </location>
   <coverage>
    <approval>
     <id extension="Jurisdiction Marketing Authorisation Number"

       root="Jurisdiction Marketing Authorisation Number System OID"/>
     <pertinentInformation>
      <policy>

       <code code="Jurisdictional Legal Status of Supply Code"
           codeSystem="Code System OID"/>
      </policy>
     </pertinentInformation>
    </approval>
   </coverage>
  </marketingAct>
 </subjectOf>
```

B.2 Marketing authorisation

User guidance	A Medicinal Product can only be placed on the market when a marketing authorisation or equivalent has been issued by a medicines regulatory agency.
Conformance	Mandatory

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

B.2.1 Marketing authorisation number

User guidance	The number as assigned to a Medicinal Product by the regulatory medicines agency of a country/jurisdiction shall be specified.
	NOTE The marketing authorisation number can also be a reference to regulations/legislation/guidance authorizing certain Medicinal Products that may not have assigned physical authorisation numbers (e.g. grandfathered Medicinal Products).
Conformance	Mandatory

For Medicinal Products which allow distribution without a formal marketing authorisation by legislation, the citation of such legislation or regulation shall be specified in the absence of a formal marketing authorisation number.

Derivative marketing authorisation: Some marketing authorisations are implicitly derived from other marketing authorisations. Such derivative marketing authorisations are correctly represented as follows.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Derivative Marketing Authorisation -->
      <code code="C80440" displayName="NDA AUTHORISED GENERIC"
        codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <sourceOf typeCode="COVBY">
       <approval><!-- Original Marketing Authorisation Reference -->
        <id extension="NDA123456" root="2.16.840.1.113883.3.150"/>
```

Implicit marketing authorisation by regulation: Regions may exempt some products from any approval procedure, exempt by virtue of legislation/regulation(s) in a region.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Derivative Marketing Authorisation -->
      <code code="C73603" displayName="OTC MONOGRAPH FINAL"
        codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <sourceOf typeCode="COVBY">
       <approval><!-- Citation of Regulation -->
        <id extension="part347" root="2.16.840.1.113883.3.149"/>
```

If there were no approval procedure variants (e.g. *OTC monograph non-final* vs. *OTC monograph final*), then the marketing authorisation could be directly stated without requiring the indirection through a derivative marketing authorisation.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Derivative Marketing Authorisation -->
      <id extension="part347" root="2.16.840.1.113883.3.149"/>
      <code code="C73603" displayName="OTC MONOGRAPH FINAL"
        codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

NOTE   If all attributes about the marketing authorisation are completely dependent on the marketing authorisation number, then a simple marketing authorisation can be specified. However, if any of the features of the marketing authorisation (e.g. code, date, etc.) vary by product for the same marketing authorisation number, then the derivative marketing authorisation structure shall be utilised.

B.2.2   Country

User guidance	The country in which the marketing authorisation has been granted shall be provided in accordance with the ISO 3166-1 alpha-2 codes.
	"EU" can be utilised to identify the "European Union". The European Union is not a country but rather an organisation with member states. ISO 3166 reserves the two-letter combination "EU" for the purpose of identifying the European Union within the framework of ISO 3166.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <author>
       <territorialAuthority>
        <territory>
         <code code="Country Code (ISO 2-alpha)"
           codeSystem="country code system OID "/>
        </territory>
```

Where a marketing authorisation spans more than one country, all the applicable countries shall be described.

If there is any need to specify more than one country in the absence of a multi-national treaty organisation, there would be different marketing authorisation in each identified country. The example below illustrates how this would be addressed.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <author>
       <territorialAuthority>
        <territory>
         <code code="BE" codeSystem="1.0.3166.1.2.2"/>
        </territory>
       </territorialAuthority>
      </author>
      <author>
       <territorialAuthority>
        <territory>
         <code code="NL" codeSystem="1.0.3166.1.2.2"/>
        </territory>
       </territorialAuthority>
      </author>
      <author>
       <territorialAuthority>
        <territory>
         <code code="LU" codeSystem="1.0.3166.1.2.2"/>
        </territory>
       </territorialAuthority>
      </author>
```

B.2.3 Legal status of supply

User guidance	The legal status of supply of the Medicinal Product as classified by the regulatory medicines agency should be specified (e.g. subject to medical prescription). The legal status of supply should be described. The term and the term identifier should be specified.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <pertinentInformation>
       <policy>
        <code code="Legal Status of Supply Code"
           codeSystem="Code System OID"/>
```

If the IDMP/SPL document is for a single region/jurisdiction only and thus contains only one marketing authorisation, the legal status of supply may be stated on the level of the Medicinal Product rather than as a feature of the marketing authorisation.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation --></approval>
    </subjectOf>
    <subjectOf>
     <policy>
      <code code="Legal Status of Supply Code" codeSystem="Code System OID"/>
     </policy>
    </subjectOf>
```

NOTE   Controlled substance enforcement measures at various levels of severity is another example of legal status of supply and handled by the same structure.

B.2.4   Authorisation status

User guidance	The status of the marketing authorisation changes throughout the lifecycle of a Medicinal Product depending on the regulatory process applicable in a region. This shall be specified. The controlled term and the controlled term identifier shall be specified.
Conformance	Mandatory

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

EXAMPLE   Marketing authorisation status codes:

Status code	Marketing authorisation status meaning
active	Marketing authorisation is currently active.
completed	Marketing authorisation is no longer active, for example, it may have expired without renewal or the manufacturer may have withdrawn the product from the market.
suspended	Marketing authorisation was temporarily suspended (by the authorisation holder or the regulator)
terminated	Marketing authorisation was terminated definitely (e.g. by the authorizing regulator).

B.2.5   Authorisation status date

User guidance	The date at which the given status has become applicable shall be specified. A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known. (i.e. YYY-MM).
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <availabilityTime value="Authorisation Status Date"/>
```

NOTE   The use case "marketing authorisation expired on 01.01.2011" is represented by the effectiveTime. Only if the status is not "active" or "completed" will the date in activityTime be of practical significance.

B.2.6   Validity period start

User guidance	The time period, described in terms of a beginning date of the marketing authorisation for the relevant status shall be specified. A date shall be specified using the ISO 8601 date format.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <effectiveTime xsi:type="IVL_TS">
       <low value="Validity Period Start Date"/>
       <high value="Validity Period End Date"/>
```

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <effectiveTime xsi:type="IVL_TS">
       <low value="20110101"/>
       <high value="20151231"/>
```

NOTE   The marketing authorisation end date may be in the future indicating a scheduled expiration date that may be open to renewal. In this case, the marketing authorisation status would be "active". When the authorisation has expired because the end date has been met, the status would be marked as "completed".

B.2.7   Validity period end

User guidance	The time period, described in terms of an end date of the marketing authorisation for the relevant status, shall be specified. A date shall be specified using the ISO 8601 date format.
Conformance	Mandatory

B.2.8 Data exclusivity start date

User guidance	Data exclusivity period refers to the period from initial authorisation of the reference product granting exclusivity for a given marketing authorisation. The time period, described in terms of a beginning data exclusivity period for the relevant status can be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Marketing Authorisation --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <outboundRelationship>
       <approval>
        <code code="data exclusivity approval" codeSystem="Code System OID"/>
        <effectiveTime>
         <low value="data exclusivity start date"/>
         <high value="data exclusivity end date"/>
```

B.2.9 Data exclusivity end date

User guidance	Data exclusivity end date refers to the period from initial authorisation of the reference product after which valid applications for generic product can be submitted and lead to the granting of a marketing authorisation. The time period, described in terms of an end data exclusivity period for the relevant status can be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Marketing Authorisation --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <outboundRelationship>
       <approval>
        <code code="data exclusivity approval" codeSystem="Code System OID"/>
        <effectiveTime>
         <low value="data exclusivity start date"/>
         <high value="data exclusivity end date"/>
```

B.2.10 Date of first authorisation

User guidance	The date of first authorisation refers to the date when the first authorisation was granted by the authorising body. A date shall be specified using the ISO 8601 date format. ISO 8601 can accommodate year and month should day of the month not be known (i.e. YYYY-MM)
Conformance	Conditional

Historically, the date of first authorisation is the marketing authorisation start date as an authorisation until updated at the time of renewal.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Marketing Authorisation --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <outboundRelationship>
       <approval>
        <code code="first approval" codeSystem="Code System OID"/>
        <effectiveTime>
         <low value="Date of First Authorisation"/>
```

B.2.11 International birth date

User guidance	The date of the first marketing authorisation for any product containing the active substance granted to any company in any country in the world.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Marketing Authorisation --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <outboundRelationship>
       <approval>
        <code code="international first approval" codeSystem="Code System OID"/>
        <effectiveTime>
         <low value="International Birth Date"/>
```

B.2.12 Marketing authorisation holder (organisation)

User guidance	Details in relation to the marketing authorisation holder to which a marketing authorisation in a region was granted shall be specified using an organisation class as described in Annex G.
	For Medicinal Products, which allow for distribution without a marketing authorisation within a region, the details of the distributor, as appearing on the package, the container or the package insert shall be provided in place of the details of the marketing authorisation holder.
	In case of Small to Medium Enterprise (SME), specific elements should be described as shown below.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <holder><!-- Marketing Authorisation Holder -->
       <role>
        <playingOrganisation>
         <id extension="316874288" root="1.3.6.1.4.1.519.1"/>
         <name>DrugCo GmbH</name>
```

B.2.13 Small to medium enterprise (SME)

If a marketing authorisation (or other product approval) was granted under special rules for Small to Medium Enterprises (SME), the SME certification details are specified on the marketing authorisation class.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <outboundRelationship typeCode="COVBY">
       <approval><!-- SME Details -->
        <id extension="SME Number" root="SME Number System (OID)"/>
        <code code="SME Type / Size Code" codeSystem="SME Type Code System (OID)"/>
        <effectiveTime>
         <low value="Date when SME Status was granted"/>
```

User guidance	This class should capture the SME information.
Conformance	Optional

B.2.13.1 SME flag

User guidance	A Boolean flag to define whether the applicant is an SME.
Conformance	Mandatory

B.2.13.2 Size

User guidance	Description of the size of the marketing authorisation holder company (e.g. micro-, small- and medium-sized enterprises (SMEs), etc.
Conformance	Optional

The SME size is a code to cite the special legal or regulatory provision under which SMEs are recognised and which recognition might influence the Medicinal Product authorisation procedure. This is entirely dependent on the regional requirements and cannot be standardised on an international level as this time.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <sourceOf typeCode="COVBY">
       <approval><!-- SME Details -->
        <id extension="SME Number" root="SME Number System (OID)"/>
        <code code="SME Type / Size Code"
           codeSystem="SME Type Code System (OID)"/>
        <effectiveTime>
         <low value="Date when SME Status was granted"/>
```

B.2.13.3 SME number

User guidance	SME number can be provided as applicable to regional implementation and requirements defining an SME.
Conformance	Optional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <sourceOf typeCode="COVBY">
       <approval><!-- SME Details -->
        <id extension="SME Number" root="SME Number System (OID)"/>
        <code code="SME Type / Size Code"
           codeSystem="SME Type Code System (OID)"/>
        <effectiveTime>
         <low value="Date when SME Status was granted"/>
```

B.2.13.4 Status date

User guidance	Date when the SME status was granted.
Conformance	Optional

B.2.14 Medicines regulatory agency (organisation)

User guidance	Details in relation to the medicines regulatory agency that granted the marketing authorisation for a Medicinal Product shall be specified using an organisation class as described in Annex G.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <author>
       <territorialAuthority>
        <territory>
         <code code="US" codeSystem="2.16.840.1.113883.5.28"/>
        </territory>
        <governingAgency>
         <id extension="927645523" root="1.3.6.1.4.1.519.1"/>
         <name>Food and Drug Administration</name>
```

B.2.15 Marketing authorisation procedure

User guidance	The regulatory procedure applied to grant or amend a marketing authorisation for a Medicinal Product shall be specified.
Conformance	Mandatory

B.2.15.1 Procedure identifier/number

User guidance	The unique identifier for the specific instance of a procedure undertaken should be provided.
Conformance	Conditional

EXAMPLE   The product was approved under a Mutual Recognition Procedure (MRP) with a procedure identifier/number PT/H/4711/002:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
     <subjectOf>
      <approval><!-- Marketing Authorisation -->
       <outboundRelationship>
        <approval><!-- Marketing Authorisation / Procedure -->
         <id extension="471190128" root="number system OID"/>
         <code code="002" displayName="MRP" codeSystem="2.16.840.1.113883.3.989.5.1.1.3"/>
```

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
     <subjectOf>
      <approval><!-- Marketing Authorisation -->
       <outboundRelationship>
        <approval><!-- Marketing Authorisation / Procedure -->
         <id extension="Procedure Identifier" root="number system OID"/>
```

B.2.15.2 Procedure type

User guidance	The type of procedure that is followed to grant or update a marketing authorisation shall be specified. The term and the term identifier shall be specified.
Conformance	Mandatory

For a simple procedure which is identical to the marketing authorisation:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <code code="Procedure Type Code" displayName="Procedure Name"
        codeSystem="Procedure Type Code System OID"/>
```

For procedures that must be distinguished from the marketing authorisation:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <outboundRelationship>
       <approval><!-- Marketing Authorisation Procedure -->
        <code code="Procedure Type Code" displayName="Procedure Name"
          codeSystem="Procedure Type Code System OID"/>
```

B.2.15.3 Procedure date start

User guidance	The date when the procedure commenced shall be described. Complete dates consisting of day, month and year shall be specified using the ISO 8601 date format.
Conformance	Conditional

```
<approval>
 <effectiveTime>
  <low value="Procedure Date Start"/>
  <high value="Procedure Date End"/>
```

This is the time of the activity of the procedure, and such procedure activity date range may be specified at any level of marketing authorisation.

B.2.15.4 Procedure date end

User guidance	The date when the procedure was completed shall be described. Complete dates consisting of day, month and year shall be specified using the ISO 8601 date format.
Conformance	Conditional

```
<approval>
 <effectiveTime>
  <low value="Procedure Date Start"/>
  <high value="Procedure Date End"/>
```

This is the time of the activity of the procedure and such procedure activity date range may be specified at any level of marketing authorisation.

B.2.16 Marketing authorisation application

User guidance	A marketing authorisation will be supported by an application, as will any change of an existing marketing authorisation (e.g. to renew, to vary or to withdraw). Details of the marketing authorisation application can be described using this class.
	A marketing authorisation shall be supported by an application(s), which may comprise of a number of submissions (regulatory activities): initial marketing application and subsequent applications for changes to an existing marketing authorisation (e.g. to renew, vary or withdraw).
Conformance	Conditional

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

NOTE   When authorisation and procedure are not distinguishable, they may be collapsed into the same act, and the application may still be referred to as a separate element utilizing the "fulfills" (FLFS) relationship:

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

NOTE   When authorisation and procedure are collapsed along with the application, then the application information is the same as the authorisation/procedure information:

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

B.2.16.1 Application identifier/number

User guidance	A unique identifier for the specific instance of an application shall be provided.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <outboundRelationship>
       <approval><!-- Marketing Authorisation Procedure -->
        <outboundRelationship>
         <approval><!-- Marketing Authorisation Application -->
          <id extension="Application Identifier / Number" root="number system OID"/>
```

B.2.16.2 Application type

User guidance	The type of the application shall be described. The controlled term and the controlled term identifier shall be specified.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <sourceOf typeCode="COMP">
       <approval><!-- Marketing Authorisation Procedure -->
        <outboundRelationship>
         <approval><!-- Marketing Authorisation Application -->
          <code code="Application Type Code" displayName="Application Type Name"
             codeSystem="Application Type Code System OID"/>
```

Marketing authorisation supplements may be specified as components of marketing authorisations and collapsed with the specific supplement application:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Marketing Authorisation -->
      <outboundRelationship>
       <approval><!-- Marketing Authorisation Supplement -->
        <outboundRelationship>
         <approval><!-- Marketing Authorisation Supplement Application -->
          <code code="Application Type Code" displayName="Application Type Name"
             codeSystem="Application Type Code System OID"/>
```

B.2.16.3 Application date

User guidance	The date on which the marketing authorisation application was made shall be specified. A date shall be specified using the ISO 8601 date format.
	NOTE ISO 8601 can accommodate year and month if day of the month is not known (i.e. YYYY-MM). Regional guidance might give date requirements for a marketing authorisation application.
Conformance	Mandatory

```
<approval>
 <outboundRelationship>
  <approval><!-- Marketing Authorisation Application -->
   <effectiveTime><low value="Application Date"/></effectiveTime>
```

B.2.17 Jurisdictional marketing authorisation

B.2.17.1 Country

User guidance	The country in which the jurisdictional marketing authorisation has been granted shall be provided in accordance with the ISO 3166-1 alpha-2 codes.
Conformance	Mandatory

B.2.17.2 Jurisdiction

User guidance	Where a marketing activity is undertaken in multiple subdivisions within a country. Such jurisdictional activities can be specified. Utilizing the term and term identifier.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Jurisdictional Marketing Authorisation -->
      <id extension="Jurisdiction Marketing Authorisation Number"
          root="Jurisdiction Marketing Authorisation Number System OID"/>
      <author>
       <territorialAuthority>
        <territory>
         <code code=" Jurisdiction Code"
             codeSystem=" Jurisdiction Code System" displayName="Country / Jurisdiction Name"/>
```

B.2.17.3 Marketing authorisation number

User guidance	The number for the marketing authorisation assigned by a medicines regulatory authority within a jurisdiction shall be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Jurisdictional Marketing Authorisation -->
      <id extension="Jurisdiction Marketing Authorisation Number"
          root="Jurisdiction Marketing Authorisation Number System OID"/>
```

B.2.17.4 Legal status of supply

User guidance	The legal status of supply for the Medicinal Product as applicable in a jurisdiction shall be described, using a suitable controlled vocabulary. The term and the term identifier shall be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <approval><!-- Jurisdictional Marketing Authorisation -->
      <pertinentInformation>
       <policy>
        <code code="Jurisdictional Legal Status of Supply Code" codeSystem="Code System OID"/>
```

B.2.18 Marketing status

User guidance	The marketing status describes the date when a packaged Medicinal Product is actually put on the market or the date as of which it is no longer available. It also indicates the legal status of supply (e.g. prescription only or non-prescription).
	There may be circumstances where additional information on marketing status is specific to local provisions within a jurisdiction (e.g. states, provinces or territories). Marketing status allows indicating these circumstances as well, where this is specifically applicable.
	Description of the status of the marketing of the Medicinal Product shall be provided (e.g. temporary cease, permanently cease, withdrawn from the market, marketed).
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <marketingAct><!-- Marketing Status -->
      <statusCode code="Marketing Status Code"/>
```

B.2.18.1 Country

User guidance	The country in which the marketing activity is undertaken shall be specified. It should be specified using the ISO 3166-1 alpha-2 codes.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <marketingAct><!-- Marketing Status -->
      <location>
       <role>
        <playingTerritory>
         <code code="Country / Jurisdiction Code"
            codeSystem="Country / Jurisdiction Code System"/>
         <name>Country / Jurisdiction Name</name>
```

B.2.18.2 Jurisdiction

User guidance	Where a marketing activity is undertaken in multiple subdivisions within a country. Such jurisdictional activities can be specified. Utilizing the term and term identifier.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <marketingAct><!-- Marketing Status -->
      <location>
       <role>
        <playingTerritory>
         <code code="Country / Jurisdiction Code"
             codeSystem="Country / Jurisdiction Code System"/>
         <name>Country / Jurisdiction Name</name>
```

B.2.18.3 Marketing status

User guidance	Information on the status of the marketing of the Medicinal Product (e.g. temporary cease, permanently cease, withdrawn from the market, marketed, not marketed)
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <marketingAct><!-- Marketing Status -->
      <statusCode code="active"/>
      <effectiveTime>
       <low value="Marketing Date Start"/>
```

The action that lead to the cessation of marketing is recorded as an action element of the marketing act, wherein all the details of the decision can be specified:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <marketingAct><!-- Marketing Status -->
      <statusCode code="suspended"/>
      <effectiveTime>
       <low value="Marketing Date Start"/>
      </effectiveTime>
      <subjectOf>
       <action>
        <code code="Marketing Cessation Action Code"
            codeSystem="Action Code System (OID)"
            displayName="Marketing Cessation Action Display Name"/>
        <effectiveTime value="Action Date"/>
        <reasonCode code="Reason Code (if necessary at all)"
             codeSystem="Reason Code System OID"
             displayName="Reason Display Name"/>
        <author><!-- Organisation Who Took the Action --></author>
```

The marketing cessation action code encodes the reason, for example "marketing ordered to be suspended under legal authority such and such, citing code of law, by section and paragraph, etc."

NOTE   If a reason code, in addition to the action code is necessary, it can be placed in the reasonCode element.

B.2.18.4 Marketing date (start/stop)

User guidance	The date when the packaged Medicinal Product is "placed on the market" by the marketing authorisation holder (or where applicable, the manufacturer/distributor) in a country and/or jurisdiction shall be provided as shall the date when the packaged Medicinal Product is "no longer available on that market".
	"Placed on the market" refers to release of the packaged Medicinal Product into the distribution chain.
	NOTE 1 "No longer available on the market" can refer to the fact that the marketing authorisation holder has taken a decision to no longer market the packaged Medicinal Product or that the marketing authorisation is no longer valid.
	NOTE 2 Marketing date(s) refers to each instance of a packaged Medicinal Product (PCID level).
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product --></manufacturedProduct>
    <subjectOf>
     <marketingAct><!-- Marketing Status -->
      <statusCode code="Marketing Status Code"/>
      <effectiveTime>
       <low value="Marketing Date Start"/>
       <high value="Marketing Date Stop"/>
```

B.2.18.5 Risk of supply shortage

User guidance	Indication of whether there is a risk of a drug supply shortage availability within a given region. Refer to regional guidance for what constitutes a risk of drug supply shortage within a given region.
Conformance	Conditional

B.2.18.6 Risk of supply shortage comment

User guidance	Any additional comment on drug supply shortage. See regional guidance for what constitutes a risk of drug supply shortage within a given region.
Conformance	Conditional

B.2.19 Status reasons

User guidance	This class shall describe the reason of a legal action taken on the marketing or on the marketing authorisation and in reference to the status of these elements (e.g. the marketing status is permanently ceased as the medicine is harmful).
Conformance	Conditional

B.2.19.1 Reason

User guidance	The reason of an action taken on the marketing or on the marketing authorisation due to any of the following grounds that may be provided: — the medicine is harmful; — the medicine lacks therapeutic efficacy; — the risk-benefit balance of the medicine is not favourable; — the qualitative and quantitative composition of the medicine are not as declared; — manufacturing or inspection issues have been identified.
Conformance	Conditional

B.2.19.2 Reason comment

User guidance	Additional comment on the reason of a legal action taken on the marketing or on the marketing authorisation.
Conformance	Conditional

B.2.19.3 Legal grounds

User guidance	The legal grounds of the action taken on the marketing or on the marketing authorisation.
Conformance	Conditional

B.2.19.4 Legal grounds comment

User guidance	Any additional description of the action taken on the marketing or on the marketing authorisation.
Conformance	Conditional

B.2.19.5 Restore date

User guidance	The date when the marketing or the marketing authorisation of the product is anticipated to be restored (e.g. the date of the lift of the marketing authorisation suspension). The date when the marketing or the marketing of the product is restored may be provided (e.g. the date of the lift of the marketing authorisation suspension). A date shall be specified using the ISO 8601 date format.
Conformance	Optional

B.2.19.6 Condition to restore

User guidance	The condition under which the marketing authorisation or the marketing is restored may be provided.
Conformance	Conditional

B.2.19.7 Condition to restore comment

User guidance	Additional comments on the date when the condition of the marketing or the marketing of the product being restored may be provided.
Conformance	Conditional

B.2.19.8 Change request organisation type

User guidance	The organisation that triggered the legal action taken on the marketing or on the marketing authorisation (e.g. marketing authorisation revoked by the competent authority, marketing authorisation not renewed by the MAH).
Conformance	Optional

B.2.19.9 Geographic area for action taken

User guidance	The geographic area where the legal action taken on the marketing or the on marketing authorisation is having effect.
Conformance	Optional

The following is the outline of package structure in HL7 SPL:

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

   <manufacturedProduct>
    <manufacturedProduct><!-- Manufactured Item / Medicinal Product -->
     <part><!-- If any parts present, the Medicinal Product is a kit -->
      <quantity><!-- Part Quantity --></quantity>
      <partProduct><!-- One Part Manufactured Item --></partProduct>
     </part>

     <part>
      <quantity><!-- Part Quantity --></quantity>
      <partProduct><!-- Other Part Manufactured Item / Device --></partProduct>
     </part>
     <asContent><!-- Immediate Package Item -->
      <quantity><!-- Packaged Quantity --></quantity>
      <containerPackagedProduct>

       <code code="PCID Item Code" codeSystem="Item Code System OID">
        <!-- presence of PCID indicates Packaged Medicinal Product -->
       </code>
       <asContent><!-- Intermediary Package Item (if any) -->
        <quantity><!-- Packaged Quantity --></quantity>
        <containerPackagedProduct>
         <code code="PCID Item Code" codeSystem="Item Code System OID">

          <!-- presence of PCID indicates Packaged Medicinal Product -->
         </code>
         <asContent><!-- Outer Package Item (if not the same as inner) -->
          <quantity><!-- Packaged Quantity --></quantity>
          <containerPackagedProduct>

           <code code="PCID Item Code" codeSystem="Item Code System OID">
            <!-- presence of PCID indicates Packaged Medicinal Product -->
           </code>
          </containerPackagedProduct>

         </asContent>
        </containerPackagedProduct>
       </asContent>
      </containerPackagedProduct>
     </asContent>
```

Please note the following to understand the relationship between the ISO 11615, packaged Medicinal Product model and the HL7 SPL representation:

SPL contains manufactured product entities which comprises the following elements: manufacturedProduct, containerPackagedProduct, and partProduct. Any Medicinal Product is considered to be a manufactured product, including Medicinal Products requiring reconstitution. The following concepts from ISO 11615 are all considered manufactured products in the HL7 SPL standard: Medicinal Product, Pharmaceutical Product, Packaged Medicinal Product, Manufactured Item, Package Item (Container), Package (Component), and Device.

