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Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information

Informatique de santé — Identification des médicaments — Éléments de données et structures pour l'identification unique et l'échange d'informations sur les médicaments contrôlés

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

ISO (the International Organization for Standardization) 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*.

This second edition cancels and replaces the first edition (ISO 11615:2012), which has been technically revised.

Introduction

This document was developed in response to a worldwide demand for internationally harmonised specifications for Medicinal Products. It is part of a set of five ISO Standards and four ISO Technical Specifications which together provide the basis for the unique Identification of Medicinal Products (IDMP).

These sets of standards and technical specifications comprise:

— ISO 11615

— ISO/TS 20443;

— ISO 11616;

— ISO/TS 20451;

— ISO 11238;

— ISO/TS 19844;

— ISO 11239;

— ISO/TS 20440;

— ISO 11240.

These standards and technical specifications for the identification of Medicinal Products (IDMP) support the activities of medicines regulatory agencies worldwide by region. These include a variety of regulatory activities related to development, registration and life cycle management of Medicinal Products, as well as pharmacovigilance and risk management.

To meet the primary objectives of the regulation of medicines and pharmacovigilance, it is necessary to reliably exchange Medicinal Product Information in a robust and consistent manner. The IDMP standards therefore support, at a minimum, the following interactions:

— regulatory medicines authority to regulatory medicines authority;

— pharmaceutical company to regulatory medicines authority;

— sponsor of a clinical trial to regulatory medicines authority;

— regulatory medicines authority to other stakeholders (as applicable);

— regulatory medicines authority to worldwide-maintained data sources.

The necessary messaging specifications are included as an integral part of the IDMP standards to secure the interactions above.

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

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 given in this document are to be applied for the concepts which are required to uniquely identify, characterise and exchange regulated Medicinal Products and associated information.

The terms and definitions adopted in this document are intended to facilitate the interpretation and application of legal and regulatory requirements.

This document has been developed in conjunction with the Common Product Model (CPM) and Structured Product Labelling (SPL) in HL7.

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 and with certainty identify Medicinal Products for human use;

— to specify definitions of terms for all data elements required to uniquely and with certainty identify Medicinal Products for human use.

In addition, reference to the use of other normative IDMP and messaging standards for Medicinal Product information is included in this document in order to support successful information exchange.

Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information

1 Scope

This document establishes definitions and 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, the standards listed in the Introduction define, characterise and uniquely identify regulated Medicinal Products for human use during their entire life cycle, i.e. from development to authorisation, 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 use of other normative IDMP messaging standards is included, which are to be applied in the context of this document.

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 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 code*

ISO 3166-1:2013, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

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

ISO/TS 19844, *Health informatics — Identification of Medicinal Products — Implementation guidelines for data elements and structures for the unique identification and exchange of regulated information on substances*

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*

ISO/TS 20443, *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11615 data elements and structures for the unique identification and exchange of regulated Medicinal Product information*

ISO/TS 20451, *Health informatics — Identification of Medicinal Products — Implementation guide for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

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

HL7 Version 3 Standard, Structured Product Labelling

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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/

3.1.1
adjuvant
component that potentiates the immune response to an antigen and/or modulates it towards the desired immune response

3.1.2
administrable dose form
pharmaceutical dose form for administration to the patient, after any necessary transformation of the *manufactured items* (3.1.37) and their corresponding *manufactured dose forms* (3.1.36) has been carried out

Note 1 to entry: The administrable dose form is identical to the manufactured dose form in cases where no transformation of the manufactured item is necessary (i.e. where the manufactured item is equal to the pharmaceutical product).

Note 2 to entry: Administered dose form and pharmaceutical administrable dose form are synonyms of administrable dose form.

3.1.3
administration device
equipment intended for correct administration of the *Medicinal Product* (3.1.50)

Note 1 to entry: An administration device may be an integral part of an *immediate container* (3.1.27) or a closure.

[SOURCE: ENV 12610:1997]

3.1.4
allergen
material (3.1.47) of concern used as *ingredient* (3.1.28) or in a device capable of stimulating a type-I hypersensitivity or allergic reaction in atopic individuals

3.1.5
authorisation date
date when the authorisation was granted by a *Medicines Regulatory Agency* (3.1.56) following a specific regulatory activity

3.1.6
authorisation procedure
formal procedure applied by a *Medicines Regulatory Agency* (3.1.56) to grant a *marketing authorisation* (3.1.40), to amend an existing one, to extend its duration or to revoke it

Note 1 to entry: The terms authorisation procedure and *marketing authorisation procedure* (3.1.43) are synonymous.

3.1.7
authorisation status
phase of the *marketing authorisation* (3.1.40) during its life cycle

Note 1 to entry: The status indicates a particular moment in its life cycle.

3.1.8
batch
specific quantity of a drug or other *material* (3.1.47) that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture

3.1.9
batch number
identifier (3.1.26) assigned to a specific *batch* (3.1.8) of a *Medicinal Product* (3.1.50) or item resulting from a manufacturing process at a specific point of time

3.1.10
characteristic
abstraction of a property of an object

3.1.11
clinical trial
investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an *Investigational Medicinal Product(s)* (3.1.31), and/or to study absorption, distribution, metabolism and excretion of Investigational Medicinal Product(s) with the object of ascertaining its safety and/or efficacy

Note 1 to entry: The terms clinical trial and clinical study are synonymous.