The pharmaceutical product is considered to be any finished dose form without material change or with a material change through a reconstitution/transformation process. In cases that include the reconstitution of several manufactured items or the loading of required applicator devices, the pharmaceutical product is the reconstituted product as authorised by a medicines regulatory agency. The manufactured item and the package item is considered the product as initially produced and delivered by the manufacturer which may require reconstitution/transformation into the pharmaceutical product. This subclause focuses on the description of the products as delivered by the manufacturer.

The ISO 11615 model has a Package Item (Container) class with a recursive relationship with zero-or-more multiplicity. The Package Item can represent multi-level packaging (i.e. packages within

packages). ISO 11615 recognises the existence of an "outer" package and "inner package", which would be assigned a PCID.

HL7 SPL accommodates the serialisation of packaging data by beginning with the single manufactured item (i.e. the amoxicillin 250 mg capsule), and then listing each direct packaging variant as nested elements named <asContent>, indicating that the mentioned element exists as the content of a container/packaged product.

The container/packaged product may exist as the content of an outer container/packaged product and so forth. The general pattern being:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Manufactured Item -->
     <asContent><!-- Immediate Package Item -->
      <quantity><!-- Packaged Quantity --></quantity>
      <containerPackagedProduct>
       <code code="Package Item Code" codeSystem="Item Code System OID"/>
       <asContent><!-- Intermediary Package Item (if any) -->
        <quantity><!-- Packaged Quantity --></quantity>
        <containerPackagedProduct>
         <code code="Package Item Code" codeSystem="Item Code System OID"/>
         <asContent><!-- Outer Package Item (if not the same as inner) -->
          <quantity><!-- Packaged Quantity --></quantity>
          <containerPackagedProduct>
           <code code="Package Item Code"
             codeSystem="Item Code System OID"/>
```

EXAMPLE   Amoxicillin trihydrate equivalent to 250 mg anhydrous amoxicillin packaged in either three blister packs of 10 in a carton, or in a bulk bottle of 1 000, is represented as:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>

    <manufacturedProduct><!-- Manufactured Item -->
     <formCode code="C25158" displayName="CAPSULE"
          codeSystem="2.16.840.1.113883.3.26.1.1" />
     <asContent><!-- Immediate Package Item #10 blister pack -->
      <quantity><numerator value="10" unit="1"/></quantity>
      <containerPackagedProduct>

       <formCode code="C43168" displayName="BLISTER PACK"
            codeSystem="2.16.840.1.113883.3.26.1.1"/>
       <asContent><!-- Outer Package Item #3 carton -->
        <quantity><numerator value="3" unit="1"/></quantity>
        <containerPackagedProduct>
         <formCode code="C43182" displayName="CARTON"
             codeSystem="2.16.840.1.113883.3.26.1.1"/>

        </containerPackagedProduct>
       </asContent>
      </containerPackagedProduct>
     </asContent>
     <asContent><!--Only (Inner and Outer) Package Item #1000 bottle -->

      <quantity><numerator value="1000" unit="1"/></quantity>
      <containerPackagedProduct>
       <formCode code="C43169" displayName="BOTTLE"
            codeSystem="2.16.840.1.113883.3.26.1.1"/>
      </containerPackagedProduct>
     </asContent>
```

Co-packaging of multiple different manufactured items in one is considered a "Kit". A Kit is defined as a manufactured product which comprises more than one different part, each part being in turn a manufactured product. The general pattern is as follows:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Package Item (co-package), Kit -->
     <formCode code="C47916" displayName="KIT"
          codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <part>
      <quantity><!-- Part Quantity --></quantity>
      <partProduct><!-- One Part Manufactured Item --></partProduct>
     </part>
     <part>
      <quantity><!-- Part Quantity --></quantity>
      <partProduct><!-- Other Part Manufactured Item / Device --></partProduct>
```

NOTE   The part-relationship is a relationship between products, the packaging is incidental. For instance, if a kit consists of a vial with a powder, another vial with 2 ml of a diluent, and a syringe with needle, such kit is considered to have as parts, (1) the powder, (2) 2 ml of diluent, and (3) the syringe, and (4) the needle:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>

    <manufacturedProduct><!-- Package Item (co-package), Kit -->
     <formCode code="C47916" displayName="KIT"
          codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <part>
      <quantity><numerator value="1" unit="1"/></quantity>

      <partProduct><!-- Powder Manufactured Item -->
       <formCode code="C42973" displayName="POWDER, FOR SOLUTION"
          codeSystem="2.16.840.1.113883.3.26.1.1"/>
      </partProduct>
     </part>
     <part>
      <quantity><numerator value="2" unit="ml"/></quantity>

      <partProduct><!-- Diluent Manufactured Item -->
       <formCode code="C42953" displayName="LIQUID"
          codeSystem="2.16.840.1.113883.3.26.1.1" />
      </partProduct>
     </part>
     <part>
      <quantity><numerator value="1" unit="1"/></quantity>
      <partProduct><!-- Syringe Device-->
       <asSpecialisedKind>
        <generalisedMaterialKind>

         <code code="FMF" displayName="Piston Syringe"
          codeSystem="2.16.840.1.113883.6.303"/>
        </generalisedMaterialKind>
       </asSpecialisedKind>
      </partProduct>
     </part>
     <part>

      <quantity><numerator value="1" unit="1"/></quantity>
      <partProduct><!-- Needle Device-->
       <asSpecialisedKind>
        <generalisedMaterialKind>
         <code code="GAA" codeSystem="2.16.840.1.113883.6.303"
          displayName="Needle, Aspiration and Injection, Disposable"/>
        </generalisedMaterialKind>
       </asSpecialisedKind>
      </partProduct>
     </part>
```

Additional information may be added for manufactured items and kit(s) (e.g. powder and diluent are in two different vials; the syringe and needle in two separate sterile bags), but does not change the direct part relationship between the manufactured items and the kit:

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

   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- (Package Item (co-package), Kit -->
     <part>
      <quantity><numerator value="1" unit="1"/></quantity>
      <partProduct><!-- Powder Manufactured Item -->

       <formCode code="C42973" displayName="POWDER, FOR SOLUTION"
            codeSystem="2.16.840.1.113883.3.26.1.1"/>
       <asContent><!-- Vial Package Item -->
        <quantity><numerator value="1" unit="1"/></quantity>
        <containerPackagedProduct>
         <formCode code="C43226" displayName="VIAL"
             codeSystem="2.16.840.1.113883.3.26.1.1"/>

        </containerPackagedProduct>
       </asContent>
      </partProduct>
     </part>
     <part>
      <quantity><numerator value="2" unit="ml"/></quantity>

      <partProduct><!-- Diluent Manufactured Item -->
       <formCode code="C42953" displayName="LIQUID"
            codeSystem="2.16.840.1.113883.3.26.1.1" />
       <asContent><!-- Bottle Package Item -->

        <quantity><numerator value="2" unit="ml"/></quantity>
        <containerPackagedProduct>
         <formCode code="C43169" displayName="BOTTLE"
             codeSystem="2.16.840.1.113883.3.26.1.1"/>
        </containerPackagedProduct>
       </asContent>
      </partProduct>
     </part>

     <part>
      <quantity><numerator value="1" unit="1"/></quantity>
      <partProduct><!-- Syringe Device-->
       <asSpecialisedKind>
        <generalisedMaterialKind>
         <code code="FMF" displayName="Piston Syringe"

             codeSystem="2.16.840.1.113883.6.303"/>
        </generalisedMaterialKind>
       </asSpecialisedKind>
       <asContent><!-- Bag Package Item -->
        <quantity><numerator value="2" unit="ml"/></quantity>
        <containerPackagedProduct>
         <formCode code="C43167" displayName="BAG"
             codeSystem="2.16.840.1.113883.3.26.1.1"/>
        </containerPackagedProduct>
       </asContent>
      </partProduct>
     </part>
```

NOTE   With containers of parts, the content quantity numerator unit is the same as the numerator unit of the part quantity, and the numerator values may be an integer fraction of the part quantity numerator value.

When the Kit as a whole is packaged, this is represented by marking the kit as the content of a container packaged product, as in the above example, where the kit is in a carton:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- (Package Item (co-package), Kit -->
     <formCode code="C47916" displayName="KIT"
     <asContent><!-- Outer Package Item #3 carton -->
      <quantity><numerator value="1" unit="1"/></quantity>
      <containerPackagedProduct>
       <formCode code="C43182" displayName="CARTON"
            codeSystem="2.16.840.1.113883.3.26.1.1"/>
      </containerPackagedProduct>
     </asContent>
           codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <part><!-- Powder Manufactured Item --></part>
     <part><!-- Diluent Manufactured Item --></part>
     <part><!-- Syringe Device --></part>
     <part><!-- Needle Device --></part>
```

NOTE   With containers of kits, the content quantity numerator unit is 1 (i.e. the kit represents one countable item) and with ISO 11615 SPL the numerator value is also 1 (i.e. exactly one kit is packaged in one kit package.)

HL7 SPL allows for item codes are specified at every level to support regional implementation requirements (see xml snippets above and below).

```
<manufacturedProduct>
 <manufacturedProduct><!-- Manufactured Item -->
  <code code="Item Code" codeSystem="Item Code System OID"/>

<asContent>
 <containerPackagedProduct><!-- Package Item -->
  <code code="Item Code" codeSystem="Item Code System OID"/>

<part>
 <partProduct><!-- (Component) Manufactured Item -->
  <code code="Item Code" codeSystem="Item Code System OID"/>
```

NOTE   Assignment of item codes is not hampered by the inability to represent such codes on the respective product at that level.

C.2 Detailed description of packaged Medicinal Product information
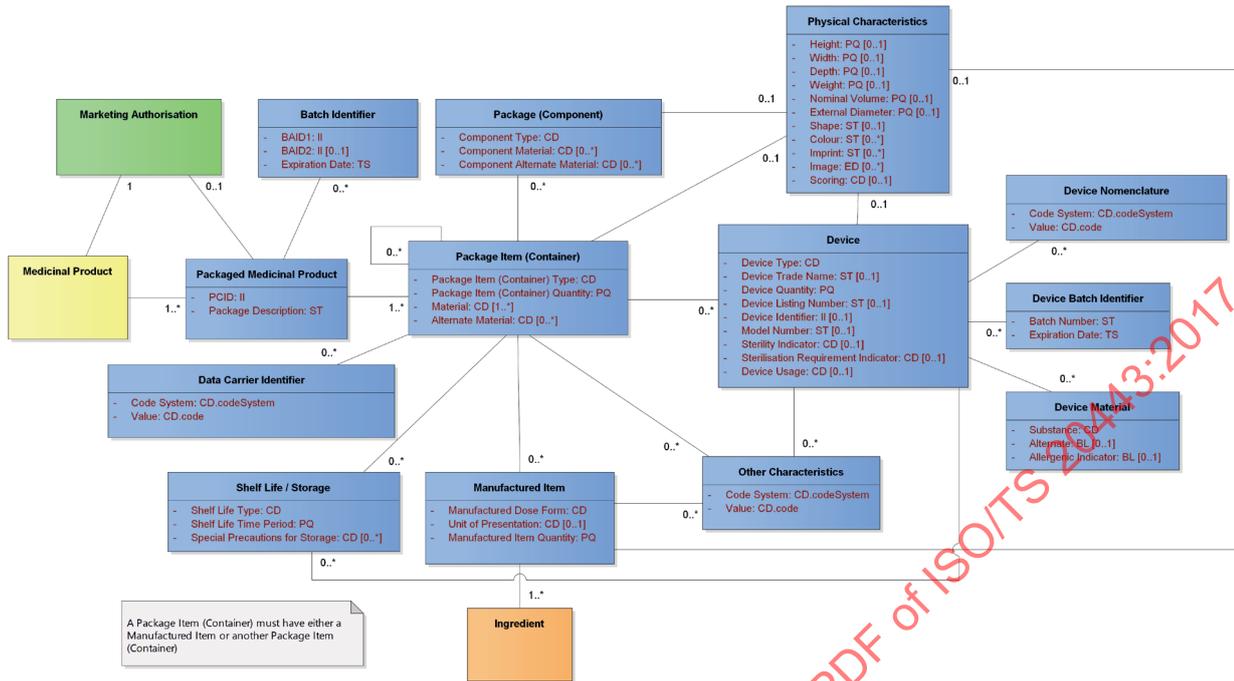
Figure C.1 — Packaged Medicinal Product section detailed description diagram

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>…
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>

    <manufacturedProduct><!-- Manufactured Item / Medicinal Product -->
     <formCode code="C47916" displayName="KIT"
          codeSystem="2.16.840.1.113883-3.26.1.1"/>
     <part><!-- If any parts present, the Medicinal Product is a kit -->
      <quantity><!-- Part Manufactured Item Quantity --></quantity>
      <partProduct><!-- One Part Manufactured Item --></partProduct>
     </part>
     <part>
      <quantity><!-- Part Manufactured Item Quantity --></quantity>
      <partProduct><!-- Other Part Manufactured Item / Device --></partProduct>

     </part>
     <part><!-- Device -->
      <code code="Device Type (Role) Code" displayName="Device Type Name"
          codeSystem="Device Type (Role) Code System (OID)"/>
      <quantity><!-- Device Quantity --></quantity>
      <partProduct>
       <asIdentifiedEntity>

        <id extension="Device Listing Number" root="Number System (OID)"/>
        <code code="Fixed Code meaning 'Device Listing Number'"
          codeSystem="Fixed Code System (OID)"/>
       </asIdentifiedEntity>
       <asIdentifiedEntity>
        <id extension="Model Number" root=" Code System (OID)"/>
        <code code="C99286" displayName="Model Number"
          codeSystem=" Code System (OID)"/>
       </asIdentifiedEntity>
       <asSpecialisedKind><!-- Device Nomenclature -->
        <generalisedMaterialKind>
```

```
          <code code="Nomenclature Term Code" displayName="Term Name"
              codeSystem="Nomenclature Coding System (OID)"/>
        </generalisedMaterialKind>
      </asSpecialisedKind>
      <ingredient>
        <!-- Device Material / Alternate Material / Allergene -->
      </ingredient>
    </partProduct>
    <subjectOf>
      <characteristic>

        <!-- Sterility / Sterilisation Required Indicator -->
        <!-- Device Usage -->
        <!-- Physical Characteristics -->
        <!-- Other Characteristics -->
        <code code="Characteristic Code" codeSystem="Code System (OID)"/>
        <value xsi:type="Value Type" ... /><!-- Characteristic Value (Various Attributes)-->
      </characteristic>
    </subjectOf>
  </part>

  <asContent><!-- Immediate Package Item -->
    <quantity><!-- Packaged Quantity --></quantity>
    <containerPackagedProduct>
      <code code="PCID Item Code" codeSystem="Item Code System OID">
        <!-- presence of PCID indicates Packaged Medicinal Product -->
      </code>
      <desc>Package Description</desc>
      <formCode code="Package Item (Container) Type Code"
          displayName="Package Type Name"
          codeSystem="Package Type Code System (OID)"/>
      <asIdentifiedEntity>

        <id extension="Data Carrier Identifier"
          root="Data Carrier Id System (OID)"/>
      </asIdentifiedEntity>
      <asSpecialisedKind>
        <generalisedMaterialKind>
          <code code="Item Code of Container as Manufactured Product"
              codeSystem="Item Code System"/>
        </generalisedMaterialKind>
      </asSpecialisedKind>

      <asContent><!-- Intermediary Package Item (if any) -->
        <quantity><!-- Packaged Quantity --></quantity>
        <containerPackagedProduct>
          <code code="PCID Item Code" codeSystem="Item Code System OID">
            <!-- presence of PCID indicates Packaged Medicinal Product -->
          </code>

          <asContent><!-- Outer Package Item (if not the same as inner) -->
            <quantity><!-- Packaged Quantity --></quantity>
            <containerPackagedProduct>
              <code code="PCID Item Code" codeSystem="Item Code System OID">
                <!-- presence of PCID indicates Packaged Medicinal Product -->
```

```
        </code>
      </containerPackagedProduct>
     </asContent>
    </containerPackagedProduct>
   </asContent>
  </containerPackagedProduct>
 </asContent>
   </manufacturedProduct>
 </manufacturedProduct>

</subject>
<subject>
 <manufacturedProduct><!-- Container Details -->
  <code code="Item Code of Container as Manufactured Product"
    codeSystem="Item Code System"/>
  <ingredient><!-- Material / Alternate Material --></ingredient>
  <part><!-- Package Component -->

   <partProduct>
   <asSpecialisedKind>
    <generalisedMaterialKind>
     <code code="Package Component Type Code" displayName="Type Name"
       codeSystem="Code System (OID)"/>
    </generalisedMaterialKind>
   </asSpecialisedKind>
   <ingredient><!-- Material / Alternate Material --></ingredient>
```

C.3 Packaged Medicinal Product

User guidance	See description below.
Conformance	Mandatory

A definitive "outer" package to a packaged Medicinal Product shall be assigned a PCID. Layers of intermediate packaging may be represented within the same manufactured item. There shall be one packaged Medicinal Product with PCID for each available packaging variant.

EXAMPLE 1   Capsules of amoxicillin 250 mg available in a bulk bottle of 1 000 or in a carton of three blister packs each holding 10 capsules. In the ISO model, this is represented as:

— Medicinal product: MPID#1 (pharmaceutical product: amoxicillin 250 mg capsule)
  — Packaged Medicinal Product PCID#1
    — 1 × package item: bottle
      —1 000 × manufactured item: amoxicillin 250 mg capsule
  — Packaged Medicinal Product PCID#2
    — 1 × package item: carton
      — 3 × package item: blister pack
        — 10 × manufactured item: amoxicillin 250 mg capsule

NOTE   Within the example, there is only one type of manufactured item, the amoxicillin 250 mg capsule, which is identical whether packaged into the bottle of 1 000 or the blister pack of 10.

HL7 SPL serialises packaging data by beginning with the single manufactured item (i.e. the amoxicillin 250 mg capsule), and then listing each direct packaging variant as nested elements named <asContent>, indicating that the mentioned element exists as the content of a container/packaged product. In turn, the container/packaged product may exist as the content of an outer container/packaged product. HL7 SPL lists every manufactured item only once, and then enumerates all the packaging variants as a tree from the inner-most to the outer-most package.

— Manufactured item: amoxicillin 250 mg capsule

  — as content in qty 1 000 of package item: bottle

— as content in qty 10 of package item: blister pack

   — as content in qty three of package item: carton

Every path through this tree of packaging variants may be called a "container lineage", in this case, there are two container lineages:

— as content in qty 1 000 of package item: b

— as content in qty 1 000 of package item: b

There would be three package lineages if the blister packs were also available separately:

   — as content in qty 1 000 of package item: bottle

   — as content in qty 10 of package item: blister pack

   — as content in qty 10 of package item: blister pack, as content in qty three of package item: carton

The ISO 11615 model would then be:

— Medicinal product: MPID#1 (pharmaceutical product: amoxicillin 250mg capsule)

   — Packaged Medicinal Product PCID#1

     — 1 × package item: bottle

       —1 000 × manufactured item: amoxicillin 250 mg capsule

   — Packaged Medicinal Product PCID#2

     — 1 × package item: carton

       — 3 × package item: blister pack

         — 10 × manufactured item: amoxicillin 250 mg capsule

   — Packaged Medicinal Product: PCID #3

     — 1 × package item: blister pack

       — 10 × manufactured item: amoxicillin 250 mg capsule

The PCID may be the item code of the outer-most package and each such lineage is represented as one packaged Medicinal Product.

In summary, whenever a container packaged product has an item code, it would be considered both a package item and a packaged Medicinal Product with the PCID representing the package item code. When there is no package item code, the element represents a package item only, not a packaged Medicinal Product.

EXAMPLE 2   Packaged Medicinal Products:

— Medicinal product: MPID#1 and manufactured item, amoxicillin 250 mg capsule
   — as content in qty 1 000 of package item: bottle, packaged Medicinal Product: PCID#1
   — as content in qty 10 of package item: blister pack
     — as content in qty three of package item: carton, packaged Medicinal Product: PCID#2

C.3.1 PCID

User guidance	The unique identifier for the packaged Medicinal Product shall be provided.
Conformance	Mandatory

```
<asContent>
 <containerPackagedProduct><!-- Packaged Medicinal Product -->
  <code code="PCID Item Code" codeSystem="Item Code System OID"/>
```

C.3.2 Package description

User guidance	A textual description of the packaged Medicinal Product shall be provided.
Conformance	Mandatory

```
<asContent>
 <containerPackagedProduct><!-- Packaged Medicinal Product -->
  <code code="PCID Item Code" codeSystem="Item Code System OID"/>
  <desc>Package Description</desc>
```

C.3.3 Batch identifier

User guidance	Identification number assigned to a particular quantity or lot of material from a single manufacturer shall be provided.
Conformance	Mandatory

C.3.3.1 BAID1

User guidance	The BAID 1 as described in ISO 11615 and within this document appears on the outer packaging of a specific batch of the Medicinal Product. Since there will be many different batches of any one packaged Medicinal Product, the cardinality of the relationship between the packaged Medicinal Product and the batch identifier is given as 1..*. In situations where a packaged Medicinal Product contains more than one manufactured item and/or includes a device, this batch number refers to the one given on the outermost packaging.
Conformance	Mandatory

A batch or lot is a bulk instance of a product. The batch has existence regardless of packaging. Batches are subdivided and combined. In a normal production activity for a finished drug product multiple ingredient lots are combined to create a fill lot which may then be subdivided into final container lots.

Batch or lot identification is connected to the product (not to the container), either the main product:

```
<!-- CPM body -->
<manufacturedProduct>
 <manufacturedProduct>
  <instanceOfKind>
```

or a part

```
<part>
 <partProduct>
  <instanceOfKind>
```

the instance of kind element has the following levels:

```
<instanceOfKind>
 <productInstance><!-- Fill Lot -->
  <id root="oid" extension="BAID2"/>
   <ingredient><!-- ingredient batch --></ingredient>
   <asMember>
    <groupProductInstance><!-- Final Container Lot -->
     <id root="oid" extension="BAID1"/>
     <expirationTime>
      <high value="Expiration Date"/>
     </expirationTime>
     <asContent>
       <container>
        <code code="PCID" codeSystem="Code System (OID)"/>
       </container>
```

C.3.3.2   BAID2

User guidance	The BAID 2, as described in ISO 11615 and within this document, appears on the immediate packaging in a multi-level package presentation.
Conformance	Conditional

C.3.3.3   Expiration date

User guidance	The expiration date for the batch shall be specified.
Conformance	Mandatory

```
<instanceOfKind>
 <productInstance>
  <id .../>
  <expirationTime>
   <high value="Expiration Date"/>
  </expirationTime>
 </productInstance>
```

C.3.4   Package item (container)

User guidance	A package item can be either a single item or package of multiple items. Those items can be of the same kind or of different kinds.
	If they are of the same kinds, it shall be represented using the as content/container packaged product elements.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Manufactured Item -->
     <asContent><!-- Immediate Package Item -->
      <quantity><!-- Packaged Quantity --></quantity>
      <containerPackagedProduct>
       <code code="Package Item Code" codeSystem="Item Code System OID"/>
      </containerPackagedProduct>
     </asContent>
```

If they are of different kinds, they are represented by defining a kit product with parts.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Package Item (co-package), Kit -->
     <formCode code="C47916" displayName="KIT"
          codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <part>
      <quantity><!-- Part Quantity --></quantity>
      <partProduct><!-- One Part Manufactured Item --></partProduct>
     </part>
     <part>
      <quantity><!-- Part Quantity --></quantity>
      <partProduct><!-- Other Part Manufactured Item / Device --></partProduct>
     </part>
```

There shall be one **packaged item** for each distinct kind of packaged item in a **packaged Medicinal Product**. The number (quantity) shall be given in the instance there are more than one identical packaged items. More detailed descriptions in related classes shall be related to the single item only.

Where a **packaged item** contains a further package, **packaged item** shall be nested to provide the correct representation.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Manufactured Item -->
     <asContent><!-- Immediate Package Item -->
      <quantity><!-- Packaged Quantity --></quantity>
      <containerPackagedProduct>
       <code code="Package Item Code" codeSystem="Item Code System OID"/>
       <asContent><!-- Intermediary Package Item (if any) -->
        <quantity><!-- Packaged Quantity --></quantity>
        <containerPackagedProduct>
         <code code="Package Item Code" codeSystem="Item Code System OID"/>
         <asContent><!-- Outer Package Item (if not the same as immediate) -->
          <quantity><!-- Packaged Quantity --></quantity>
          <containerPackagedProduct>
           <code code="Package Item Code" codeSystem="Code System OID"/>
```

EXAMPLE 1   A Medicinal Product presented as a packaged Medicinal Product with a single package, a bottle containing an oral solution (no outer box), will have a single package item (related directly to a single manufactured item).

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Manufactured Item / Medicinal Product -->
     <code code="MPID Item Code" codeSystem="Item Code System OID"/>
     <formCode code="C42986" displayName="SOLUTION"
          codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <asContent><!-- Only Package Item / Packaged Medicinal Product -->
      <containerPackagedProduct>
       <code code="PCID Item Code" codeSystem="Item Code System OID"/>
       <formCode code="C43169" displayName="BOTTLE"
            codeSystem="2.16.840.1.113883.3.26.1.1"/>
      </containerPackagedProduct>
     </asContent>
    </manufacturedProduct>
```

EXAMPLE 2   A Medicinal Product presented as a packaged Medicinal Product with an outer package with immediate packaging, a box of two blister sleeves each containing 20 capsules, will be represented as multi-level package items; the parent package item to describe the box and the child packaged item to describe the blister (the latter then related to the manufactured item) – in SPL, the "parent" is the manufactured item and the packages nested from inner to outer level.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Manufactured Item / Medicinal Product -->
     <code code="MPID Item Code" codeSystem="Item Code System OID"/>
     <formCode code="C25158" displayName="CAPSULE"
          codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <asContent><!-- Immediate Package Item -->
      <quantity><numerator value="20" unit="1"/></quantity>
      <containerPackagedProduct>
       <formCode code="C43168" displayName="BLISTER PACK"
            codeSystem="2.16.840.1.113883.3.26.1.1"/>
       <asContent><!-- Outer Package Item / Packaged Medicinal Product -->
        <quantity><numerator value="2" unit="1"/></quantity>
        <containerPackagedProduct>
         <code code="PCID Item Code" codeSystem="Item Code System OID"/>
         <formCode code="C43178" displayName="BOX"
              codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

EXAMPLE 3   A carton containing 4 vials of solution for injection, will have two recursed package items; the parent package item to describe the carton and the child packaged item to describe the blister or the vial (the latter then related to the Manufactured Item), in SPL, the "parent" is the manufactured item and the packages nested from inner to outer level.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Manufactured Item / Medicinal Product -->
     <code code="MPID Item Code" codeSystem="Item Code System OID"/>
     <formCode code="C42945" displayName="INJECTION, SOLUTION"
          codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <asContent><!-- Immediate Package Item -->
      <quantity><numerator value="1" unit="ml"/></quantity>
      <containerPackagedProduct>
       <formCode code="C43226" displayName="VIAL"
            codeSystem="2.16.840.1.113883.3.26.1.1"/>
       <asContent><!-- Outer Package Item / Packaged Medicinal Product -->
        <quantity><numerator value="4" unit="1"/></quantity>
        <containerPackagedProduct>
         <code code="PCID Item Code" codeSystem="Item Code System OID"/>
         <formCode code="C43182" displayName="CARTON"
              codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

EXAMPLE 4   A Medicinal Product "kit" presented as a packaged Medicinal Product with an outer package containing more than one type of content, for example, a box containing a tube (of cream) and a blister sleeve containing a tablet, will have a recursed parent package item to describe the box and two child packaged items to describe the tube and the blister (each then related to an manufactured item) – in SPL a kit is considered a manufactured item by itself, independent of its packaging, and it has two manufactured items as parts, and each of the three manufactured items (the kit and the two different parts) also have package specifications:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>

    <manufacturedProduct><!-- Kit Manufactured Item / Medicinal Product -->
     <code code="MPID Item Code" codeSystem="Item Code System OID"/>
     <formCode code="C47916" displayName="KIT"
          codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <part>
          codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <quantity><numerator value="5" unit="g"/></quantity>
      <partProduct><!-- Part Manufactured Item -->
       <formCode code="C28944" displayName="CREAM"
            codeSystem="2.16.840.1.113883.3.26.1.1"/>
       <asContent><!-- Part Package Item -->

        <quantity><numerator value="5" unit="g"/></quantity>
        <containerPackagedProduct>
         <formCode code="C42794" displayName="TUBE"
              codeSystem="2.16.840.1.113883.3.26.1.1"/>

        </containerPackagedProduct>
       </asContent>
      </partProduct>
     </part>
     <part>
```

```
   <quantity><numerator value="1" unit="1"/></quantity>
   <partProduct><!-- Part Manufactured Item -->
    <formCode code="C42998" displayName="TABLET"
         codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <asContent><!-- Part Package Item -->

     <quantity><numerator value="1" unit="1"/></quantity>
     <containerPackagedProduct>
      <formCode code="C43168" displayName="BLISTER PACK"
          codeSystem="2.16.840.1.113883.3.26.1.1"/>
     </containerPackagedProduct>
    </asContent>

   </partProduct>
  </part>
  <part>
  <asContent><!-- Outer Package Item / Packaged Medicinal Product -->
   <quantity><numerator value="1" unit="1"/></quantity>
   <containerPackagedProduct>
    <code code="PCID Item Code" codeSystem="Item Code System OID"/>
    <formCode code="C43178" displayName="BOX"
```

C.3.4.1 Package item (container) type

User guidance	"Package Item (Container) Type" describes the physical type of the container of the medicine in accordance with ISO 11239 and its resulting terminology. A term and a term identifier shall be specified.
Conformance	Mandatory

```
   <asContent>
    <containerPackagedProduct>
     <formCode code="Package Item (Container) Type Code"
          displayName="Package Type Name"
          codeSystem="Package Type Code System (OID)"/>
```

C.3.4.2 Package item (container) quantity

User guidance	The quantity (or count number) of the package item should be described. NOTE Because the package item class recurses to describe containers within containers, the first (outermost) container will always have a quantity of "1". This note does not apply to SPL, where the quantity is a property of the container-content-relationship, and because the outermost package item is not contained in anything else, no quantity need to be stated.
Conformance	Mandatory

```
   <asContent>
    <quantity>
     <numerator value="Package Item (Container) Quantity"
          unit="Quantity Unit"/>
     <denominator value="1" unit="1"/>
    </quantity>
    <containerPackagedProduct>
```

Quantity is always represented as numerator and denominator. The numerator is the amount of content and the denominator the number of containers. With packaging specification, the denominator shall always be one (1) (i.e. the numerator contains the quantity of content in one (1) container). Because of this, the denominator tag is usually omitted for brevity in the aforementioned XML snippets.

The numerator quantity unit shall be commensurate to the type of content. In all but inner packages, it is always "1" (i.e. the quantity of inner content-packages is simply counted). However, in inner packages the numerator quantity unit should be the same as the unit of the denominator of the strength.

NOTE   If the manufactured item is a countable ("each"), such as tablet, capsule, etc., then the unit is also "1".

If the manufactured item is measured by volume (millilitre, ml) or by mass (gram, g), then the inner package quantity numerator unit shall also be ml or g, respectively.

For part quantities, the format is similar:

```
<part>
 <quantity>
  <numerator value="Package Item (Container) / Manufactured Item Quantity"
       unit="Quantity Unit"/>
  <denominator value="1" unit="1"/>
 </quantity>
 <partProduct>
```

C.3.4.3   Material

User guidance	The material of the packaged item shall be described in accordance with ISO 11238 and its resulting terminology as applicable. A controlled term and a term identifier shall be specified
Conformance	Mandatory

The container is described in itself as a manufactured product:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct><!-- Container as Manufactured Product -->
    <code code="Item Code of Container as Manufactured Product"
       codeSystem="Item Code System"/>
    <ingredient classCode="INGR"><!-- Material -->
     <ingredientSubstance>
      <code code="Material Code" codeSystem="Code System (OID)"/>
      <name>Material Name</name>
```

The package item is a specialisation of a container described as a manufactured product within the item code:

```
<asContent><!-- Package Item -->
 <containerPackagedProduct>
  <asSpecialisedKind>
   <generalisedMaterialKind>
    <code code="Item Code of Container as Manufactured Product"
       codeSystem="Item Code System"/>
```

All the other details about the container are described in the element for the "Container as a Manufactured Product."

C.3.4.4   Alternate material

User guidance	The alternate material of the packaged item shall be described in accordance with ISO 11238, and its resulting terminology as applicable. A controlled term and a term identifier shall be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct><!-- Container as Manufactured Product -->
    <code code="Item Code of Container as Manufactured Product"
        codeSystem="Item Code System"/>
    <ingredient><!-- Material --></ingredient>
    <ingredient classCode="INGR"><!-- Alternate Material -->
     <ingredientSubstance>
      <code code="Alternate Material Code" codeSystem=" Code System (OID)"/>
      <name>Alternate Material Name</name>
     </ingredientSubstance>
    </ingredient>
```

C.3.5   Data carrier identifier

User guidance	Data carrier identifiers such as barcodes can be presented at each packaging level. Regulatory requirements can specify the data carrier(s) to be utilised. The data carrier identifier should be specified as required. The data carrier identification system itself should be specified using an appropriate identification system. The individual value from the identification system that applies to the packaged Medicinal Product and each package level should be specified.
Conformance	Optional

```
    <asContent><!-- Package Item -->
     <containerPackagedProduct>
      <asIdentifiedEntity>
       <id extension="Data Carrier Identifier"
         root="Data Carrier Id System (OID)"/>
```

C.3.5.1   (Data carrier identifier) code system

User guidance	The code describing the data carrier is specified using an appropriate controlled terminology.
	EXAMPLE Data carrier identification code system: GTIN.
Conformance	Mandatory

```
 <subjectOf>
  <characteristic>
   <code code="Data Carrier Code" codeSystem="Code System (OID)"
     displayName="Name of Characteristic"/>
```

C.3.5.2   (Data carrier identifier) value

User guidance	The individual value of the data carrier is specified.
Conformance	Mandatory

C.3.6   Package (component)

User guidance	See below.
Conformance	Mandatory

Any part of the packaging of a packaged Medicinal Product can be further described using the package (component) class. The description can be of a complete container or a part of a container, such as a closure.

To describe details about the container, the container is described in itself as a manufactured product, here with any number of parts, each of which has a container part nomenclature code and substances to describe their material.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct><!-- Container as Manufactured Product -->
    <code code="Item Code of Container as Manufactured Product"
       codeSystem="Item Code System"/>
    <part><!-- Package Component -->
     <partProduct>
      <asSpecialisedKind>
       <generalisedMaterialKind>
        <code code="Package Component Type Code" displayName="Type Name"
           codeSystem="Code System (OID)"/>
       </generalisedMaterialKind>
      </asSpecialisedKind>
      <ingredient classCode="INGR"><!-- Material / Alternate Material -->
       <ingredientSubstance>
        <code code="Material Code" codeSystem="Code System (OID)"/>
        <name>Material Name</name>
```

The described containers as a manufactured product with an item code of itself can be referenced as a generalisation of the package item:

```
    <asContent><!-- Package Item -->
     <containerPackagedProduct>
      <asSpecialisedKind>
       <generalisedMaterialKind>
        <code code="Item Code of Container as Manufactured Product"
           codeSystem="Item Code System"/>
```

C.3.6.1 Component type

User guidance	The type of component whose material is being described should be specified, using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.
Conformance	Mandatory

```
    <part><!-- Package Component -->
     <partProduct>
      <asSpecialisedKind>
       <generalisedMaterialKind>
        <code code="Package Component Type Code" displayName="Type Name"
           codeSystem="Code System (OID)"/>
```

C.3.6.2 Component material

User guidance	The material of the component can be specified. Materials shall be described in accordance with ISO 11238 standard and its resulting terminology. A controlled term and a controlled term identifier shall be specified as applicable.
Conformance	Optional

```
<part><!-- Package Component -->
 <partProduct>
  <ingredient classCode="INGR"><!-- Material -->
   <ingredientSubstance>
    <code code="Material Code" codeSystem="Code System (OID)"/>
    <name>Material Name</name>
```

C.3.6.3   Component alternate material

User guidance	Alternative materials for the component can be specified. Materials shall be described in accordance with ISO 11238 standard and its resulting terminology. A controlled term and a controlled term identifier shall be specified as applicable.
	Alternate material is used when alternative specific material(s) are allowed to be used for the manufacturing of the package (e.g. different types of rubber for a stopper).
Conformance	Optional

```
<part><!-- Package Component -->
 <partProduct>
  <ingredient><!-- Material --></ingredient>
  <ingredient classCode="INGR"><!-- Alternate Material -->
   <ingredientSubstance>
    <code code="Alternate Material Code" codeSystem="Code System (OID)"/>
    <name>Alternate Material Name</name>
```

The element is repeated as necessary.

C.3.7   Shelf life/storage

User guidance	The shelf life and storage information shall be described using the attributes of the shelf life/storage class.
	NOTE The shelf life and storage information for a package item (container) can be described using the shelf life/storage class.
Conformance	Conditional

```
<subject>
 <!-- CPM body -->
 <manufacturedProduct>
  <manufacturedProduct><!-- Medicinal Product -->
   <asContent><!-- Packaging -->
    <containerPackagedProduct>
     <asManufacturedProduct>
      <subjectOf>
       <storage>
        <code code="Shelf Life Type Code" codeSystem="Code System (OID)"/>
        <effectiveTime>
         <width value="Shelf Life Time Period (Number)" unit="Time Unit"/>
        </effectiveTime>
        <controlVariable>
         <storageCondition>
          <code code="Storage Condition Parameter Code" codeSystem="Code System (OID)" displayName="Display Name"/>
```

zero

true

standard

normal

C.3.7.1 Shelf life type

User guidance	This refers to the shelf life taking into account various scenarios such as shelf life of the packaged Medicinal Product itself, shelf life after transformation where necessary, shelf life after first opening of a bottle, etc. The shelf life type shall be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.
Conformance	Mandatory

```
<subject>
 <!-- CPM body -->
 <manufacturedProduct>
  <manufacturedProduct><!-- Medicinal Product -->
   <asContent><!-- Packaging -->
    <containerPackagedProduct>
     <asManufacturedProduct>
      <subjectOf>
       <storage>
        <code code="Shelf Life Type Code" codeSystem="Code System (OID)"/>
```

C.3.7.2 Shelf life time period

User guidance	The shelf life time period can be specified using as an interval of physical quantities. The unit of measure symbol and the symbol identifier as defined in ISO 11240 standard and its resulting controlled vocabulary shall be specified.
Conformance	Mandatory

```
<subject>
 <!-- CPM body -->
 <manufacturedProduct>
  <manufacturedProduct><!-- Medicinal Product -->
   <asContent><!-- Packaging -->
    <containerPackagedProduct>
     <asManufacturedProduct>
      <subjectOf>
       <storage>
        <code code="Shelf Life Type Code" codeSystem="Code System (OID)"/>
        <effectiveTime>
         <width value="Shelf Life Time Period (Number)" unit="Time Unit"/>
        </effectiveTime>
```

EXAMPLE 1   Three years unopened:

```
<subject>
 <!-- CPM body -->
 <manufacturedProduct>
  <manufacturedProduct><!-- Medicinal Product -->
   <asContent><!-- Packaging -->
    <containerPackagedProduct>
     <asManufacturedProduct>
      <subjectOf>
       <storage>
        <code code="Code for 'Unopened'" displayName="Unopened" codeSystem="Code System (OID)"/>
         <effectiveTime xsi:type="PQ">
          <width value="3" unit="a"/>
```

EXAMPLE 2   Twenty eight days after opening:

```
<subject>
 <!-- CPM body -->
 <manufacturedProduct>
   <manufacturedProduct><!-- Medicinal Product -->
    <asContent><!-- Packaging -->
     <containerPackagedProduct>
      <asManufacturedProduct>
       <subjectOf>
        <storage>
         <code code="Code for 'Opened'" displayName="Opened" codeSystem="Code System (OID)"/>
         <effectiveTime xsi:type="PQ">
          <width value="28" unit="d"/>
```

C.3.7.3   Special precautions for storage

User guidance	Special precautions for storage, if any, can be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.
Conformance	Conditional

```
<subject>
 <!-- CPM body -->
 <manufacturedProduct>
   <manufacturedProduct><!-- Medicinal Product -->
    <asContent><!-- Packaging -->
     <containerPackagedProduct>
      <asManufacturedProduct>
       <subjectOf>
        <storage>
         <code code="Shelf Life Type Code" codeSystem="Code System (OID)"/>
         <effectiveTime>
          <width value="Shelf Life Time Period (Number)" unit="Time Unit"/>
         </effectiveTime>
         <controlVariable>
          <storageCondition>
           <code code="Storage Condition Parameter Code" codeSystem="Code System (OID)" displayName="Display
Name"/>
```

C.3.8   Device

User guidance	Medicinal products may be authorised with accompanying devices. Devices may be of several types (see below in device type), such as separate administration devices, an integral administration device or a part of a Medicinal Product. Where a Medicinal Product is combined with a medical device and where the pharmacological, immunological or metabolic action should be considered as the principal mode of action, the medical device is presented as part of the pharmaceutical product.
Conformance	Conditional

```
<part>
<!-- Device -->
<code code="Device Type (Role) Code" displayName="Device Type Name"
        codeSystem="Device Type (Role) Code System (OID)"/>
<quantity><!-- Part Device Quantity --></quantity>
<partProduct>

 <name>Device Trade Name</name>
 <asIdentifiedEntity>
  <id extension="Device Listing Number" root="Number System (OID)"/>
  <code code="Fixed Code meaning 'Device Listing Number'" codeSystem="Fixed Code System (OID)"/>
 </asIdentifiedEntity>
 <asIdentifiedEntity>

  <id extension="Model Number" root=" Code System (OID)"/>
   <code code="C99286" displayName="Model Number" codeSystem=" Code System (OID)"/>
 </asIdentifiedEntity>
 <asSpecialisedKind><!-- Device Nomenclature -->
  <generalisedMaterialKind>
   <code code="Nomenclature Term Code" displayName="Term Name"

        codeSystem="Nomenclature Coding System (OID)"/>
  </generalisedMaterialKind>
 </asSpecialisedKind>
 <ingredient>
  <!-- Device Material / Alternate Material / Allergene -->
 </ingredient>
</partProduct>

<subjectOf>
 <characteristic>
  <!-- Sterility / Sterilisation Required Indicator -->
  <!-- Device Usage -->
  <!-- Physical Characteristics -->
  <!-- Other Characteristics -->
  <code code="Characteristic Code" codeSystem="Code System (OID)"/>
  <value xsi:type="Value Type" ... /><!-- Characteristic Value (Various Attributes)-->
```

C.3.8.1   Device type

User guidance	The type of Device shall be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.
Conformance	Mandatory

```
<part>
 <code code="Device Type (Role) Code" displayName="Device Type Name"
      codeSystem="Device Type (Role) Code System (OID)"/>
 <partProduct><!-- Device -->
```

C.3.8.2   Device trade name

User guidance	This can be used to specify the trade name of the device, where applicable.
Conformance	Conditional

```
<part>
 <partProduct><!-- Device -->
  <name>Device Trade Name</name>
```

```
  <part>
   <partProduct><!-- Device -->
    <asIdentifiedEntity>
     <id nullFlavor="NI" extension="Device Listing Number""/><!-- Number is a string, so use nullFlavor -->
     <code code="C99286" displayName="Model Number" codeSystem=" Code System (OID)"/>
```

C.3.8.7 Sterility indicator

User guidance	This shall be used to specify if the device is supplied as sterile using an appropriate controlled terminology. The controlled term and the controlled term identifier shall be specified.
Conformance	Conditional

The most important indication is about whether the device is intended for sterile use:

```
  <part>
   <partProduct><!-- Device --></partProduct>
   <subjectOf>
    <characteristic><!-- Sterility Indicator -->
     <code code="Sterility Indicator Characteristic Code" codeSystem="Code System (OID)"/>
     <value xsi:type="CV" code=" Sterility Indicator Code" codeSystem="Code System (OID)"/>
```

Example:

```
  <part>
   <partProduct><!-- Device --></partProduct>
   <subjectOf>
    <characteristic><!-- Sterility Indicator -->
     <code code="SPLSTERILEUSE" codeSystem="2.16.840.1.113883.1.11.19255"/>
     <value xsi:type="CV" code="Code meaning 'Sterile'" codeSystem="2.16.840.1.113883.3.26.1.1"
displayName="sterile"/>
```

Every sterile product will be inside at least an inner sealed package, for which see below, sterilisation requirement indicator.

C.3.8.8 Sterilisation requirement indicator

User guidance	Where applicable, this can be used to specify if the device shall be sterilised before use based on an appropriate controlled terminology. The controlled term and the controlled term identifier shall be specified.
Conformance	Conditional

If a device is not sterile in a package, but is intended for sterile use, then sterilisation is required. This need not be stated, but may be stated specifically at the level of the packaging:

```
  <part>
   <partProduct><!-- Device -->
    <asContent>
     <containerPackagedProduct><!-- Device Package --></containerPackagedProduct>
     <subjectOf>
      <characteristic><!-- Sterilisation Requirement Indicator -->
       <code code="SPLHYG" codeSystem="2.16.840.1.113883.1.11.19255"/>
       <value code="Code for 'to be sterilised'"
          codeSystem="2.16.840.1.113883.3.26.1.1"
          displayName="to be sterilised" xsi:type="CV"/>
```

C.3.8.9   Device usage

User guidance	This can be specified, where the number of times of use of the device is defined in the regulated product information. An appropriate controlled terminology shall be applied and the controlled term and the controlled term identifier specified.
Conformance	Conditional

```
<part>
 <partProduct><!-- Device --></partProduct>
 <subjectOf>
  <characteristic><!-- Device Usage -->
   <code code="Device Usage Characteristic Code" codeSystem="Code System (OID)"/>
   <value value="1" xsi:type="INT"/>
```

Example:

```
<part>
 <partProduct><!-- Device --></partProduct>
 <subjectOf>
  <characteristic><!-- Device Usage -->
   <code code="SPLUSE" codeSystem="2.16.840.1.113883.1.11.19255"/>
   <value value="1" xsi:type="INT"/>
```

SPLUSE specifies how often a product may be re-used. Typical values are 1 for single use (as above) or the "positive infinity" to mark unlimited uses.

Or if the usage is coded instead of purely numeric:

```
<part>
 <partProduct><!-- Device --></partProduct>
 <subjectOf>
  <characteristic><!-- Device Usage -->
   <code code="Device Usage Characteristic Code" codeSystem="2.16.840.1.113883.1.11.19255"/>
   <value xsi:type="CD" code="Device Usage as a code" codeSystem="Code System OID"/>
```

C.3.9   Device nomenclature

User guidance	There are a variety of nomenclature systems available to identify devices. This structure supports the description of the device in these nomenclature systems.
Conformance	Conditional

```
<part>
 <partProduct><!-- Device -->
  <asSpecialisedKind><!-- Device Nomenclature -->
   <generalisedMaterialKind>
    <code code="Device Nomenclature Value (Term Code)" displayName="Term Name"
      codeSystem="Device Nomenclature Code System (OID)"/>
```

C.3.9.1 (Device nomenclature) code system

User guidance	The device nomenclature system shall be specified using an appropriate identification system.
	NOTE The Unique Device Identifier (UDI) is an example of device identification system developed by the International Medical Device Regulators Forum (IMDRF) to address global identification of a medical device. If a regional authority chooses to implement the UDI standard, it can be captured within the Device Nomenclature Class.
	Example: Unique Device Identifier (UDI)
	User guidance: An identifier that unambiguously identifies a device through its distribution
	Conformance: Optional
	Although this category is optional, the listed conformance within the user guidance of this subclause corresponds to regions who shall mandate the UDI category in accordance with the IMDRF standards as applicable.
	Device Identifier (DI):
	User guidance: Device Identifier (DI): a mandatory, fixed portion of a UDI that identifies the specific product number of a device and the labeller of that device; for Medtronic products, this is the GS1 Global Trade Item Number (GTIN).
	Conformance: Optional
	Although this category is optional, the listed conformance within the user guidance of this subclause corresponds to regions who shall mandate the device category in accordance with the IDMP standards as applicable.
	If a Unique Device Identifier (UDI) is mandated in a particular region, the device identifier shall be the UDI in within the device classification.
	Production Identifier (PI):
	User guidance: Production Identifier (PI): A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
	— the lot or batch within which a device was manufactured;
	— the serial number of a specific device;
	— the expiration date of a specific device;
	— the date a specific device was manufactured;
	— for an HCT/P regulated as a device, the distinct.
	Conformance: Optional
	Although this category is optional, the listed conformance within the user guidance of this subclause corresponds to regions who shall mandate the UDI category in accordance with the IMDRF standards as applicable.
Conformance	Mandatory

```
<part>
 <partProduct><!-- Device -->
  <asSpecialisedKind><!-- Device Nomenclature -->
   <generalisedMaterialKind>
    <code code="Device Nomenclature Term Code" displayName="Term Name"
       codeSystem="Device Nomenclature Code System (OID)"/>
```

C.3.9.2 (Device nomenclature) value

User guidance	The term for the device from the specified nomenclature system shall be specified.
Conformance	Mandatory

```
<part>
 <partProduct><!-- Device -->
  <asSpecialisedKind><!-- Device Nomenclature -->
   <generalisedMaterialKind>
    <code code="Device Nomenclature Value (Term Code)" displayName="Term Name"
      codeSystem="Device Nomenclature Code System (OID)"/>
```

C.3.10 Device batch identifier

User guidance	This class can be used to describe the batch number and/or expiry date of a device in a packaged Medicinal Product.
Conformance	Conditional

C.3.10.1 Batch number

User guidance	The batch number for the device shall be specified, in text.
Conformance	Mandatory

```
<part>
 <partProduct><!-- Device -->
  <instanceOfKind><!-- Batch Number -->
   <productInstance>
    <id root="Root with MPID Suffix"
      extension="Lot Number"/>
   </productInstance>
```

The lot or batch number is in the id @extension attribute; however, all identifiers shall be made globally unique by adding an appropriate root composed from the PCID of the product. This shall be done by the following algorithm.

Take a base root OID, for example, "1.3.6.1.4.1.32366.1.2.10." (2) append the PCID converted into a decimal number. For instance, if the PCID is "0002-023-45", the conversion into a decimal number yields 202345. More precisely, any PCID format which is a pure digit string is converted by using only that string, stripping leading zeroes and any spacing and decorator characters. This is predicated on the PCID system not to have meaning in leading zeroes (if some system does have meaning in leading zeroes, place a "1" immediately before.) Replace letter characters, A-Z (case insensitive), with 901 for A, 902 for B, 903 for C, ... 910 for J, 911 for K, etc. In that case, write an actual digit 9 as 99. For example, "1234-92A-C5" would become: "12349929019035". These rules allow any computer system to automatically convert a product PCID as printed on the product barcode into a globally unique OID root. This method (or an equivalent method of constructing a unique OID for the PCID) is the only way to create proper lot identification which supports pooling of data.

C.3.10.2 Expiration date

User guidance	The expiry date for the batch shall be specified.
Conformance	Mandatory

```
<part>
 <partProduct><!-- Device -->
  <instanceOfKind><!-- Batch Number -->
   <productInstance>
    <id root="Root with MPID Suffix"
      extension="Lot Number"/>
    <expirationTime>
     <high value="Expiration Date"/>
    </expirationTime>
   </productInstance>
```

C.3.11 Shelf life/storage

The shelf life and storage information for a device can be described using the shelf life/storage class (see C.3.7).

C.3.12 Manufacturer/establishment (organisation)

The manufacturer of the device can be described using the manufacturer/establishment set of classes (see H.2).

C.3.13 Manufactured item

User guidance	The manufactured item(s), as contained in the "Packaged Medicinal Product", shall be described. This is the actual manufactured item - the tablet, the liquid, the cream contained within the package - as it is delivered from the manufacturer but before any transformation if applicable for administration to or use by the patient.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Manufactured Item / Medicinal Product -->
     <formCode code="C47916" displayName="KIT"
         codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <part><!-- If any parts present, the Medicinal Product is a kit -->
      <quantity><!-- Part Quantity --></quantity>
      <partProduct><!-- One Part Manufactured Item --></partProduct>
     </part>
     <part>
      <quantity><!-- Part Quantity --></quantity>
      <partProduct><!-- Other Part Manufactured Item / Device --></partProduct>
     </part>
     <asContent><!-- Immediate Package Item -->
      <quantity><!-- Packaged Quantity --></quantity>
      <containerPackagedProduct>
       <code code="PCID Item Code" codeSystem="Item Code System OID">
        <!-- presence of PCID indicates Packaged Medicinal Product -->
        </code>
```

C.3.13.1 Manufactured dose form

User guidance	This describes the pharmaceutical dose form of the manufactured item, where applicable, before reconstitution/transformation into the pharmaceutical product. The manufactured dose form shall be specified in accordance with ISO 11239 and its resulting terminology. A term and a term shall be used.
	NOTE A Medicinal Product can have two manufactured items, one with a manufactured dose form of *powder for solution for injection* and the other with a manufactured dose form of solvent for *solution for injection*. These are then to be reconstituted/transformed to a *powder and solvent for solution for injection* before the medicine can be administered to a patient. *Solution for injection* is the "Administrable Dose Form", which is an attribute of "Pharmaceutical Product".
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Manufactured Item -->
     <formCode code="C47916" displayName="KIT"
         codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <part><!-- If any parts present, the Medicinal Product is a kit -->
      <quantity><!-- Part Quantity --></quantity>
      <partProduct><!-- One Part Manufactured Item -->
       <formCode code="Manufactured Dose Form" displayName="KIT"
           codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

or, more simply, for simple finished dose form products:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Manufactured Item -->
     <formCode code="Manufactured Dose Form code"
         displayName="Manufactured Dose Form Name"
         codeSystem="Manufactured Dose Form Code System OID"/>
```

C.3.13.2 Unit of presentation

User guidance	This specifies the "real world" units in which the quantity of the manufactured item is described. The unit of presentation shall be specified in accordance with ISO 11239 and its resulting terminology. The controlled term and the controlled term identifier shall be specified.
	For items where their quantity is a measured quantity of weight or volume the unit of presentation shall not be given since it is the same as the units of that quantity (that is ml, mg or %). For solid dose forms and other items that are measured by counting integer quantities, the unit for quantity shall be "unit" and the "unit of presentation" shall be the item that is counted.
Conformance	Conditional

```
<asContent>
    <quantity>
     <numerator value="Manufactured Item  Quantity"
          unit="Quantity Unit">
      <translation code="Unit of Presentation Code"
           codeSystem="Unit of Presentation Code System OID"/>
     </numerator>
     <denominator value="1" unit="1"/>
    </quantity>
    <containerPackagedProduct>
```

C.3.13.3 Manufactured item quantity

User guidance	The quantity (or count number) of the manufactured item shall be described. It shall be specified as a value and units, and the units shall be specified as a symbol and a symbol identifier as defined in ISO 11240/TS 20440 and the resulting terminology.
	For solid dose forms and other items that are measured by counting integer quantities, the unit for quantity shall be "unit" and the "unit of presentation" shall be the item that is counted within the immediate container.
Conformance	Mandatory

In HL7 SPL, utilizing the UCUM terminology, the0 unit "U" for "Unit (of catalytic activity)" shall not be used; the meaning of the ISO 11615 text prescribing the use of "Unit" can only be understood as the "unity", which is the unit 1.

```
<asContent>
 <quantity>
  <numerator value="Manufactured Item Quantity"
       unit="Quantity Unit"/>
  <denominator value="1" unit="1"/>
 </quantity>
 <containerPackagedProduct>
```

Quantity is always represented as numerator and denominator. The numerator is the amount of content and the denominator the number of containers. With packaging specification, the denominator shall always be one (1), i.e. the numerator contains the quantity of content in one (1) container. Because of this, the denominator tag is omitted for brevity in the aforementioned snippets.

The numerator quantity unit shall be commensurate to the type of content. In all but inner packages, it is always "1", i.e. the quantity of inner content-packages is simply counted. However, in inner packages, the numerator quantity unit should be the same as the unit of the denominator of the strength. That is, if the manufactured item is a countable ("each"), such as tablet, capsule, etc., then the unit is also "1"; if the manufactured item is measured by volume (millilitre, ml) or by mass (gram, g), then the inner package quantity numerator unit shall also be ml or g, respectively.

For part quantities, the format is similar:

```
<part>
 <quantity>
  <numerator value="Package Item (Container) / Manufactured Item Quantity"
       unit="Quantity Unit"/>
  <denominator value="1" unit="1"/>
 </quantity>
 <partProduct>
```

C.3.14 Physical characteristics

The physical characteristics (height, width, depth, weight, shape, etc.) of the manufactured item can be described using the physical characteristics class.

User guidance	Where applicable (see NOTE 2), its physical characteristics can be specified.
	NOTE 1 The physical characteristics (height, width, depth, weight, shape, etc.) of the package item (container) can be described using the physical characteristics class. One or more images of the package item (container) can be also included as applicable.
	NOTE 2 Physical characteristics can be applicable to package item (container), package (component), manufactured item and device.
Conformance	Optional
	NOTE Although this category is optional, the listed conformance within the user guidance of this subclause corresponds to regions who shall mandate the physical characteristics category in accordance with the IDMP standards as applicable.

Physical size characteristics are of type physical quantity (PQ):

```
<subjectOf>
  <characteristic>
    <code code="Characteristic Code" codeSystem="Code System (OID)"/>
    <value xsi:type="PQ" value="Quantity Value" unit="Quantity Unit">
```

The shape may be specified as:

```
<subjectOf>
 <characteristic>
  <code code="SPLSHAPE" codeSystem="2.16.840.1.113883.1.11.19255"/>
  <value xsi:type="ST">Name of the Shape</value>
```

C.3.14.1 Height

User guidance	The height can be specified. The unit of measurement shall be specified in accordance with ISO 11240 and the resulting terminology. The symbol and the symbol identifier shall be used.
Conformance	Optional

```
<subjectOf>
  <characteristic>
    <code code="Code meaning 'Height'" codeSystem="Code System (OID)"/>
    <value xsi:type="PQ" value="Height Number" unit="Length Unit">
```

C.3.14.2 Width

User guidance	The width can be specified. The unit of measurement shall be specified in accordance with ISO 11240 and the resulting terminology. The symbol and the symbol identifier shall be used.
Conformance	Optional

```
<subjectOf>
  <characteristic>
    <code code="Code meaning 'Width'" codeSystem="Code System (OID)"/>
    <value xsi:type="PQ" value="Width Number" unit="Length Unit">
```

C.3.14.3 Depth

User guidance	The depth can be specified. The unit of measurement shall be specified in accordance with ISO 11240 and the resulting terminology. The symbol and the symbol identifier shall be used
Conformance	Optional

```
<subjectOf>
 <characteristic>
  <code code="Code meaning 'Depth'" codeSystem="Code System (OID)"/>
  <value xsi:type="PQ" value="Depth Number" unit="Length Unit">
```

C.3.14.4 Weight

User guidance	The weight can be specified. The unit of measurement shall be specified in accordance with ISO 11240 and the resulting terminology. The symbol and the symbol identifier shall be used.
Conformance	Optional

```
<subjectOf>
 <characteristic>
  <code code="Code meaning 'Mass'" codeSystem="Code System (OID)"/>
  <value xsi:type="PQ" value="Mass Number" unit="Mass Unit">
```

C.3.14.5 Nominal volume

User guidance	Nominal value can be specified. The unit of measurement shall be specified in accordance with ISO 11240 and the resulting terminology. The symbol and the symbol identifier shall be used.
Conformance	Optional NOTE This attribute pertains to liquid preparations (e.g. parenterals) and liquid-filled solid dosage forms)

```
<subjectOf>
 <characteristic>
  <code code="Code meaning 'Nominal Volume'" codeSystem="Code System (OID)"/>
  <value xsi:type="PQ" value="Volume Number" unit="Volume Unit">
```

C.3.14.6 External diameter

User guidance	The external diameter can be specified. The unit of measurement shall be specified in accordance with ISO 11240 and the resulting terminology. The symbol and the symbol identifier shall be used.
Conformance	Optional

```
<subjectOf>
 <characteristic>
  <code code="Code meaning 'External Diameter'" codeSystem="Code System (OID)"/>
  <value xsi:type="PQ" value="Diameter Number" unit="Length Unit">
```

A special simplified case is the greatest external diameter (used routinely to specify oral solid dose forms). This should always be specified in units of 1 mm (1 mm):

```
<subjectOf>
 <characteristic>
  <code code="SPLSIZE" codeSystem="2.16.840.1.113883.1.11.19255"/>
  <value unit="mm" value="Diameter in mm" xsi:type="PQ"/>
```

C.3.14.7 Shape

User guidance	The shape can be specified. An appropriate reference terminology shall be used. The term and the term identifier shall be used.
Conformance	Optional

```
<subjectOf>
 <characteristic>
  <code code="SPLSHAPE" codeSystem="2.16.840.1.113883.1.11.19255"/>
  <value xsi:type="ST">Name of the Shape</value>
```

C.3.14.8 Colour

User guidance	The colour can be specified. An appropriate reference terminology should be used. The term and the term identifier should be used.
Conformance	Optional

```
<subjectOf>
 <characteristic>
  <code code="SPLCOLOUR" codeSystem="2.16.840.1.113883.1.11.19255"/>
  <value xsi:type="ST">Name for the Colour</value>
```

NOTE   This unit may be repeatable given the instance of a multi-coloured presentation.

C.3.14.9 Image

User guidance	Where applicable, the image can be provided. The format of the image shall follow ISO 12639 and shall be held in an ED data type.
Conformance	Optional

```
<subjectOf>
 <characteristic classCode="OBS">
  <code code="SPLIMAGE" codeSystem="2.16.840.1.113883.1.11.19255"/>
  <value xsi:type="ED" mediaType="image/jpeg">
   <reference value="File Name.jpg"/>
```

The file name references a file in the same directory in which the HL7 SPL file resides (e.g. within a submission folder or a directory entry inside a ZIP file).

C.3.14.10   Imprint

User guidance	Where applicable, the imprint can be specified as text.
Conformance	Optional

```
<subjectOf>
 <characteristic>
  <code code="SPLIMPRINT" codeSystem="2.16.840.1.113883.1.11.19255"/>
  <value xsi:type="ST">Imprint with Parts Separated by Semicolon</value>
```

C.3.14.11   Scoring

User guidance	Where applicable, the scoring can be specified as CV/text.
	There is only one score element.
Conformance	Optional

```
<subjectOf>
 <characteristic>
  <code code="SPLSCORE" codeSystem="2.16.840.1.113883.1.11.19255"/>
  <value value="1" xsi:type="INT"/>

If the value is 1, 2, 3, 4, or nullFlavor="OTH" (for SPLSCORE):

<subjectOf>
 <characteristic>
  <code code="SPLSCORE" codeSystem="2.16.840.1.113883.1.11.19255"/>
  <value nullFlavor="OTH" xsi:type="INT"/>
```

C.3.15 Other characteristics

Other characteristics can be described using the other characteristics class.

User guidance	Where applicable for a Package Item (container), a Manufactured Item or a Device, other characteristics beyond the physical characteristics can be specified.
Conformance	Optional

```
<!-- CPM body -->
<manufacturedProduct>
 <manufacturedProduct><!-- Manufactured Item --></manufacturedProduct>
 <subjectOf>
  <characteristic>
   <code code="Characteristic Code" codeSystem="Code System (OID)"/>
   <value xsi:type="Value Type" ... /><!-- Characteristic Value (Various Attributes) -->
```

or under parts:

```
<part>
 <partProduct><!-- Manufactured Item --></partProduct>
 <subjectOf>
  <characteristic>
   <code code="Characteristic Code" codeSystem="Code System (OID)"/>
   <value xsi:type="Value Type" ... /><!-- Characteristic Value (Various Attributes) -->
```

C.3.15.1 (Other characteristics) code system

User guidance	The code describing the characteristic is specified using an appropriate controlled terminology.
Conformance	Mandatory

```
<subjectOf>
 <characteristic>
  <code code="Characteristic Code" codeSystem="Code System (OID)"
     displayName="Name of Characteristic"/>
```

C.3.15.2 (Other characteristics) value

User guidance	The individual value of the characteristics code system is specified.
Conformance	Mandatory

Characteristics use one of a number of different data types. Each data type uses slightly different XML elements and attributes as shown in the templates below.

Characteristic of type physical quantity (PQ):

```
<subjectOf>
 <characteristic>
  <code code="Characteristic Code" codeSystem="Code System (OID)"/>
  <value xsi:type="PQ" value="quantity value" unit="quantity unit">
```

Characteristic of type number (REAL):

```
<subjectOf>
 <characteristic>
  <code code="Characteristic Code" codeSystem="Code System (OID)"/>
  <value xsi:type="REAL" value="quantity value"/>
```

Characteristic of type integer number (INT):

```
<subjectOf>
 <characteristic>
  <code code="Characteristic Code" codeSystem="Code System (OID)"/>
  <value xsi:type="INT" value="quantity value"/>
```

Characteristic of coded type (CV):

```
<subjectOf>
 <characteristic>
  <code code="Characteristic Code" codeSystem="Code System (OID)"/>
  <value xsi:type="CV" code="value code"
     codeSystem="value code system OID"
     displayName="value code display name">
```

Characteristic of type character string (ST):

```
<subjectOf>
 <characteristic>
  <code code="Characteristic Code" codeSystem="Code System (OID)"/>
  <value xsi:type="ST">value string</value>
```

Characteristic of type interval of physical quantity (IVL<PQ>):

```
<subjectOf>
 <characteristic>
  <code code="Characteristic Code" codeSystem="Code System (OID)"/>
  <value xsi:type="IVL_PQ">
   <low value="quantity value low boundary" unit="quantity unit"/>
   <high value="quantity value high boundary" unit="quantity unit"/>
  </value>
```

Characteristic of type Boolean (true/false value)

```
<subjectOf>
 <characteristic>
  <code code="Characteristic Code" codeSystem="Code System (OID)"/>
  <value xsi:type="BL" value="true or false"/>
```

C.3.16 Device material

User guidance	The material of the device shall be described in accordance with ISO 11238 and other device material identification sources, and its resulting terminology. A term and a term identifier shall be specified for each material as applicable.
Conformance	Optional

```
<part>
 <partProduct><!-- Device -->
  <ingredient classCode="INGR"><!—Device Material -->
   <ingredientSubstance>
    <code code="Material Code" codeSystem="2.16.840.1.113883.4.9"/>
    <name>Material Name</name>
   </ingredientSubstance>
   <subjectOf>
    <characteristic>
     <code code="Allergenic Indicator Characteristic" codeSystem="Code System OID"/>
     <value xsi:type="BL" value="true"/>
```

C.3.16.1 Substance

User guidance	The material of the device can be described in accordance with ISO 11238 and other device material identification sources, and its resulting terminology. A term and a term identifier shall be specified for each material as applicable.
Conformance	Mandatory

```
<part>
 <partProduct><!-- Device -->
  <ingredient classCode="INGR"><!-- Device Material -->
   <ingredientSubstance>
    <code code="Material Code" codeSystem="2.16.840.1.113883.4.9"/>
    <name>Material Name</name>
   </ingredientSubstance>
   <subjectOf>
    <characteristic>
     <code code="Alternate Material Characteristic" codeSystem="Code System OID"/>
     <value xsi:type="BL" value="true"/>
    </characteristic>
   </subjectOf>
   <subjectOf>
    <characteristic>
     <code code="Allergenic Indicator Characteristic" codeSystem="Code System OID"/>
     <value xsi:type="BL" value="false"/>
    </characteristic>
   </subjectOf>
```

C.3.16.2 Alternate

User guidance	The alternative material of the device can be described by using this class, and the substance attribute, and then using the alternate flag set to "true".
	NOTE Alternate material is utilised when alternative specific material(s) are allowed to be used for the manufacturing of the package (e.g. different types of plastic for a spoon).
Conformance	Conditional

```
<part>
 <partProduct><!-- Device -->
  <ingredient classCode="INGR"><!—Device Material -->
   <ingredientSubstance>
    <code code="Material Code" codeSystem="2.16.840.1.113883.4.9"/>
    <name>Material Name</name>
   </ingredientSubstance>
   <subjectOf>
    <characteristic>
     <code code="Alternate Material Characteristic" codeSystem="Code System OID"/>
     <value xsi:type="BL" value="true"/>
    </characteristic>
   </subjectOf>
```

C.3.16.3 Allergenic indicator

User guidance	Where applicable, this can be used to specify if the device material(s)/alternative material(s) contains allergens and/or materials of concern.
Conformance	Conditional

```
<part>
 <partProduct>
  <ingredient classCode="INGR">
   <ingredientSubstance>
    <code code="Device Material" codeSystem="Substance Code System (OID)"/>
     <name>Device Material</name>
   </ingredientSubstance>
   <subjectOf>
    <characteristic>
     <code code="Allergenic Indicator Characteristic Code" codeSystem=" Characteristic Code System (OID)"/>
     <value xsi:type="BL" value="Allergenic Indicator"/>
    </characteristic>
   </subjectOf>
```

Any material listed as ingredient may be a material of concern. When listed, the concern does not need to be carried or flagged in any special way. For instance, a nickel-containing buckle or a latex containing tube may be simply specified as the material or alternate material.

Annex D
(normative)

Ingredient, substance and strength

D.1 General

This annex describes the ingredients of the Medicinal Product through its representations as the Manufactured Item(s) and the Pharmaceutical Product(s), based on ISO 11238, ISO 11239, ISO 11240, and their resulting technical specifications and terminology.

The ingredients class and associated substance specified substance, strength and reference strength classes are used in the further description of manufactured item and pharmaceutical product class. In addition, an ingredient and associated classes can be associated with a manufacturer/establishment (see Annex H).

The substance class represents the value set that can be used to describe any allergens/materials from the device class and the materials and alternative materials attributes of the package item (container) and package (component) classes.

An ingredient shall be specified as a substance and additionally as any of the types of its associated specified substance(s). Any substance or specified substance shall have its strength specified in accordance with the regulated Medicinal Product information as applicable. Additionally, strength can be further specified by description of a reference strength. Again, this shall be specified where applicable in accordance with the regulated Medicinal Product information.

When described, a reference strength shall specify either the substance or the specified substance that it references.

The manufactured item and pharmaceutical product, their ingredients, and the device ingredient(s) as applicable per regional requirements, are represented in HL7 SPL in the following way:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Pharmaceutical Product / Manufactured Item -->
     <ingredient><!-- Ingredient -->
      <quantity><!-- Strength --></quantity>
      <ingredientSubstance><!-- Substance -->
       <activeMoiety>
        <!-- Reference Strength -->
       </activeMoiety>
       <asEquivalentSubstance>
        <!-- Reference Strength -->
```
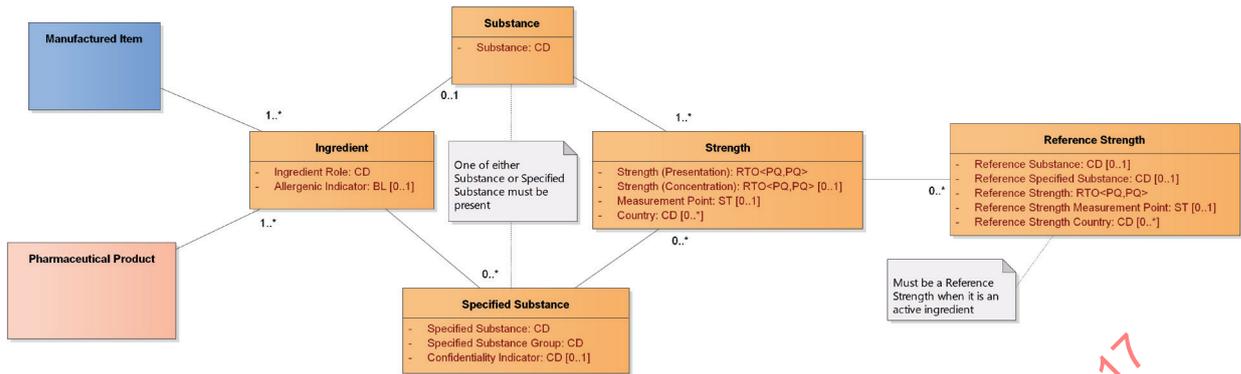
Figure D.1 — Ingredients, substance and strength section detailed description diagram

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Pharmaceutical Product / Manufactured Item -->

     <ingredient classCode="Ingredient Role"><!-- Ingredient -->
      <quantity><!-- Strength -->
       <numerator xsi:type="URG_PQ"><!-- Strength Range -->
        <low value="Strength Low Number" unit="Strength Unit"/>
        <high value="Strength High Number" unit="Strength Unit"/>

       </numerator>
       <denominator value="Strength Denominator Number"
             unit="Strength Denominator Unit"/>
      </quantity>
      <ingredientSubstance><!-- Substance -->
       <code code="Substance Code" codeSystem="Code System (OID)"/>
       <name><!-- Substance Name --></name>

       <activeMoiety><!-- Reference Strength (Active Moiety) -->
        <quantity><!-- Reference Strength Quantity --></quantity>
        <activeMoiety>
         <code code="Substance Code" codeSystem="Code System (OID)"/>
         <name><!-- Substance Name --></name>
        </activeMoiety>

       </activeMoiety><!-- Reference Strength Quantity -->
       <asEquivalentSubstance><!-- Reference Strength (Reference Substance) -->
        <quantity>
         <numerator xsi:type="URG_PQ"><!-- Reference strength -->
          <low value="Strength Low Number" unit="Strength Unit"/>
          <high value="Strength High Number" unit="Strength Unit"/>

         </numerator>
         <denominator value="Strength Denominator Number"
               unit="Strength Denominator Unit"/>
        </quantity>
        <definingSubstance>

         <code code="Substance Code" codeSystem="Code System (OID)"/>
         <name><!-- Substance Name --></name>
        </definingSubstance>
       </asEquivalentSubstance>
      <ingredientSubstance>
      <subjectOf>
       <substanceSpecification><!-- Specified Substance -->
        <code code="Substance Specification Code" code="Code System (OID)"
           displayName="Substance Specification Name"/>
```

D.2 Ingredient

User guidance	There shall be one instance of the "ingredient" class for each actual ingredient for either the manufactured item or pharmaceutical product, as appropriate.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Pharmaceutical Product / Manufactured Item -->
     <ingredient><!-- Ingredient 1 --></ingredient>
     <ingredient><!-- Ingredient 2 --></ingredient>
     <ingredient><!-- Ingredient 3 --></ingredient>
```

or under parts (Manufactured Item)

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Package Item (co-package), Kit -->
     <formCode code="C47916" displayName="KIT"
         codeSystem="2.16.840.1.113883.3.26.1.1"/>
     <part>
      <quantity><!-- Part Quantity --></quantity>
      <partProduct><!-- One Part Manufactured Item -->
       <ingredient><!-- Ingredient 1 --></ingredient>
       <ingredient><!-- Ingredient 2 --></ingredient>
       <ingredient><!-- Ingredient 3 --></ingredient>
```

D.2.1 Ingredient role

User guidance	The role of the ingredient as part of the manufactured item/pharmaceutical product shall be specified (see below). The controlled term and a term identifier should be specified.
Conformance	Mandatory

```
<ingredient classCode="Ingredient Role">
```

The ingredient roles are the following and included in the HL7 SPL file in the full upper case letters as specified in Table D.1.

Table D.1 — Ingredient roles (classCodes)

Code	Description
INGR	Ingredient not otherwise specified, used in cases of devices or foods where further classification is not common.
ACTI	Active ingredient – ingredient that has the pharmacological action. Use only if basis of strength *cannot* be specified, otherwise use ACTIB, ACTIM, or ACTIR.
ACTIB	Active ingredient, where the entire substance is the basis of strength. For example, propranolol hydrochloride quantified as the propranolol hydrochloride salt.

Table D.1 *(continued)*

Code	Description
ACTIM	Active ingredient, where the active moiety is basis of strength. For example, 287 mg amoxicillin trihydrate equivalent to 250 mg anhydrous amoxicillin.
ACTIR	Active ingredient, where another reference substance is the basis of strength. For example, metoprolol succinate quantified by amount of metoprolol tartrate with the equal amount of metoprolol active moiety.
ADJV	Adjuvant – an ingredient(s) which augments or promotes the pharmacological effect of the active ingredient(s) without itself being considered active (typically used with vaccines.)
IACT	Inactive ingredient, i.e. ingredients added for a purpose other than the intended pharmacological action.
COLR	Colour ingredient – ingredient added to alter the colour appearance.
FLVR	Flavour ingredient – ingredient added to alter the taste of the product.
PRSV	Preservative ingredient – ingredient added to delay the risk of the product's spoiling.
STBL	Stabiliser ingredient – ingredient added to keep the mixture homogenic (e.g. prevent the phases of an emulsion to separate).
MECH	Mechanical ingredient – ingredient which, as a whole, lends a spatial structure to the product, which structure is meaningful to the delivery of the pharmacologically active ingredients near the target site. For example, a collagen matrix used as a base for transplanting skin cells. NOTE Such ingredient has a function other than merely delivering the pharmacologically active substances into a systemic compartment (such as, for example, an ordinary capsule would have.)
BASE	The base of a preparation, i.e. water, vaseline, ethanol.
ADTV	Any additive added, use only when there is no described pharmacological action and classification as merely "inactive" ingredient is not appropriate.
CNTM	Contaminant - ingredient whose presence is not intended but may not be reasonably avoided given the circumstances of the mixture's nature or origin.

D.2.2 Allergenic indicator

User guidance	Where applicable, this can be used to indicate if an ingredient is a known or suspected allergen.
Conformance	Conditional

```
<ingredient classCode="INGR"><!-- Allergenic Indicator -->
 <subjectOf>
  <characteristic>
   <code code="Allergenic Indicator Code" codeSystem="Code System (OID)"/>
   <value xsi:type="BL" value="Allergenic Indicator"/>
```

D.2.3 Manufacturer/establishment (organisation)

User guidance	An ingredient can be associated with one or more manufacturers/establishments. The information related to the for the manufacturer/establishment organisation undertaking the particular manufacturing operation should be described using the pattern for organisation described in Annex G.
Conformance	Conditional

D.2.4   Substance

User guidance	A substance can be specified for each ingredient role described.
	NOTE 1 In regions that choose to implement specified substance, according to regional guidance, it might be permissible to utilise specified substance instead of substance.
	NOTE 2 A specified substance can be utilised to meet the requirement above as a specified substance, as specified substance is always associated with a substance.
	NOTE 3 There are exceptions to the substance/specified substance relationship for herbal preparations and allergens for unique identification (see ISO 11238/ISO/TS 19844).
Conformance	Conditional

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <ingredientSubstance><!-- Substance -->
```

D.2.4.1   Substance

User guidance	The substance shall be described in accordance with ISO 11238 and its resulting terminology. A term and a term identifier shall be used.
	NOTE 1 In regions that choose to implement specified substance, according to regional guidance, it might be permissible to utilise specified substance instead of substance.
	NOTE 2 A specified substance can be utilised to meet the requirement above as a specified substance, as specified substance is always associated with a substance.
	NOTE 3 There are exceptions to the substance/specified substance relationship for herbal preparations and allergens for unique identification (see ISO 11238/ISO/TS 19844).
	The ingredient refers to the role of the substance or specified substance in the Medicinal Product, for example: active or inactive. This element (substance) refers to the name of the specific substance.
Conformance	Mandatory

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <ingredientSubstance><!-- Substance -->
  <code code="Substance Code" codeSystem="Code System (OID)"/>
  <name><!-- Substance Name --></name>
```

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <ingredientSubstance><!-- Substance -->
  <code code="1Y17CTI5SR" codeSystem="2.16.840.1.113883.4.9"/>
  <name>INSULIN HUMAN</name>
```

D.2.5   Specified substance

User guidance	For each substance, one or more specified substance groups as described in ISO 11238 can be described, as applicable.
	There shall always be a substance term and ID. Although the specified substance category is optional, the specified substance shall contain a substance level term/ID as a part of its make up as specified substance when implemented as mandatory within a jurisdiction. Specified substance(s) is simply more detailed/granular information about a substance.
	NOTE There are exceptions to the substance/specified substance relationship for herbal preparations and allergens for unique identification (see ISO 11238/ISO/TS 19844).
Conformance	Optional

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <ingredientSubstance><!-- Substance --></ingredientSubstance>
 <subjectOf>
  <substanceSpecification><!-- Specified Substance -->
```

D.2.5.1   Specified substance

User guidance	When a specified substance is described, it shall be presented in accordance with ISO 11238 and its resulting terminology. A term and a term identifier shall be used.
Conformance	Mandatory

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <ingredientSubstance><!-- Substance --></ingredientSubstance>
 <subjectOf>
  <substanceSpecification><!-- Specified Substance -->
   <code code="Substance Specification Code"
      codeSystem="Code System (OID)"
      displayName="Substance Specification Name">
```

D.2.5.2   Specified substance group

User guidance	The group to which a specified substance is assigned in accordance with ISO 11238 and its resulting terminology can be specified. A term and a term identifier shall be used.
	The "specified substance group" is implicitly associated with the specified substance code. One specified substance code has exactly one specified substance group.
Conformance	Mandatory

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <ingredientSubstance><!-- Substance --></ingredientSubstance>
 <subjectOf>
  <substanceSpecification><!-- Specified Substance -->
   <code code="Substance Specification Code" codeSystem="Code System (OID)"
      displayName="Substance Specification Name">
   <subjectOf>
    <characteristic>
     <code code="Specified Substance Group" codeSystem="Code System (OID)"
        displayName="Specified Substance Group Name"/>
```

D.2.5.3   Confidentiality indicator

User guidance	The confidentiality level of the specified substance information described for the ingredient can be specified using an appropriate controlled vocabulary. The controlled term and a term identifier shall be specified.
Conformance	Conditional for regions implementing specified substance(s)

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <ingredientSubstance><!-- Substance --></ingredientSubstance>
  <subjectOf>
   <substanceSpecification><!-- Specified Substance -->
    <code code="Substance Specification Code" codeSystem="Code System (OID)"
       displayName="Substance Specification Name">
    <subjectOf>
     <characteristic>
      <code code="Specified Substance Confidentiality" codeSystem="Code System (OID)"
         displayName="Specified Substance Confidentiality Name"/>
```

D.2.5.4   Strength

User guidance	The strength of the substance and/or specified substance shall be specified as a quantity of the substance/specified substance present in a given manufactured item or pharmaceutical product. A numerator value and numerator unit as well as a denominator value and denominator unit shall be specified.
	Strength can be expressed in two ways: Strength (presentation) and strength (concentration).
	When the strength of a pharmaceutical product that has undergone a transformation (for example reconstitution) is to be specified, it shall be specified using the strength resulting from transformation undertaken exactly in accordance with the regulated Medicinal Product authorisation.
	NOTE Per ISO 11616, strength after reconstitution is required per authorisation, independent of whether the reconstituting agent(s) is provided in the packaged Medicinal Product or obtained separately.
Conformance	Mandatory

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <quantity><!-- Strength -->
  <numerator xsi:type="URG_PQ"><!-- Strength Range -->
   <low value="Strength Low Number" unit="Strength Unit"/>
   <high value="Strength High Number" unit="Strength Unit"/>

  </numerator>
  <denominator value="Strength Denominator Number"
        unit="Strength Denominator Unit"/>
 </quantity>
 <ingredientSubstance><!-- Substance -->
  <code code="Substance Code" codeSystem="Code System (OID)"/>
  <name><!-- Substance Name --></name>
  <activeMoiety><!-- Reference Strength (Active Moiety) -->
   <quantity><!-- Reference Strength Quantity --></quantity>
   <activeMoiety>
    <code code="Substance Code" codeSystem="Code System (OID)"/>
    <name><!-- Substance Name --></name>

   </activeMoiety>
  </activeMoiety><!-- Reference Strength Quantity -->
  <asEquivalentSubstance><!-- Reference Strength (Reference Substance) -->
   <quantity>
    <numerator xsi:type="URG_PQ"><!-- Reference strength -->
     <low value="Strength Low Number" unit="Strength Unit"/>
     <high value="Strength High Number" unit="Strength Unit"/>
    </numerator>
    <denominator value="Strength Denominator Number"
          unit="Strength Denominator Unit"/>
   </quantity>
   <definingSubstance>
    <code code="Substance Code" codeSystem="Code System (OID)"/>
    <name><!-- Substance Name --></name>
```

D.2.5.4.1   Strength (presentation)

User guidance	Strength (presentation) shall be specified as a quantity of the substance/specified substance present in a given quantity of the pharmaceutical product or manufactured item.
	The unit of presentation shall be specified in accordance with ISO 11239 and its resulting terminology. The controlled term and a term identifier for the unit of presentation shall be specified in the associated manufactured item or pharmaceutical product. The representation of this information is further described in Annex C for the manufactured item or, in Annex E for the pharmaceutical product.
	The unit of measure symbol and the symbol identifier as defined in ISO 11240 and its resulting controlled vocabulary shall be specified.
	Where the strength is defined on the basis of a "Unit of Presentation", the term and term identifier shall be used as defined in ISO 11239 and its resulting controlled vocabulary.
Conformance	Mandatory

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <quantity><!-- Strength -->
  <numerator xsi:type="URG_PQ"><!-- Strength (Presentation) -->
   <low value="Strength Low Number" unit="Strength Unit"/>
   <high value="Strength High Number" unit="Strength Unit"/>
  </numerator>
  <denominator value="Strength Denominator Number" unit="Denominator Unit"/>
```

If the strength is specified as a simple value instead of a range, the format is much simpler:

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
  <quantity><!-- Strength -->
    <numerator value="Strength Low Number" unit="Strength Unit"/>
    <denominator value="Strength Denominator Number" unit="Denominator Unit"/>
```

"10 mg/5 ml":

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
  <quantity><!-- Strength -->
    <numerator value="10" unit="mg"/>
    <denominator value="5" unit="ml"/>
```

"2 mg/1 unit of presentation":

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
  <quantity><!-- Strength -->
    <numerator value="2" unit="mg"/>
    <denominator value="1" unit="1"/>
```

NOTE   The "unit of presentation" is the same as the form code of the product containing the ingredient.

D.2.5.4.2   Strength (concentration)

User guidance	Strength (concentration) can be specified as a quantity of the substance/specified substance present per one unit of the pharmaceutical product or manufactured item, for example 2 mg/1 tablet.
	For solid dose forms this is generally the same as strength (presentation) and therefore is not required to be expressed separately. The strength (presentation) only is required. The representation of this information is described below.
	The unit of measure symbol and the symbol identifier as defined in ISO 11240 and its resulting controlled vocabulary shall be specified.
	Where the strength is defined on the basis of a "unit of presentation", the term and term identifier shall be used as defined in ISO 11239 and its resulting controlled vocabulary.
	Since only one strength is allowed per ingredient, the substance ingredient should be repeated for each strength expression. To unambiguously differentiate a strength (concentration) from a strength (presentation) use a subjectOf/characteristic.
Conformance	Conditional

```
<ingredient>
  <quantity><!-- Range Strength -->
    <numerator xsi:type="URG_PQ"><!-- Strength (Concentration) -->
      <low value="Strength Low Number" unit="Strength Unit"/>
      <high value="Strength High Number" unit="Strength Unit"/>
    </numerator>
    <denominator value="Strength Denominator Number" unit="Denominator Unit"/>
```

If the strength is specified as a simple value instead of a range, the format is much simpler:

```
<ingredient>
  <quantity><!-- Simple Strength -->
    <numerator value="Strength Number" unit="Strength Unit"/>
    <denominator value="Strength Denominator Number" unit="Denominator Unit"/>
```

EXAMPLE 1   "2 mg/1 ml":

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <quantity><!-- Strength -->
  <numerator value="2" unit="mg"/>
  <denominator value="1" unit="ml"/>
```

EXAMPLE 2   "2 mg/1 tablet":

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <quantity><!-- Strength -->
  <numerator value="2" unit="mg"/>
  <denominator value="1" unit="1"/>
```

NOTE   The "unit of presentation" is the same as the form code of the product containing the ingredient.

D.2.5.4.3   Measurement point

User guidance	There are some Medicinal Products in some regions, where strength is measured at a particular point (for example the strength of the ingredient in some inhalers are measured at a particular distance from the point of aerosolisation). In these instances, the measurement point can be described using text, as applicable.
Conformance	Conditional

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <quantity><!-- Strength --></quantity>
 <ingredientSubstance><!-- Ingredient Substance --></ingredientSubstance>
 <subjectOf>
  <characteristic>
   <code code="Code meaning 'Measurement Point'" codeSystem="Code System OID"/>
   <value xsi:type="CV" code="Measurement Point Code"
      codeSystem="Code System OID" displayName="Point Name">
```

D.2.5.4.4   Country

User guidance	The country (or countries) for which the measurement point(s) is valid can be specified using values from the ISO 3166-1-alpha-2 code elements.
Conformance	Conditional

This country specification is only necessary when the measurement point specification varies in those countries.

EXAMPLE   When two observations are considered different and such difference is not specified by any other attribute, then the observation code should different. Therefore, the difference of measurement points as applicable in different countries will be primarily indicated by the terminology of the measurement point observation code.

```
<ingredient classCode="Ingredient Role"><!-- Ingredient -->
 <quantity><!-- Strength --></quantity>
 <ingredientSubstance><!-- Ingredient Substance --></ingredientSubstance>
 <subjectOf>
  <characteristic>
   <code code="Code meaning strength country" codeSystem="Code System OID"/>
   <value xsi:type="CV" code="Country where strength applies" codeSystem="Code System OID"
      displayName="Country Name"/>
```

The terminology for country specific measurement points is to be defined and maintained by the applicable maintenance organisation.

D.2.5.5   Reference strength

User guidance	Strength can be further described by a reference strength.
	A reference strength is an expression of the strength in terms of either a reference substance and/or a reference specified substance.
Conformance	Mandatory

```
<ingredient classCode="ACTIM">
 <quantity>
  <numerator value="Reference Strength Number" unit="Strength Unit"/>
  <denominator value="Amount of Product Number" unit="Product Unit"/>
 </quantity>
 <ingredientSubstance>
  <code code="Substance Code" codeSystem="Code System (OID)"/>
  <name><!-- Substance Name --></name>
  <activeMoiety>
   <quantity>
    <numerator value="Actual Strength Number" unit="Strength Unit"/>
    <denominator value="Reference Strength,  Amount of Product Number" unit="Strength Unit"/>
   </quantity>
   <activeMoiety>
    <code code="Reference Substance Code" codeSystem="Code System (OID)"/>
    <name><!-- Substance Name --></name>
```

EXAMPLE 1   Each capsule contains 250 mg amoxicillin as the trihydrate – what is contained is 287 mg amoxicillin trihydrate, but the strength, 250 mg, is specified in terms of the anhydrous amoxicillin moiety.

```
<ingredient classCode="ACTIM">
 <quantity>
  <numerator value="287" unit="mg"/>
  <denominator value="1" unit="1"/>
 </quantity>
 <ingredientSubstance>
  <code code="804826J2HU" codeSystem="2.16.840.1.113883.4.9"/>
  <name>AMOXICILLIN TRIHYDRATE </name>
 <activeMoiety>
 <quantity>
   <numerator value="250" unit="mg"/>
   <denominator value="1" unit="1"/>
 </quantity>
 <activeMoiety><!-- Reference Substance (Active Moiety) -->
  <activeMoiety>
   <code code="9EM05410Q9" codeSystem="2.16.840.1.113883.4.9"/>
   <name>AMOXICILLIN ANHYDROUS </name>
```

In this case, a quantity on the active moiety relationship is not required, because the strength was only specified in terms of 250 mg of the anhydrous amoxicillin moiety and the trihydrate will have a slightly greater mass.

EXAMPLE 2   Apraclonidine hydrochloride 5,75 mg equivalent to apraclonidine base 5 mg.

```
<ingredient classCode="ACTIM">
 <quantity>
  <numerator value="5.75" unit="mg"/>
  <denominator value="1" unit="1"/>
 </quantity>
 <ingredientSubstance>
  <code code="D2VW67N38H" codeSystem="2.16.840.1.113883.4.9"/>
  <name> APRACLONIDINE HYDROCHLORIDE</name>

  <activeMoiety><!-- Reference Substance (Active Moiety) -->
   <quantity>
    <numerator value="5.0" unit="mg"/>
    <denominator value="1" unit="mg"/>
   </quantity>
   <activeMoiety>
    <code code="843CEN85DI" codeSystem="2.16.840.1.113883.4.9"/>
    <name> APRACLONIDINE</name>
    <ingredient classCode="ACTIR">
     <quantity>

      <numerator value="Reference Strength Number" unit="Strength Unit"/>
      <denominator value="Amount of Product Number" unit="Product Unit"/>
     </quantity>
     <ingredientSubstance>
     <code code="Substance Code" codeSystem="Code System (OID)"/>
     <name><!-- Substance Name --></name>
     <asEquivalentSubstance>
      <quantity>
       <numerator value="Actual Strength Number" unit="Strength Unit"/>
       <denominator value="Reference Strength should be Amount of product Number" unit="Strength
Unit"/>
      </quantity>
      <definingSubstance>
       <code code="Reference Substance Code" codeSystem="Code System (OID)"/>
       <name><!-- Substance Name --></name>
```

EXAMPLE 3   Metoprolol succinate (190 mg) equivalent to 100 mg metoprolol tartrate.

```
<ingredient classCode="ACTIR">
 <quantity>
  <numerator value="190" unit="mg"/>
  <denominator value="1" unit="1"/>
 </quantity>
 <ingredientSubstance>
  <code code="TH25PD4CCB" codeSystem="2.16.840.1.113883.4.9"/>
  <name>METOPROLOL SUCCINATE</name>
  <asEquivalentSubstance><!-- Reference Strength (Reference Substance) -->
   <quantity>
    <numerator value="100" unit="mg"/>
    <denominator value="1" unit="1"/>
   </quantity>
   <definingSubstance>
    <code code="W5S57Y3A5L" codeSystem="2.16.840.1.113883.4.9"/>
    <name>METOPROLOL TARTRATE</name>
```

Even when a reference strength is not required, one may quantify the active moiety relationship to express the amount of active moiety.

EXAMPLE 4   Lithium carbonate 450 mg refers to 12,2 mmol lithium ion.

```
<ingredient classCode="ACTIB">
 <quantity>
  <numerator value="450" unit="mg"/>
  <denominator value="1" unit="1"/>
 </quantity>
 <ingredientSubstance>
  <code code="2BMD2GNA4V" codeSystem="2.16.840.1.113883.4.9"/>
  <name>LITHIUM CARBONATE</name>
  <activeMoiety><!-- Reference Strength (Active Moiety) -->
   <quantity>
    <numerator value="12.2" unit="mmol"/>
    <denominator value="1" unit="1"/>
   </quantity>
   <activeMoiety>
    <code code="9FN79X2M3F" codeSystem="2.16.840.1.113883.4.9"/>
    <name>LITHIUM</name>
```

D.2.5.5.1 Reference substance

User guidance	When reference substance needs to be specified based on the regulated product information, it shall be described in accordance with ISO 11238 and its resulting terminology. A term and a term identifier shall be used.
Conformance	Conditional
	NOTE Mandatory for active ingredients.

When reference substance is a moiety of the ingredient substance:

```
<ingredient classCode="ACTIM">
 <ingredientSubstance>
  <activeMoiety>
   <activeMoiety>
    <code code="Reference Substance Code" codeSystem="Code System (OID)"/>
    <name><!-- Substance Name --></name>
```

When reference substance is not part of the ingredient substance:

```
<ingredient classCode="ACTIR">
 <ingredientSubstance>
  <asEquivalentSubstance>
   <definingSubstance>
    <code code="Reference Substance Code" codeSystem="Code System (OID)"/>
    <name><!-- Substance Name --></name>
```

D.2.5.5.2 Reference specified substance

User guidance	When reference strength at the level of the specified substance needs to be specified based on the regulated product information, it shall be described in accordance with ISO 11238 and its resulting terminology. A term and a term identifier shall be used.
Conformance	Conditional

When reference substance is a moiety of the ingredient substance:

```
<ingredient classCode="ACTIM">
 <ingredientSubstance>
  <activeMoiety>
   <activeMoiety>...</activeMoiety>
   <subjectOf>
    <substanceSpecification><!-- Specified Substance -->
     <code code="Substance Specification Code"
        codeSystem="Code System (OID)"
        displayName="Substance Specification Name">
```

When reference substance is not part of the ingredient substance:

```
<ingredient classCode="ACTIR">
 <ingredientSubstance>
  <asEquivalentSubstance>
   <definingSubstance>...</definingSubstance>
   <subjectOf>
    <substanceSpecification><!-- Specified Substance -->
     <code code="Substance Specification Code"
        codeSystem="Code System (OID)"
        displayName="Substance Specification Name">
```

D.2.5.5.3 Reference strength

User guidance	If a reference strength needs to be described based on the regulated product information, it should be described in accordance with ISO 11238 and its resulting terminology. A term and a term identifier should be used.
Conformance	Mandatory

```
<ingredient classCode="ACTIR">
 <ingredientSubstance>
  <asEquivalentSubstance>
   <quantity><!-- Range Strength -->
    <numerator xsi:type="URG_PQ"><!-- Strength Range -->
     <low value="Strength Low Number" unit="Strength Unit"/>
     <high value="Strength High Number" unit="Strength Unit"/>
    </numerator>
    <denominator value="Strength Denominator Number" unit="Denominator Unit"/>
```

If the strength is specified as a simple value instead of a range, the format is much simpler:

```
<quantity><!-- Simple Strength -->
 <numerator value="Strength Number" unit="Strength Unit"/>
 <denominator value="Strength Denominator Number" unit="Denominator Unit"/>
```

D.2.5.5.4 Reference strength measurement point

User guidance	The reference strength measurement point, if applicable, should be described as outlined in the measurement point section above.
Conformance	Conditional

When reference substance is a moiety of the ingredient substance:

```
<ingredient classCode="ACTIM">
 <ingredientSubstance>
  <activeMoiety>
   <activeMoiety>…</activeMoiety>
   <subjectOf>
    <characteristic>
     <code code="Code meaning 'Measurement Point'" codeSystem="Code System OID"/>
     <value xsi:type="CV" code="Measurement Point Code"
        codeSystem="Code System OID" displayName="Point Name">
```

When reference substance is not part of the ingredient substance:

```
<ingredient classCode="ACTIR">
 <ingredientSubstance>
  <asEquivalentSubstance>
   <definingSubstance>…</definingSubstance>
   <subjectOf>
    <characteristic>
     <code code="Code meaning 'Measurement Point'"
        codeSystem="Code System OID"/>
     <value xsi:type="CV" code="Measurement Point Code"
        codeSystem="Code System OID" displayName="Point Name">
```

D.2.5.5.5   Reference strength country

User guidance	Where a reference strength country is applicable as outlined in section strength – country above, it can be specified based on the ISO 3166-1-alpha-2 code elements.
Conformance	Conditional

When reference substance is a moiety of the ingredient substance:

```
<ingredient classCode="ACTIM">
 <ingredientSubstance>
  <activeMoiety>
   <activeMoiety>…</activeMoiety>
   <subjectOf>
    <characteristic>
     <code code="Code meaning strength country" codeSystem="Code System OID"/>
     <value xsi:type="CV" code="Country where strength applies" codeSystem="Code System OID"
        displayName="Country Name"/>
```

When reference substance is not part of the ingredient substance:

```
<ingredient classCode="ACTIR">
 <ingredientSubstance>
  <asEquivalentSubstance>
   <definingSubstance>…</definingSubstance>
   <subjectOf>
    <characteristic>
     <code code="Code meaning 'Measurement Point', country specific"
        codeSystem="Code System OID"/>
     <value xsi:type="CV" code="Measurement Point Code"
        codeSystem="Code System OID" displayName="Point Name">
```

The terminology for country specific measurement points is to be defined and maintained by the applicable maintenance organisation.

Annex E
(normative)

Pharmaceutical product and device

E.1 General

This annex describes the Medicinal Product in terms of its qualitative and quantitative composition and in the pharmaceutical dose form approved for administration in line with the regulated product information. These characteristics of the Medicinal Product are referred to as pharmaceutical product.

For certain medicines, a device can form an integral part of the Medicinal Product, for example, to support the administration of the medicine. In these instances, the pharmaceutical product contains the device component information as an additional characteristic.

A Medicinal Product is associated with the pharmaceutical product class – in terms of its qualitative and quantitative composition and the pharmaceutical dose form approved for administration in line with the regulated product information. The nature of the association of the Medicinal Product with the pharmaceutical product is that the pharmaceutical product is the result of fully reconstituting the Medicinal Product and all its package items using its various manufactured items (and devices if applicable). In addition, it is also the result of reconstituting the manufactured item in accordance with the product information (i.e. with other pharmaceutical products not included in the Medicinal Product, for example, water for injection or sucrose solution).

Both Medicinal Product and pharmaceutical product are represented in HL7 SPL as top-level manufactured product elements. The Medicinal Product (with its MPID) shall be specified first, followed by pharmaceutical product.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Medicinal Product -->
     <code code="MPID#1" codeSystem="MPID Code System OID"/>
     <!-- Medicinal Product Details -->
    </manufacturedProduct>
   </manufacturedProduct>
  </subject>
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Pharmaceutical Product -->
     <!-- Pharmaceutical Product Details -->
    </manufacturedProduct>
    <productOf>
     <reconstitution>
      <consumable>
       <manufacturedProduct>
        <code code="MPID#1" codeSystem="MPID Code System OID"/>
```

The pharmaceutical product is associated with various pharmaceutical product characteristics, which can describe various aspects of the pharmaceutical product, such as its onset of action.

The pharmaceutical product may be associated with a device class, which represents information about any integral device to support the administration of the product - and therefore is of type "integrated device". The device can have a set of physical characteristics and other characteristics associated with it.

The pharmaceutical product shall be described in terms of the ingredients it contains. Ingredients are described in greater detail in <u>Annex D</u>.

The pharmaceutical product is associated with a set of PhPIDs, as documented in ISO 11616 and ISO/TS 20451.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>...
    <productOf>
     <reconstitution>

      <consumable>
       <adminstrableMaterial>
        <administrableProduct><!-- Pharmaceutical Product -->
         <formCode code="Administrable Dose Form code" codeSystem="Code System (OID)" displayName="Form
Name"/>
          <asSpecialisedKind>

           <generalisedMaterialKind>
            <code code="PhPID" codeSystem="PhPID Code System OID" .../>
           </generalisedMaterialKind>
          </asSpecialisedKind>
          <ingredient classCode="Ingredient Role"><!-- Ingredient -->
           <quantity><!-- Strength -->

            <numerator xsi:type="URG_PQ"><!-- Strength Range -->
             <low value="Strength Low Number" unit="Strength Unit"/>
             <high value="Strength High Number" unit="Strength Unit"/>
            </numerator>
            <denominator value="Strength Denominator Number" unit="Strength Denominator Unit"/>
           </quantity>

           <ingredientSubstance><!-- Substance -->
            <code code="Substance Code" codeSystem="Code System (OID)"/>
            <name><!-- Substance Name --></name>
            <activeMoiety><!-- Reference Strength (Active Moiety) -->
             <quantity><!-- Reference Strength Quantity --></quantity>
             <activeMoiety>
              <code code="Substance Code" codeSystem="Code System (OID)"/>

              <name><!-- Substance Name --></name>
             </activeMoiety>
            </activeMoiety><!-- Reference Strength Quantity -->
            <asEquivalentSubstance><!-- Reference Strength (Reference Substance) -->
             <quantity>

              <numerator xsi:type="URG_PQ"><!-- Reference strength -->
               <low value="Strength Low Number" unit="Strength Unit"/>
               <high value="Strength High Number" unit="Strength Unit"/>
              </numerator>
              <denominator value="Strength Denominator Number" unit="Strength Denominator Unit"/>
             </quantity>
             <definingSubstance>

              <code code="Substance Code" codeSystem="Code System (OID)"/>
              <name><!-- Substance Name --></name>
             </definingSubstance>
            </asEquivalentSubstance>
           </ingredientSubstance>
           <subjectOf>

            <substanceSpecification><!-- Specified Substance -->
             <code code="Substance Specification Code" codeSystem="Code System (OID)"
                 displayName="Substance Specification Name"/>
            </substanceSpecification>
           </subjectOf>
          </ingredient>
          <part><!-- Device as integral part of the Pharmaceutical Product --></part>
        </administrableProduct>...
```
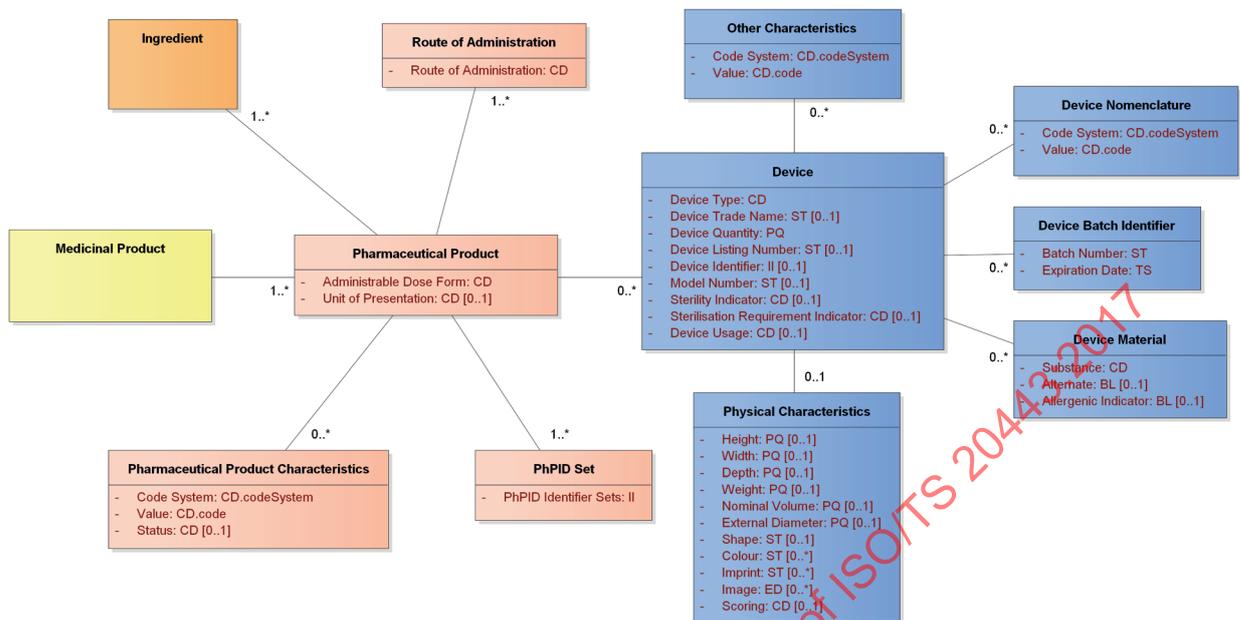
Figure E.1 — Pharmaceutical product and device section detailed description diagram

E.2 Pharmaceutical product

User guidance	A pharmaceutical product shall be described in terms of its qualitative and quantitative composition and the pharmaceutical dose form approved for administration (administrable dose form) in line with the regulated product information.
	The "qualitative and quantitative composition" pharmaceutical product consists of its ingredients and parts (may include a device that is integral to the pharmaceutical product in combination).
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>...
    <productOf>
     <reconstitution>
      <consumable>
       <adminstrableMaterial>
        <administrableProduct><!-- Pharmaceutical Product -->
         <formCode code="Administrable Dose Form code" codeSystem="Code System (OID)"
               displayName="Form Name"/>
         <ingredient><!-- Ingredient --></ingredient>
         <part><!-- Device (as integral part) --></part>
```


E.2.1   Administrable dose form

User guidance	This shall describe the administrable dose form in accordance with the regulated product information. This is after it has undergone any necessary reconstitution or transformation, where applicable. The administrable dose form shall be specified in accordance with ISO 11239, ISO/TS 20440, and the resulting terminology. The term and term identifier shall be specified.
	In certain instances, the administrable dose form differs from the manufactured dose form when a transformation of the manufactured dose form has been carried out.
	EXAMPLE The manufactured dose forms of two manufactured items are described as "powder for solution for injection" and "solvent for solution for injection" which, after transformation, corresponds to the administrable dose form "solution for injection".
Conformance	Mandatory

NOTE 1   In certain instances, the administrable dose form differs from the manufactured dose form (i.e. a transformation of the manufactured dose form has been carried out).

NOTE 2   The administrable dose form is as authorised by a medicines regulatory agency, regardless of whether the necessary components for reconstitution/transformation are co-packaged or packaged separately.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>...
    <productOf>
      <reconstitution>
        <consumable>
         <adminstrableMaterial>
           <adminstrableProduct><!-- Pharmaceutical Product -->
             <formCode code="Administrable Dose Form code" codeSystem="Code System (OID)"
                   displayName="Form Name"/>
```

E.2.2   Unit of presentation

User guidance	The unit of presentation is a qualitative term describing the discrete unit in which a pharmaceutical product is presented to describe strength or quantity in cases where a quantitative unit of measurement is not appropriate. It is a term and a term identifier as defined in the ISO 11239 and the resulting terminology.
	For pharmaceutical products whose strength is measured as a quantity of weight or volume, the "unit of presentation" can be specified as the immediate (lowest level) container.
	For solid dose forms and other items whose strength is described on the basis of the amount in the unit of presentation, and which are counted in integer quantities, the unit for quantity should be "1 unit" and the unit of presentation should be the item that is counted, specified as a term and a term identifier as defined in the ISO 11239, ISO/TS 20440, and the resulting terminology.
Conformance	Conditional

EXAMPLE 1   Qualitative measurement: To describe a strength representing a qualitative value: tablet, spray, puff, for instance, "contains 100 mcg per actuation", actuation would represent the unit of presentation per the user guidance.

If the manufactured product is an aerosol for inhalation, and it is delivered from a metered dose inhaler ("dispenser"), then the administrable dose form concept, fully specified, should be "the portion of

aerosol dispensed by one actuation of the dispenser". That is the actual administrable dose form and item for which ingredients per actuation can be specified as well as the item that is referenced in the unambiguous administration instructions.

```
<manufacturedProduct>
 <formCode code="Code for 'Portion Delivered by Pump Spray Actuation'" codeSystem="Code System (OID)"
       displayName="SPRAY"/>
 <ingredient classCode="ACTI">
  <quantity>
   <numerator value="100" unit="ug"/>
   <denominator value="1" unit="1">
    <translation value="1" code="Code for 'Actuation'"
        codeSystem="Code System (OID)" displayName="ACTUATION [UoP]"/>
```

EXAMPLE 2 To describe quantity: bottle, vial; "contains 100 ml per bottle" (unit of presentation = bottle).

NOTE In this instance, the unit of presentation is referring a unit level count (e.g. each).

As a package, if the need for specifying "bottle" as a count noun is determined, this can be done on the package specification of the manufactured product as follows:

```
<manufacturedProduct>
 <asContent>
  <quantity>
   <numerator value="100" unit="ug"/>
   <denominator value="1" unit="1">
    <translation value="1" code="Code for 'Bottle' as 'Unit of Presentation'"
        codeSystem="Code System (OID)" displayName="BOTTLE [UoP]"/>
   </denominator>
  </quantity>
  <containerPackagedProduct>
   <formCode code="Code for 'Bottle' as package type"
       codeSystem="Code System (OID)" displayName="BOTTLE">
```

E.2.3   PhPID set

User guidance	This class shall be assigned the relevant identifiers as defined by ISO 11616 and ISO/TS 20451. This provides a uniform representation of the pharmaceutical product using the substance(s)/specified substance(s), their (reference) strength(s), the administrable dose form and, where applicable, the integral device.
Conformance	Mandatory

E.2.3.1   PhPID Identifier sets

User guidance	The identifier sets themselves
Conformance	Mandatory

E.2.4   Route of administration

The Route of Administration is a concept that is used to describe the path by which the Pharmaceutical Product is taken into or makes contact with the body.

User guidance	The Route of Administration shall be specified using terms and a term identifiers as defined in ISO 11239, ISO/TS 20440, and its resulting terminology.
Conformance	Mandatory

E.2.4.1   Route of administration

User guidance	The route of administration is specified with this attribute.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <productOf>
     <reconstitution>
      <consumable>
       <administrableMaterial><!-- Pharmaceutical Product -->
        <consumedIn>
         <substanceAdministration1>
          <routeCode code="Route Code" codeSystem="Code System (OID)" displayName="Route Name"/>
```

EXAMPLE 1   Oral.

```
<routeCode code="C38288" codeSystem="2.16.840.1.113883.3.26.1.1"
     displayName="ORAL"/>
```

EXAMPLE 2   Subcutaneous.

```
<routeCode code="C38299" codeSystem="2.16.840.1.113883.3.26.1.1"
     displayName="SUBCUTANEOUS"/>
```

EXAMPLE 3   Ophthalmic.

```
<routeCode code="C38287" codeSystem="2.16.840.1.113883.3.26.1.1"
     displayName="OPHTHALMIC"/>
```

E.2.5 Pharmaceutical product characteristics

User guidance	The distinguishing qualities of a pharmaceutical product or substance.
	EXAMPLE 1 Duration of time it takes for a drug's effects to come to prominence upon administration (i.e. onset of action).
	EXAMPLE 2 Of solution for a reconstituted product/product after transformation.
	EXAMPLE 3 Pharmacokinetic/pharmacodynamic properties (PK/PD).
	This element should be used to describe various characteristics of the pharmaceutical product.
	The code describing the type of characteristic shall be specified using an appropriate identification system and the individual value from the code system that describes the actual characteristic should be specified using a term and a term identifier from the code system.
Conformance	Optional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <productOf>
     <reconstitution>
      <consumable>
       <administrableMaterial><!-- Pharmaceutical Product -->
        <subjectOf>
         <characteristic>
          <!-- Pharmaceutical Product Characteristics -->
          <code code="Pharmaceutical Product Characteristic Code(fixed)" codeSystem="Characteristic Code System
(OID)"/>
          <value xsi:type="CV" code="Pharmaceutical Product Characteristic Value"
             codeSystem="Pharmaceutical Product Characteristic Code System"/>
```

E.2.5.1 (Pharmaceutical product characteristics) code system

User guidance	The code system describing the characteristic is specified using an appropriate controlled terminology.
Conformance	Mandatory

```
<subjectOf>
 <characteristic>
  <!-- Pharmaceutical Product Characteristics -->
  <code code="Pharmaceutical Product Characteristic Code(fixed)" codeSystem="Characteristic Code System (OID)"/>
  <value xsi:type="CV" code="Pharmaceutical Product Characteristic Value"
          codeSystem="Pharmaceutical Product Characteristic Code System"/>
```

E.2.5.2 (Pharmaceutical product characteristics) value

User guidance	The value from the pharmaceutical product characteristics system can be specified.
Conformance	Mandatory

```
<subjectOf>
 <characteristic>
  <!-- Pharmaceutical Product Characteristics -->
  <code code="Pharmaceutical Product Characteristic Code(fixed)" codeSystem="Characteristic Code System (OID)"/>
  <value xsi:type="CV" code="Pharmaceutical Product Characteristic Value"
          codeSystem="Pharmaceutical Product Characteristic Code System"/>
```

E.2.5.3 Status

User guidance	The status of the pharmaceutical product characteristics value can be specified.
Conformance	Optional

```
<subjectOf>
  <characteristic>
   <!-- Pharmaceutical Product Characteristics --> ...
   <subjectOf>
     <characteristic>
      <code code="Characteristic Status" codeSystem="Code System (OID)" displayName="Name of Characteristic Sta-
tus"/>
     </characteristic>
   </subjectOf>
  </characteristic>
</subjectOf>
```

E.2.6 Device

For pharmaceutical products where the associated Medicinal Product is combined with a medical device and where the pharmacological, immunological or metabolic action should be considered as the principal mode of action, the medical device presented as part of the Medicinal Product, should be described, using the **Device**, **Device Nomenclature**, **Batch Identifier**, **Physical Characteristics** and **Other Characteristics** classes. The detail of these three classes is as described in Annex C.

In these instances, the device is considered as an "ingredient" of the pharmaceutical product, and is described here, as it will be referenced in the PhPID identification of the pharmaceutical product (see Annex E).

Annex F
(normative)

Clinical particulars

F.1   General

This annex specifies information that primarily refers to the description of the clinical particulars for a Medicinal Product. This information should be described for each Medicinal Product.

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct>

     <!-- Medicinal / Pharmaceutical Product -->
    </manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <reason><!-- Indication --></reason>
      <precondition><!-- Population Specifics --></precondition>
      <subjectOf>

       <issue>
        <code code="C41332" codeSystem="2.16.840.1.113883.3.26.1.1"
           displayName="ADVERSE REACTION"/>
         <!-- Undesirable Effect -->
       </issue>
      </subjectOf>
      <subjectOf>
       <issue>
        <code code="C54346" codeSystem="2.16.840.1.113883.3.26.1.1"
           displayName="CONTRAINDICATION "/>
         <!-- Contraindication -->
       </issue>
      </subjectOf>
```

A Medicinal Product is associated with a set of clinical particulars. These consist of information about the Medicinal Product's indication(s), its contraindication(s) and its undesirable effect(s) (not all-inclusive as other clinical particulars may be identified in regional guidance/implementation).

Both indication(s) and contraindication(s) can be qualified by a Specific Population referencing a particular indication or contraindication and by Other Therapy Specifics (i.e. the use of the Medicinal Product in relation to other medication(s).
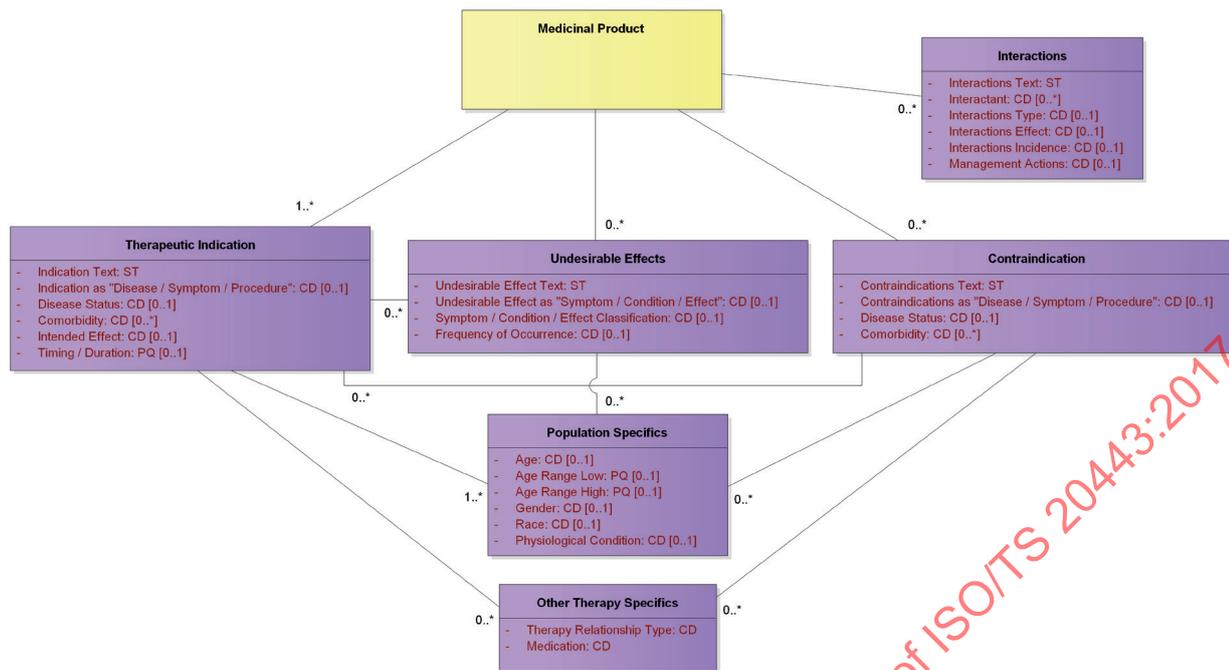
Figure F.1 — Clinical particulars section detailed description diagram

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>…
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>

    <manufacturedProduct>
     <!-- Medicinal / Pharmaceutical Product -->
    </manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <reason>
       <indicationObservationCriterion>
        <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
           displayName="Medical Problem"/>

        <text><!-- Indication Text --></text>
        <value code="Indication as Disease or Symptom Code"
           codeSystem="2.16.840.1.113883.6.96"
           displayName="Disease Name" xsi:type="CE"/>
       </indicationObservationCriterion>

      </reason>
      <precondition>
       <observationCriterion>
        <code code="30525-0" codeSystem="2.16.840.1.113883.6.1"
           displayName="Age"/>
        <value xsi:type="IVL_PQ">

         <low value="Age Range low limit" unit="a"/>
         <high value="Age Range high limit" unit="a"/>
        </value>
       </observationCriterion>
      </precondition>
      <precondition>
```

```
  <observationCriterion>
   <code code="21840-4" codeSystem="2.16.840.1.113883.6.1"
     displayName="Gender"/>
   <value xsi:type="CV" code="Gender Code">
   </value>
  </observationCriterion>

 </precondition>
 <precondition>
  <observationCriterion>
   <code code="32624-9" codeSystem="2.16.840.1.113883.6.1"
     displayName="Race"/>
   <value xsi:type="CV" code="Race Code">

   </value>
  </observationCriterion>
 </precondition>
 <precondition>
  <observationCriterion>
   <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
     displayName="Medical Problem"/>

   <value xsi:type="CV" code="Co-Morbidity / Physiological Condition Code">
   </value>
  </observationCriterion>
 </precondition>
 <goal>
  <effect>
   <code code="Intended Effect" codeSystem="code system (OID)" displayName="Intended Effect Code
Description"/>
  <effect>
 <goal>
 <subjectOf>
  <issue>
   <code code="C41332" codeSystem="2.16.840.1.113883.3.26.1.1"
     displayName="ADVERSE REACTION"/>

   <text><!-- Undesirable Effect Text --></text>
   <risk>
    <consequenceObservationCriterion>
     <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
       displayName="Medical Problem"/>

     <value code="Undesired Effect as Symptom or Condition Code"
       codeSystem="2.16.840.1.113883.6.96"
       displayName="Disease Name" xsi:type="CE"/>
    </consequenceObservationCriterion>
   </risk>

  </issue>
 </subjectOf>
 <subjectOf>
  <issue>
   <code code="C54346" codeSystem="2.16.840.1.113883.3.26.1.1"
     displayName="CONTRAINDICATION "/>

   <text><!-- Contraindication Text --></text>
   <subject>
    <observationCriterion>
     <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
       displayName="Medical Problem"/>

     <value code="Contraindication as Disease or Symptom Code"
       codeSystem="2.16.840.1.113883.6.96"
       displayName="Disease Name" xsi:type="CE"/>
    </observationCriterion>
   </subject>
  </issue>
 </subjectOf>
```

F.2 Therapeutic indication

User guidance	This class should be used to describe the authorised indication(s) for the Medicinal Product in accordance with the regulated product information.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct>
     <!-- Medicinal / Pharmaceutical Product -->
    </manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <reason>
       <indicationObservationCriterion>
        <code code="44100-6" codeSystem="2.16.840.1.113883.6.1" displayName="Medical Problem"/>
        <value code="Indication as Disease or Symptom Code" codeSystem="2.16.840.1.113883.6.96" displayName="Disease Name" xsi:type="CE">
                 originalText value="Indication Text"/>
```

F.2.1 Indication text

User guidance	The authorised therapeutic indication(s) should be described in text.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product Details --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <reason>
       <indicationObservationCriterion>
        <text><!-- Indication Text --></text>
```

F.2.2 Indication as "disease/symptom/procedure"

User guidance	The underlying disease, symptom or procedure that is the indication for treatment should be specified as it is referenced in the regulated product information using an appropriate controlled reference terminology. The controlled term and the controlled term identifier should be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product Details --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <reason>
       <indicationObservationCriterion>
        <code code="44100-6" codeSystem="2.16.840.1.113883.6.1" displayName="Medical Problem"/>
        <value code="Indication as Disease or Symptom Code" codeSystem="2.16.840.1.113883.6.96" displayName="Disease Name" xsi:type="CE"/>
```

F.2.3   Disease status

User guidance	The status of the disease or symptom of the indication can be specified as it is referenced in the regulated product information using an appropriate controlled vocabulary. The controlled term and the controlled term identifier should be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product Details --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <reason>
       <indicationObservationCriterion>
        <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"displayName="Medical Problem"/>
        <value code="Indication as Disease or Symptom Code" codeSystem="2.16.840.1.113883.6.96"
              displayName="Disease Name" xsi:type="CD">
         <qualifier>
          <name code="Code meaning 'Disease Status" codeSystem="2.16.840.1.113883.6.96"
               displayName="Disease Status"/>
          <value code="Disease Status Code" codeSystem="2.16.840.1.113883.6.96" displayName="Disease Status Name"/>
```

F.2.4   Co-morbidity

User guidance	If there is any co-morbidity (concurrent condition) or co-infection described as part of the indication as it is referenced in the regulated product information, it can be specified here using an appropriate controlled reference terminology. The controlled term and the controlled term identifier should be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product Details --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <reason>
       <indicationObservationCriterion>
        <!-- Indication Condition Details -->
       </indicationObservationCriterion>
      </reason>
      <precondition>
      <observationCriterion>
       <code code="44100-6" codeSystem="2.16.840.1.113883.6.1" displayName="Medical Problem"/>
       <value xsi:type="CV" code="Comorbidity Code"/>
```

F.2.5   Intended effect

User guidance	The intended effect can be specified as it is referenced in the regulated product information using an appropriate controlled vocabulary. The controlled term and the controlled term identifier should be specified.
	The intended effect is specifically the part of the indication that describes the type of outcome or result intended for the target condition, whereas the Indication is the full text description of the benefits from the medicine for the target condition in the target population
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct>
     <!-- Medicinal / Pharmaceutical Product -->
    </manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <goal>
       <effect>
        <code code="Intended Effect" codeSystem="code system (OID)" displayName="Intended Effect Code Descrip-
tion"/>
       <effect>
      <goal>
```

F.2.6   Timing/duration

User guidance	Timing or duration information described as part of the indication as it is referenced in the regulated product information can be specified here. The ISO data type PQ should be used, but can also be extended to URG<PQ> if a range is necessary.
Conformance	Conditional

EXAMPLES   Prevention of atherothrombotic events in patients with ischaemic stroke (from 7 days until less than 6 months).

```
 <consumedIn>
  <substanceAdministration1><!-- Clinical Particulars -->
   <reason typeCode="PRYLX">
    <indicationObservationCriterion>
     <code code="44100-6" codeSystem="2.16.840.1.113883.6.1" displayName="Medical Problem"/>
     <value xsi:type="CV" code="Code for 'atherothrombotic event'" codeSystem="Code System OID"/>
    </indicationObservationCriterion>
   </reason>
   <precondition>
    <pauseQuantity value="7" unit="d">
    <!-- Or a range can be represented  e.g. -->
    <!-- pauseQuantity xsi:type="URG_PQ">
     <low value="7" unit="d"/>
     <high value="6" unit="mo"/>
    </pauseQuantity -->
    <observationCriterion>
     <code code="44100-6" codeSystem="2.16.840.1.113883.6.1" displayName="Medical Problem"/>
     <value xsi:type="CV" code="Code for 'ischemic stroke'" codeSystem="Code System OID"/>
```

F.2.7 Population specifics

User guidance	This class can be used to describe the population for each identified indication(s), undesirable effects, or contraindication(s) applies as authorised for the Medicinal Product in accordance with the regulated Medicinal Product information.
Conformance	Mandatory

For the indication:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <precondition>
       <observationCriterion>
        <code .../>
        <value .../>
```

For the contraindication:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <subjectOf>
       <issue>
        <code code="C54346" codeSystem="2.16.840.1.113883.3.26.1.1" displayName="CONTRAINDICATION "/>
        <subject>
         <observationCriterion>
          <code code="44100-6" codeSystem="2.16.840.1.113883.6.1" displayName="Medical Problem"/>
          <value code="Contraindication as Disease or Symptom Code" codeSystem="2.16.840.1.113883.6.96"
             displayName="Disease Name" xsi:type="CE"/>
        </subject>
        <subject>
         <observationCriterion>
          <code .../>
          <value .../>
```

F.2.7.1   Age

User guidance	The age group of the specific population for an indication, undesirable effect, or a contraindication as authorised for the Medicinal Product in accordance with the regulated Medicinal Product information can be specified using an appropriate controlled terminology. The controlled term and the controlled term identifier shall be specified.
Conformance	Conditional

```
<observationCriterion>
 <code code="Code meaning 'Age Group'"
    codeSystem="2.16.840.1.113883.6.1"
    displayName="Age Group"/>
 <value code="Age Group Code" codeSystem="Code System (OID)"
    displayName="Age Group Name" xsi:type="CV">
```

F.2.7.2   Age range (low and high)

User guidance	The age range of the specific population for an indication, undesirable effect, or a contraindication as authorised for the Medicinal Product in accordance with the regulated Medicinal Product information can be specified.
Conformance	Conditional

```
<observationCriterion>
 <code code="30525-0" codeSystem="2.16.840.1.113883.6.1"
    displayName="Age"/>
 <value xsi:type="IVL_PQ">
  <low value="Age Range low limit" unit="a"/>
  <high value="Age Range high limit" unit="a"/>
 </value>
</observationCriterion>
```

F.2.7.3   Gender

User guidance	The gender of the specific population for an indication, undesirable effect, or a contraindication in accordance with the regulated product information should be specified using ISO/IEC 5218.
Conformance	Conditional

```
<observationCriterion>
<code code="21840-4" codeSystem="2.16.840.1.113883.6.1"
    displayName="Gender"/>
<value xsi:type="CV" code="Gender Code">
```

F.2.7.4   Race

User guidance	The race of the specific population for an indication, undesirable effect, or a contraindication in accordance with the regulated Medicinal Product information can be specified using an appropriate controlled terminology. The controlled term and the controlled term identifier shall be specified.
Conformance	Conditional

```
<observationCriterion>
<code code="32624-9" codeSystem="2.16.840.1.113883.6.1"
    displayName="Race"/>
<value xsi:type="CV" code="Race Code">
```

F.2.7.5   Physiological condition

User guidance	Various aspects of the physiological condition of the specific population for an indication, undesirable effect, or a contraindication in accordance with the regulated product information can be specified using an appropriate controlled reference terminology. The controlled term and the controlled term identifier should be specified.
Conformance	Conditional

```
<observationCriterion>
<code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
    displayName="Medical Problem"/>
<value xsi:type="CV" code="Physiological Condition Code">
```

F.2.8   Other therapy specifics

User guidance	Information about the use of the Medicinal Product in relation to other therapies described as part of the indication, undesirable effect, or a contraindication in accordance with the regulated Medicinal Product information, can be specified using this information structure.
Conformance	Conditional

```
<substanceAdministration1><!-- Clinical Particulars -->
 <subjectOf>
  <issue>
   <code code="Indication Other Therapy" codeSystem="Code System OID"/>
    <subject>
    <localVariableName value="Therapy Relationship Type"/>
     <substanceAdministrationCriterion>
      <consumable>
       <administrableMaterial>
        <administrableMaterialKind>
         <code code="Other Therapy Specifics Medication" codeSystem="Code System OID"/>
```

F.2.8.1 Therapy relationship type

User guidance	The type of relationship between the Medicinal Product indication or a contraindication and a specific other therapy should be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier should be specified.
Conformance	Mandatory

```
<substanceAdministration1><!-- Clinical Particulars -->
 <subjectOf>
  <issue>
   <code code="Indication Other Therapy" codeSystem="Code System OID"/>
    <subject>
    <localVariableName value="Therapy Relationship Type"/>
     <substanceAdministrationCriterion>
      <consumable>
       <administrableMaterial>
        <administrableMaterialKind>
         <code code="Other Therapy Specifics Medication" codeSystem="Code System OID"/>
```

F.2.8.2 Medication

User guidance	Reference to a specific medication, expressed as an active substance, a Medicinal Product or class of Medicinal Products which refers to a specific indication or a contraindication, in accordance with the regulated product information, can be specified using an appropriate controlled reference terminology. The controlled term and the controlled term identifier shall be specified.
Conformance	Mandatory

```
<substanceAdministration1><!-- Clinical Particulars -->
 <subjectOf>
  <issue>
   <code code="Indication Other Therapy" codeSystem="Code System OID"/>
    <subject>
    <localVariableName value="Therapy Relationship Type"/>
     <substanceAdministrationCriterion>
      <consumable>
       <administrableMaterial>
        <administrableMaterialKind>
         <code code="Other Therapy Specifics Medication" codeSystem="Code System OID"/>
```

F.3   Contraindication

User guidance	This class shall be utilised to describe the authorised contraindication(s) for the Medicinal Product as described in the regulated product information.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <subjectOf>
       <issue>
        <code code="C54346" codeSystem="2.16.840.1.113883.3.26.1.1"
          displayName="CONTRAINDICATION "/>
        <text><!-- Contraindication Text --></text>
        <subject>
         <observationCriterion>
          <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
            displayName="Medical Problem"/>
          <value code="Contraindication as Disease or Symptom Code"
            codeSystem="2.16.840.1.113883.6.96"
            displayName="Disease Name" xsi:type="CE"/>
```

F.3.1   Contraindications text

User guidance	The text of the contraindication(s) in line with the regulated product information shall be described.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <subjectOf>
       <issue>
        <code code="C54346" codeSystem="2.16.840.1.113883.3.26.1.1"
          displayName="CONTRAINDICATION "/>
        <text><!-- Contraindication Text --></text>
```

F.3.2   Contraindications as "disease/symptom/procedure"

User guidance	The underlying disease, symptom or procedure of the contraindication should be specified as it is referenced in the regulated product information using an appropriate controlled reference terminology. The controlled term and the controlled term identifier should be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <subjectOf>
       <issue>
        <code code="C54346" codeSystem="2.16.840.1.113883.3.26.1.1"
           displayName="CONTRAINDICATION "/>
        <subject>
         <observationCriterion>
          <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
             displayName="Medical Problem"/>
          <value code="Contraindication as Disease or Symptom Code"
             codeSystem="2.16.840.1.113883.6.96"
             displayName="Disease Name" xsi:type="CD"/>
```

F.3.3   Disease status

User guidance	The status of the disease or symptom of the contraindication can be specified as it is referenced in the regulated product information using an appropriate controlled vocabulary. The controlled term and the controlled term identifier should be specified.
Conformance	Conditional

The disease status is considered a property of the disease concept. If the disease code system allows post-coordination, such "status" may be post-coordinated:

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <subjectOf>
       <issue>
        <code code="C54346" codeSystem="2.16.840.1.113883.3.26.1.1"
           displayName="CONTRAINDICATION "/>
        <subject>
         <observationCriterion>
          <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
             displayName="Medical Problem"/>
          <value code="Contraindication as Disease or Symptom Code"
             codeSystem="2.16.840.1.113883.6.96"
             displayName="Disease Name" xsi:type="CD">
         <qualifier>
          <name code="Code meaning 'Disease Status'"
            codeSystem="2.16.840.1.113883.6.96"
            displayName="Disease Status"/>
          <value code="Disease Status Code"
            codeSystem="2.16.840.1.113883.6.96"
            displayName="Disease Status Name"/>
```

F.3.4 Co-morbidity

User guidance	If there is any co-morbidity (concurrent condition) or co-infection described as part of the contraindication as it is referenced in the regulated product information, it can be specified here using an appropriate controlled reference terminology. The controlled term and the controlled term identifier should be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <subjectOf>
       <issue>
        <code code="C54346" codeSystem="2.16.840.1.113883.3.26.1.1"
           displayName="CONTRAINDICATION "/>
        <text><!-- Contraindication Text --></text>
        <subject>
         <observationCriterion>
            <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
            displayName="Medical Problem"/>
             <value xsi:type="CV" code="Co-Morbidity Code"/>
```

F.4 Undesirable effects

User guidance	This class should be used to describe the undesirable effects of the Medicinal Product as described in the regulated product information.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <subjectOf>
       <issue>
        <code code="C41332" codeSystem="2.16.840.1.113883.3.26.1.1"
           displayName="ADVERSE REACTION"/>
        <text><!-- Undesirable Effect Text --></text>
        <risk>
         <consequenceObservationCriterion>
          <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
             displayName="Medical Problem"/>
          <value code="Undesirable Effect as Symptom or Condition Code"
             codeSystem="2.16.840.1.113883.6.96"
             displayName="Disease Name" xsi:type="CD"/>
```

F.4.1 Undesirable effect text

User guidance	The text of the undesirable effect shall be given.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <subjectOf>
       <issue>
        <code code="C41332" codeSystem="2.16.840.1.113883.3.26.1.1"
           displayName="ADVERSE REACTION"/>
        <text><!-- Undesirable Effect Text --></text>>
```

F.4.2 Undesirable effect as "symptom/condition/effect"

User guidance	The symptom, condition or effect in relation to the undesirable effect as described in the regulated product information should be specified using an appropriate controlled reference terminology. The controlled term and the controlled term identifier should be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <subjectOf>
       <issue>
        <code code="C41332" codeSystem="2.16.840.1.113883.3.26.1.1"
           displayName="ADVERSE REACTION"/>
        <risk>
         <consequenceObservationCriterion>
          <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
             displayName="Medical Problem"/>
          <value code="Undesirable Effect as Symptom or Condition Code"
             codeSystem="2.16.840.1.113883.6.96"
             displayName="Disease Name" xsi:type="CE"/>
```

F.4.3 Symptom/condition/effect classification

User guidance	The classification of the "symptom/condition/effect" can be specified. The controlled term and the controlled term identifier should be specified using an appropriate controlled reference terminology.
Conformance	Conditional

```
    <issue>
     <code code="C41332" codeSystem="2.16.840.1.113883.3.26.1.1"
        displayName="ADVERSE REACTION"/>
     <risk>
      <consequenceObservationCriterion>
       <code code="Code for 'Medical Problem' with Classification"
          codeSystem="Code System (OID)"
          displayName="Display Name"/>
       <value code="Undesirable Effect as Symptom or Condition Code"
          codeSystem="2.16.840.1.113883.6.96"
          displayName="Disease Name" xsi:type="CE"/>
```

NOTE   The purpose of this attribute is to permit the grouping of adverse effects by system or other categories. The properties of the symptoms/conditions/effects are determined by their definition, and this categorisation shall not be used to post-coordinate the clinical meaning, as in symptom = "pain" or classification = "abdominal symptoms."

F.4.4   Frequency of occurrence

User guidance	The frequency of occurrence of the "symptom/condition/effect" can be specified, using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <component><structuredBody><component><section>...
  <subject>
   <!-- CPM body -->
   <manufacturedProduct>
    <manufacturedProduct><!-- Product --></manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <subjectOf>
       <issue>
        <code code="C41332" codeSystem="2.16.840.1.113883.3.26.1.1"
           displayName="ADVERSE REACTION"/>
       <text><!-- Undesirable Effect Text --></text>
        <risk>
         <consequenceObservationCriterion>
          <code code="44100-6" codeSystem="2.16.840.1.113883.6.1"
             displayName="Medical Problem"/>
          <value code="Undesirable Effect as Symptom or Condition Code"
             codeSystem="2.16.840.1.113883.6.96"
             displayName="Disease Name" xsi:type="CE"/>
       <subjectOf>
         <frequency>
          <code code="Code meaning 'Frequency'"
             codeSystem="Code System (OID)"/>
          <value code="Frequency Code" codeSystem="Code System (OID)"
             displayName="Frequency Name" xsi:type="CV"/>
```

F.4.5   Population specifics

This class should be described as in F.2.7.

F.5   Interactions

User guidance	This class should be used to describe the interactions of the Medicinal Product and other forms of interaction as described in the regulated product information.
Conformance	Conditional

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

   <manufacturedProduct>
    <manufacturedProduct>
     <!-- Medicinal / Pharmaceutical Product -->
    </manufacturedProduct>
    <consumedIn>
     <substanceAdministration1><!-- Clinical Particulars -->
      <subjectOf>

       <issue>
        <code code="Interaction Type with Management Action Code" codeSystem="Code System (OID)"
           displayName="Interaction Type / Management Action Name"/>
        <text><!-- Interaction Text --></text>
        <risk>
         <consequenceObservation>
          <code code="44100-6" codeSystem="2.16.840.1.113883.6.1" displayName="Medical Problem"/>
          <value code="Interaction Effect as Symptom or Condition Code" codeSystem="2.16.840.1.113883.6.96"

             displayName="Interaction Effect Display Name" xsi:type="CE"/>
          <subjectOf>
           <frequency>
            <code code="Code for 'Interaction Incidence'"/>
            <value code="Interaction Incidence (Code)" xsi:type="CV" codeSystem="Code System (OID)"
               displayName="Interaction Incidence (Display Name)"/>
           </frequency>

          </subjectOf>
         </consequenceObservation>
        </risk>
        <subject>
         <substanceAdministrationCriterion>
          <consumable>
           <administrableMaterial>
            <administrableMaterialKind>

             <code code="Interactant Value (Code)"
                codeSystem="Interactant Code System (OID)" displayName="Interactant Value Name"/>
            </administrableMaterialKind>
           </administrableMaterial>
          </consumable>
         </substanceAdministrationCriterion>
        </subject>
       </issue>
      </subjectOf>
```

F.5.1   Interactions text

User guidance	The text of the interaction in accordance with the regulated product information should be provided.
Conformance	Mandatory

```
<substanceAdministration1><!-- Clinical Particulars -->
 <subjectOf>
  <issue>
   <code code="Interaction Type with Management Action Code"
      codeSystem="Code System (OID)"
      displayName="Interaction Type / Management Action Name"/>
   <text><!-- Interaction Text --></text>
```

F.5.2 Interactant

User guidance	This element should be used to describe the specific medication, food or laboratory test that is the secondary interactant of the interaction as described in the regulated product information.
	The code system being used to describe the secondary interactant shall be specified using an appropriate identification system and the individual value from the code system that describes the actual interactant shall be specified using a controlled term identifier and a controlled term.
Conformance	Conditional

```
<substanceAdministration1><!-- Clinical Particulars -->
 <subjectOf>
  <issue>
   <code code="Interaction Type with Management Action Code"
      codeSystem="Code System (OID)"
      displayName="Interaction Type / Management Action Name"/>
   <risk>
   <subject>
    <substanceAdministrationCriterion>
     <consumable>
      <administrableMaterial>
       <administrableMaterialKind>
        <code code="Interactant Value (Code)"
          codeSystem="Interactant Code System (OID)"
          displayName="Interactant Value Name"
       </administrableMaterialKind>
      </administrableMaterial>
     </consumable>
    </substanceAdministrationCriterion>
   </subject>
  </issue>
 </subjectOf>
```

F.5.3 Interactions type

User guidance	The type of interaction in line with the regulated product information should be described using an appropriate controlled reference vocabulary.
Conformance	Conditional

```
<substanceAdministration1><!-- Clinical Particulars -->
 <subjectOf>
  <issue>
   <code code="Interaction Type" codeSystem="Code System (OID)" displayName="Interaction Type"/>
```

F.5.4   Interactions effect

User guidance	The effect of the interaction in line with the regulated product information should be described using an appropriate controlled reference vocabulary.
Conformance	Conditional

```
<substanceAdministration1><!-- Clinical Particulars -->
 <subjectOf>
  <issue>
   <code code="Interaction Type" codeSystem="Code System (OID)" displayName="Interaction Type "/>
   <risk>
    <consequenceObservation>
     <code code="44100-6" codeSystem="2.16.840.1.113883.6.1" displayName="Medical Problem"/>
     <value code="Interaction Effect as Symptom or Condition Code" codeSystem="2.16.840.1.113883.6.96"
            displayName="Interaction Effect Display Name" xsi:type="CE"/>
```

F.5.5   Interactions incidence

User guidance	The incidence of the interaction in accordance with the regulated product information should be described using an appropriate controlled reference vocabulary.
Conformance	Conditional

```
<substanceAdministration1><!-- Clinical Particulars -->
 <subjectOf>
  <issue>
   <code code="Interaction Type" codeSystem="Code System (OID)" displayName="Interaction Type "/>
   <risk>
    <consequenceObservation>
     <subjectOf>
      <frequency>
       <code code="Code for 'Interaction Incidence'">
       <value code="Interactions Incidence (Code)" xsi:type="CV" codeSystem="Code System (OID)"
              displayName="Interaction Incidence (Display Name)"
```

F.5.6   Management actions

User guidance	The actions to provide management of the interaction in accordance with the regulated product information should be described.
Conformance	Conditional

```
<substanceAdministration1><!-- Clinical Particulars -->
 <subjectOf>
  <issue>
   <mitigatedBy>
    <requirement>
     <code code="Management Action Code" codeSystem="Code System (OID)" displayName="Management Action Name"/>
```

Annex G
(normative)

Organisation

G.1   General

Whenever a class is described as an "organisation", the following general set of information should be specified for the appropriate instance of the organisation. This information is applicable to marketing authorisation holder, Medicines Regulatory Agency and Manufacturer/Establishment. Regional guidance/implementation shall determine the exact role to be utilised for organisation identification.
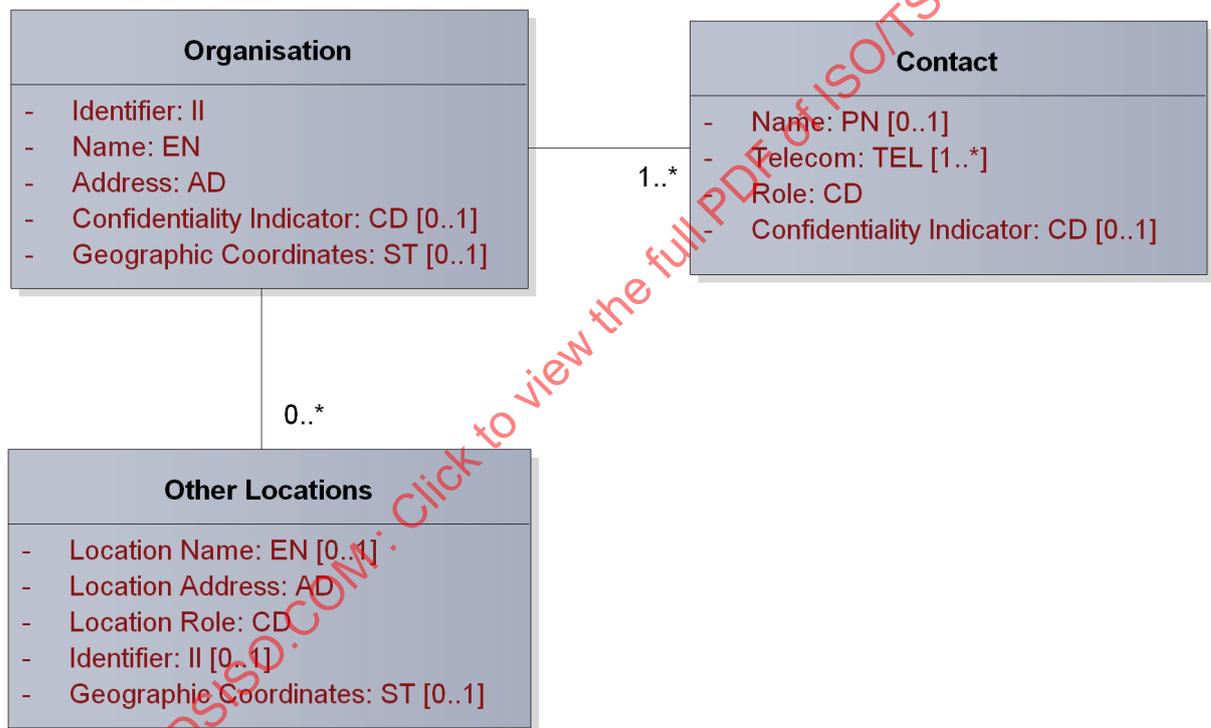

Figure G.1 — Organisation detailed description diagram

G.2   Organisation

User guidance	An entity responsible for any regulated activity related to a Medicinal Product as defined by a medicines regulatory agency within a given region/jurisdiction.
	Information on organisation shall be provided.
Conformance	Mandatory

```
<someRole>
 <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>
 <someOrganisation>
  <id extension="Identifier" root="Identifier System"/>
  <name>Weckerle GmbH</name>
  <addr><!-- Address -->
   <streetAddressLine>address</streetAddressLine>
   <city>city</city>
   <state>state</state>
   <postalCode>postal code</postalCode>
   <country code="country code" codeSystem="1.0.3166.1.2.3">country name</country>
  </addr>
  <contactParty>
  <code code="Role Code" displayName="Role Name"
     codeSystem="Role Code System OID" />
  <telecom value="tel:Telecom Telephone Number"/>
  <telecom value="mailto: Telecom Email Address"/>
  <contactPerson>
   <name>Name of Contact Person</name>
```

G.2.1   Identifier

User guidance	The unique identifier of the organisation shall be provided. An international coding system for unique organisation identifiers can be used
Conformance	Mandatory

```
<someRole>
 <someOrganisation>
  <id extension="Identifier" root="Identifier System"/>
```

G.2.2   Name

User guidance	The name of the organisation shall be provided in text.
Conformance	Mandatory

```
<someRole>
 <someOrganisation>
  <name>DrugCo</name>
```

G.2.3   Address

User guidance	The address of the organisation shall be provided. The use of the ISO data type for Addresses is specified.
Conformance	Mandatory

```
<someRole>
 <someOrganisation>
  <addr><!-- Address -->
   <streetAddressLine>address</streetAddressLine>
   <city>city</city>
   <state>state</state>
   <postalCode>postal code</postalCode>
   <country code="country code" codeSystem="1.0.3166.1.2.3">country name</country>
  </addr>
```

G.2.4 Confidentiality indicator

User guidance	The confidentiality level of the organisation information can be specified using an appropriate controlled vocabulary. The controlled term and a term identifier should be specified.
Conformance	Conditional

```
<someRole>
 <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>
```

G.2.5 Geographic coordinates

User guidance	ISO 6709 is the international standard for representation of latitude, longitude and altitude for geographic point locations.
Conformance	Optional

G.2.6 Contact

User guidance	This class is used to specify a contact person from within the organisation and the role of that person.
Conformance	Conditional

```
<someRole>
 <someOrganisation>
  <contactParty>
   <code code="Role Code" displayName="Role Name"
       codeSystem="Role Code System OID" />
   <telecom value="tel:Telecom Telephone Number"/>
   <telecom value="mailto: Telecom Email Address"/>
   <contactPerson>
    <name>Name of Contact Person</name>
```

G.2.6.1 Name

User guidance	The name of the contact person shall be provided. The use of the ISO data type for person name is specified.
Conformance	Conditional

```
<someRole>
 <someOrganisation>
  <contactParty>
   <contactPerson>
    <name>Name of Contact Person</name>
```

G.2.6.2 Telecom

User guidance	The telecom information (telephone, e-mail, etc.) of the contact person shall be provided.
Conformance	Mandatory

```
<someRole>
 <someOrganisation>
  <contactParty>
   <telecom value="tel:Telecom Telephone Number"/>
   <telecom value="mailto: Telecom Email Address"/>
```

G.2.6.3   Role

User guidance	The role of the contact person within the organisation in the context of the Medicinal Product being described should be specified using a suitable controlled vocabulary. The controlled term and the controlled term identifier should be specified.
Conformance	Mandatory

```
<someRole>
 <someOrganisation>
  <contactParty>
   <code code="Role Code" displayName="Role Name"
      codeSystem="Role Code System OID" />
```

G.2.6.4   Confidentiality indicator

User guidance	The confidentiality level of the contact person's information can be specified using an appropriate controlled vocabulary. The controlled term and a term identifier should be specified.
Conformance	Conditional

```
<someRole>
 <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>
```

G.2.7   Other locations

User guidance	This class is used to specify one or more other significant locations of the organisation and the role of that location.
Conformance	Conditional

```
<someOrganisation>
 <otherLocation>
  <id root="Complete Globally Unique Identifier or Identifier System (OID)"
    extension="Identifier in Identifier System"/>
  <code code="Location Role Code" displayName="Role Name"
     codeSystem="Role Code System OID" />
  <addr><!--Location Address --></addr>
```

G.2.7.1   Location name

User guidance	The name of the organisation shall be provided in text.
Conformance	Conditional

```
<someRole>
 <someOrganisation>
  <name>DrugCo</name>
```

G.2.7.2   Location address

User guidance	The address of the location of the organisation should be provided using a standardised structured address format.
Conformance	Mandatory

```
<someOrganisation>
 <otherLocation>
  <addr><!-- Location Address --></addr>
```

G.2.7.3   Location role

User guidance	The role of the location within the organisation in the context of the Medicinal Product being described should be specified using a suitable controlled vocabulary. The controlled term and the controlled term identifier should be specified.
Conformance	Mandatory

```
<someOrganisation>
 <otherLocation>
  <code code="Location Role Code" displayName="Role Name"
     codeSystem="Role Code System OID" />
```

G.2.7.4   Identifier

User guidance	The unique identifier of the location can be provided. An international coding system for unique organisation identifiers can be used per regional requirements.
Conformance	Conditional

```
<otherLocation>
 <id root="Complete Globally Unique Identifier or Identifier System (OID)"
   extension="Identifier in Identifier System"/>
```

G.2.7.5   Geographic coordinates

User guidance	ISO 6709 is the international standard for representation of latitude, longitude and altitude for geographic point locations.
Conformance	Optional

Annex H
(normative)

Manufacturer/establishment

H.1 General

This annex describes the manufacturer and/or establishment information for a Medicinal Product.

Figure H.1 — Manufacturer/establishment section high level diagram

The Medicinal Product is associated with **Organisation** information for one or more **Manufacturers** or **Establishments** which undertake various **Manufacturing Operations** in order to produce a Medicinal Product. These are overseen by an appropriate **Medicines Regulatory Agency.**

NOTE   Figure 19 can be associated with the following classes:

  a) Medicinal Product;

  b) packaged Medicinal Product;

  c) package item (container);

  d)   package (component);

  e) manufactured item;

  f) ingredient.

In HL7 SPL, all establishments are written as (indirectly) associated with the responsible document author. Within this context, the responsible document author of a regulated document is ultimately the marketing authorisation holder. There are traditionally four levels of organisations:

— marketing authorisation holder (also called "labeller"), the author/represented organisation;

— owner/operator of manufacturing facilities/establishments (also called "registrant");

— manufacturing facility/establishment;

— agent representative and importer of foreign manufacturing facility/establishment.

As applicable, these organisations shall be supplied in an SPL document at the appropriate level of nesting as shown in the following template:

```
<!-- SPL header -->
<document>
 <author>
  <assignedEntity><!-- Authorisation Holder Organisation -->
   <representedOrganisation>
    <assignedEntity><!-- Establishment Owner/Operator Organisation -->
     <assignedOrganisation>
      <assignedEntity><!-- Manufacturer / Establishment Organisation -->
```

If a higher-level organisation is not included, the respective level is still included in the SPL document without any further elements.

EXAMPLE   Only marketing authorisation holder and manufacturer facility, no owner/operator:

```
<!-- SPL header -->
<document>
 <author>
  <assignedEntity><!-- Authorisation Holder Organisation -->
   <id extension="Identifier" root="Identifier System"/>
   <name>Alpha DrugCo</name>
   <representedOrganisation>
    <assignedEntity><!-- Establishment Owner/Operator Organisation -->
     <assignedOrganisation>
      <assignedEntity><!-- Manufacturer / Establishment Organisation -->
       <id extension="Identifier" root="Identifier System"/>
       <name> Alpha-1 MFR</name>
```

Manufacturer/establishment organisations are linked with one or more manufacturing operations to one or more Medicinal Products as shown in the following outline:

```
<!-- SPL header -->
<document>
 <author>
  <assignedEntity><!-- Authorisation Holder Organisation -->
   <representedOrganisation>
    <assignedEntity><!-- Establishment Owner/Operator Organisation -->
     <assignedOrganisation>
      <assignedEntity><!-- Manufacturer / Establishment Organisation -->
       <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>
       <assignedOrganisation>...</assignedOrganisation>
       <performance>
        <actDefinition><!-- Manufacturing Operation -->
         <code code="Operation Type Code" displayName="Operation Type Name"
            codeSystem="Operation Type Code System OID"/>
         <product>
          <!-- CPM body -->
         <manufacturedProduct>
          <manufacturedMaterialKind><!-- Medicinal Product Reference -->
           <code code="MPID" codeSystem="MPID Code System OID"/>
          </manufacturedMaterialKind>
         <manufacturedProduct>
         </product>
        </actDefinition>
       </performance>
```

The MPID provided in the Medicinal Product reference serves as a reference to the MPID included with full description in the body of the SPL document further below:

```
<component><structuredBody><component><section>...
 <subject>
  <!-- CPM body -->
  <manufacturedProduct>
   <manufacturedProduct><!-- Medicinal Product -->
    <code code="MPID#1" codeSystem="MPID Code System OID"/>
    <!-- MPID full description -->
   </manufacturedProduct>
  </manufacturedProduct>
 </subject>
```

This way the many-to-many association between manufacturing facilities/establishments and their operations on different Medicinal Products can be freely specified.

```
<!-- SPL header -->
<document>
 <author>
  <assignedEntity><!-- Authorisation Holder Organisation -->
   <representedOrganisation>
    <assignedEntity><!-- Establishment Owner/Operator Organisation -->
     <assignedOrganisation>

      <assignedEntity><!-- Manufacturer / Establishment Organisation -->
       <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>
       <assignedOrganisation>...</assignedOrganisation>
       <performance>
        <actDefinition><!-- Manufacturing Operation -->
         <code code="Operation Type Code" displayName="Operation Type Name"

            codeSystem="Operation Type Code System OID"/>
         <product>
          <!-- CPM body -->
          <manufacturedProduct>
           <manufacturedMaterialKind><!-- Medicinal Product Reference -->
            <code code="MPID" codeSystem="MPID Code System OID"/>
           </manufacturedMaterialKind>

          </manufacturedProduct>
         </product>
        </actDefinition>
       </performance>            <performance>
        <actDefinition><!-- Manufacturing Operation -->
         <code code="Operation Type Code" displayName="Operation Type Name"
            codeSystem="Operation Type Code System OID"/>

         <product>
          <!-- CPM body -->
          <manufacturedProduct>
           <manufacturedMaterialKind><!-- Medicinal Product Reference -->
            <code code="MPID#1" codeSystem="MPID Code System OID"/>
           </manufacturedMaterialKind>
          <manufacturedProduct>

         </product>            </actDefinition>
       </performance>
      </assignedEntity>
      <assignedEntity><!-- Manufacturer / Establishment Organisation -->
       <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>
       <assignedOrganisation>...</assignedOrganisation>

       <performance>
        <actDefinition><!-- Manufacturing Operation -->
         <code code="Operation Type Code" displayName="Operation Type Name"
            codeSystem="Operation Type Code System OID"/>
         <product>
          <!-- CPM body -->
          <manufacturedProduct>
```

```
        <manufacturedMaterialKind><!-- Medicinal Product Reference -->
         <code code="MPID#2" codeSystem="MPID Code System OID"/>
        </manufacturedMaterialKind>
       <manufacturedProduct>
      </product>
     </actDefinition>
    </performance>
   <performance>

    <actDefinition><!-- Manufacturing Operation -->
     <code code="Operation Type Code" displayName="Operation Type Name"
        codeSystem="Operation Type Code System OID"/>
     <product>
      <!-- CPM body -->
      <manufacturedProduct>
       <manufacturedMaterialKind><!-- Medicinal Product Reference -->

        <code code="MPID#1" codeSystem="MPID Code System OID"/>
       </manufacturedMaterialKind>
       <manufacturedProduct>
      </product>
     </actDefinition>
    </performance>
   </assignedEntity>
  </assignedOrganisation>

  </assignedEntity>
 </representedOrganisation>
</assignedEntity>
</author>
<component><structuredBody><component><section>...
 <subject>

  <!-- CPM body -->
  <manufacturedProduct>
   <manufacturedProduct><!-- Medicinal Product #1 -->
    <code code="MPID#1" codeSystem="MPID Code System OID"/>
    <!-- MPID definition -->

   </manufacturedProduct>
  </manufacturedProduct>
 </subject>
 <subject>
  <!-- CPM body -->
  <manufacturedProduct>

   <manufacturedProduct><!-- Medicinal Product #2 -->
    <code code="MPID#2" codeSystem="MPID Code System OID"/>
    <!-- MPID definition -->
   </manufacturedProduct>
  </manufacturedProduct>
 </subject>
```
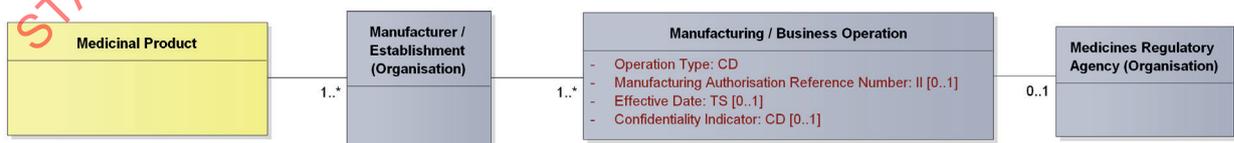
H.2 Manufacturer/establishment (organisation)

Figure H.2 — Manufacturer/establishment section detailed diagram

User guidance	A Medicinal Product shall be associated with one or more manufacturers/establishments. The information related to the manufacturer/establishment for the organisation undertaking the particular manufacturing operation should be described using the pattern for organisation described in Annex G.
	NOTE Manufacturer/establishment (organisation) can be associated with the following classes:
	— Medicinal Product;
	— packaged Medicinal Product;
	— package item (container);
	— package (component);
	— manufactured item;
	— ingredient.
Conformance	Mandatory for Medicinal Product
	Conditional for other classes

```
<!-- SPL header -->
<document>
 <author>
  <assignedEntity><!-- Authorisation Holder Organisation -->
   <representedOrganisation>
    <assignedEntity><!-- Establishment Owner/Operator Organisation -->
     <assignedOrganisation>
      <assignedEntity><!-- Manufacturer / Establishment Organisation -->
       <assignedOrganisation>
        <name>Company ABC</name>
       </assignedOrganisation>
       <performance>
        <actDefinition><!-- Manufacturing Operation -->
         <code code="…" displayName="BATCH RELEASE"
            codeSystem="…"/>
        </actDefinition>
       </performance>
      </assignedEntity>
     <assignedEntity><!-- Manufacturer / Establishment Organisation -->
      <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>
      <assignedOrganisation>
       <name>Company DEF</name>
      </assignedOrganisation>
      <performance>
       <actDefinition><!-- Manufacturing Operation -->
        <code code="…" displayName="RE-LABELING"
           codeSystem="…"/>
```

H.2.1   Manufacturing/business operation

User guidance	The manufacturing operation being undertaken by the particular manufacturer/establishment organisation should be specified.
Conformance	Mandatory

H.2.1.1   Operation type

User guidance	The type of manufacturing operation shall be specified using a suitable controlled vocabulary. The controlled term and the controlled term identifier shall be specified.
Conformance	Mandatory

```
<!-- SPL header -->
<document>
 <author>
  <assignedEntity><!-- Authorisation Holder Organisation -->
   <representedOrganisation>
    <assignedEntity><!-- Establishment Owner/Operator Organisation -->
     <assignedOrganisation>
      <assignedEntity><!-- Manufacturer / Establishment Organisation -->
       <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>
       <assignedOrganisation>...</assignedOrganisation>
       <performance>
        <actDefinition><!-- Manufacturing Operation -->
         <code code="Operation Type Code" displayName="Operation Type Name"
            codeSystem="Operation Type Code System OID"/>
```

H.2.1.2 Manufacturing authorisation reference number

User guidance	The reference number of the authorisation for manufacturing or equivalent shall be specified in text.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <author>
  <assignedEntity><!-- Authorisation Holder Organisation -->
   <representedOrganisation>
    <assignedEntity><!-- Establishment Owner/Operator Organisation -->
     <assignedOrganisation>
      <assignedEntity><!-- Manufacturer / Establishment Organisation -->
       <assignedOrganisation>...</assignedOrganisation>
       <performance>
        <actDefinition><!-- Manufacturing Operation -->
         <subjectOf>
          <approval>
           <id extension="Manufacturing Authorisation Reference Number"
             root="Reference Number System OID"/>
```

H.2.1.3 Effective date

User guidance	The effective date of the manufacturing authorisation stated in the attribute above shall be specified. Complete dates consisting of day, month and year shall be specified using the ISO 8601 date format.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <author>
  <assignedEntity><!-- Authorisation Holder Organisation -->
   <representedOrganisation>
    <assignedEntity><!-- Establishment Owner/Operator Organisation -->
     <assignedOrganisation>
      <assignedEntity><!-- Manufacturer / Establishment Organisation -->
       <assignedOrganisation>...</assignedOrganisation>
       <performance>
        <actDefinition><!-- Manufacturing Operation -->
         <effectiveTime value="Effective Date"/>
```

H.2.1.4   Confidentiality indicator

User guidance	The level of confidentiality of the manufacturing operation can be specified using an appropriate controlled vocabulary. The controlled term and a term identifier should be specified.
Conformance	Conditional

```
<!-- SPL header -->
<document>
 <author>
  <assignedEntity><!-- Authorisation Holder Organisation -->
   <representedOrganisation>
    <assignedEntity><!-- Establishment Owner/Operator Organisation -->
     <assignedOrganisation>
      <assignedEntity><!-- Manufacturer / Establishment Organisation -->
       <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>
       <assignedOrganisation>...</assignedOrganisation>
```

When the confidentialityCode with code = "B" is present, it means the organisation information is confidential to this file. If the confidentialityCode is absent or if the nullFlavor attribute is provided, then the company is not confidential.

Confidential:

```
<assignedEntity><!-- Manufacturer / Establishment Organisation -->
 <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>
 <assignedOrganisation>...</assignedOrganisation>
```

Not confidential

```
<assignedEntity><!-- Manufacturer / Establishment Organisation -->
 <assignedOrganisation>...</assignedOrganisation>
```

or

```
<assignedEntity><!-- Manufacturer / Establishment Organisation -->
 <confidentialityCode nullFlavor="NI"/>
 <assignedOrganisation>...</assignedOrganisation>
```

NOTE   The difference between the two examples is the following:

a) not mentioning the confidentiality code will leave whatever confidentiality assumption that existed before;

b) by specifying confidentiality code as null clears the indicator that may have been previously set.

H.3   Medicines regulatory agency (organisation)

User guidance	The medicines regulatory agency which oversees a specific manufacturing operation should be described using the pattern for organisation described in Annex G.
Conformance	Conditional