3.1.12
clinical trial authorisation
approval given by a *Medicines Regulatory Agency* (3.1.56) to conduct a *clinical trial* (3.1.11) in a *region* (3.1.73)

3.1.13
class
set of objects that share the same specifications of features, constraints, and semantics

3.1.14
combined pharmaceutical dose form
two or more *manufactured items* (3.1.37) that are intended to be combined in a specific way to produce a single pharmaceutical product, and that includes information on the *manufactured dose form* (3.1.36) of each manufactured item and the *administrable dose form* (3.1.2) of the pharmaceutical product

3.1.15
common name
official non-proprietary or generic name recommended by the World Health Organisation (WHO), or, if one does not exist, a non-proprietary name recommended by the *region* (3.1.73) within which the name is used

Note 1 to entry: Generic name and international non-proprietary name are synonymous of common name.

[SOURCE: WHO 46th Consultation on International Nonproprietary Names (INNs) for Pharmaceutical Substances]

3.1.16
container
item of packaging that is part of a *Medicinal Product* (3.1.50) and is used for storage, identification and/or transport of the components of the Medicinal Product

3.1.17
contraindication
situations where the *Medicinal Product* (3.1.50) shall not be given for safety reasons

3.1.18
controlled vocabulary
finite set of values that represent the only allowed values for a data item

Note 1 to entry: The allowed values can be codes, text or numeric.

[SOURCE: CDISC Clinical Research Glossary V10.0, 2016]

3.1.19
datatype
set of distinct values, characterised by properties of those values, and by operations on those values

[SOURCE: ISO 11404:2007, 3.12]

3.1.20
device listing number
number assigned by a *Medicines Regulatory Agency* (3.1.56) during registration and/or listing to all devices in commercial distribution, regardless of pre-market authorisation requirements, per regional registration and listing requirements

3.1.21
device model number
identifier (3.1.26) assigned by a medical device *manufacturer* (3.1.38) to a particular design or version of a *medical device* (3.1.49)

3.1.22
distributor
organisation in possession of a license covering the procuring, holding, supplying or exporting of *Medicinal Products* (3.1.50), apart from supplying Medicinal Products to the public

Note 1 to entry: This is applicable to "wholesale distribution of Medicinal Products".

3.1.23
dose
specified quantity of a medicine, to be taken at one time or at stated intervals

3.1.24
dose form
physical manifestation of a *Medicinal Product* (3.1.50) that contains the active *ingredient(s)* (3.1.28) and/or inactive ingredient(s) that are intended to be delivered to the patient

Note 1 to entry: Dose form, dosage form and pharmaceutical dose form are synonymous. "Pharmaceutical dose form" can refer to the *administrable dose form* (3.1.2) or the *manufactured dose form* (3.1.36).

3.1.25
Global Trade Item Number
GTIN
GS1 unique *identifier* (3.1.26) of items that are traded [e.g. pharmaceuticals, *medical devices* (3.1.49)] in the supply chain

Note 1 to entry: A GTIN is used to identify any item upon which there is a need to retrieve predefined information and that may be priced, ordered or invoiced at any point in any supply chain. GTINs may be 8, 12, 13 or 14 digits in length.

3.1.26
identifier
description that is sufficient to represent an object in a given environment

Note 1 to entry: In the context of this document, this is a list of identifying *characteristics* (3.1.10) that together unambiguously identify a *Medicinal Product* (3.1.50), pharmaceutical product, *substance* (3.1.80), *specified substance* (3.1.77), *route of administration* (3.1.76), pharmaceutical dose form or any other element which requires to be uniquely identified.

[SOURCE: ENV 12610:1997]

3.1.27
immediate container
packaging in which a *manufactured item* (3.1.37) or pharmaceutical product is contained and with which it is in direct contact

Note 1 to entry: An immediate container can be fitted with or have integrated into it an *administration device* (3.1.3) and/or closure. A pharmaceutical dose form can fulfil the role of an immediate container, e.g. a capsule containing a powder for inhalation; the capsule in this case is not a *container* (3.1.16). An alternative, compatible definition of immediate container ("immediate packaging") is given in Directive 92/27/EEC.

[SOURCE: ENV 12610:1997]

3.1.28
ingredient
material (3.1.47) used in the preparation of a medicinal/pharmaceutical product

Note 1 to entry: The ingredient is part of a *Medicinal Product* (3.1.50), either alone or in combination with other ingredients. The ingredient is also a component of a pharmaceutical product. Ingredient is equal to a *substance* (3.1.80) with the indication of the specific role it is playing in the product.

3.1.29
intermediate packaging
container (3.1.16) between the *outer packaging* (3.1.57) and the *immediate container* (3.1.27)

3.1.30
invented name
proprietary name for a *Medicinal Product* (3.1.50) as authorised by a *Medicines Regulatory Agency* (3.1.56) in a *region* (3.1.73)

Note 1 to entry: The term invented name is synonymous with trade name and with brand name for a Medicinal Product.

3.1.31
Investigational Medicinal Product
pharmaceutical product or combination of pharmaceutical products or placebo(s) being tested or used as a reference in a *clinical trial* (3.1.11), including products already with a *marketing authorisation* (3.1.40) but used or assembled (packaged) in a way different from the authorised form, used for an unauthorised indication, or used to gain further information about the authorised form

3.1.32
Investigational Medicinal Product Identifier
unique *identifier* (3.1.26) allocated to an *Investigational Medicinal Product* (3.1.31) supplementary to any existing identifier as ascribed by a *Medicines Regulatory Agency* (3.1.56) in a *region* (3.1.73)/*jurisdiction* (3.1.34) or a sponsor of a *clinical trial* (3.1.11)

Note 1 to entry: This is an alphanumeric text field.

Note 2 to entry: This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of *Medicinal Products* (3.1.50) worldwide.

3.1.33
Investigational Medicinal Product Package Identifier
unique *identifier* (3.1.26) allocated to an Investigational Packaged Medicinal Product at package level supplementary to any existing identifier as ascribed by a *Medicines Regulatory Agency* (3.1.56) in a *region* (3.1.73)/*jurisdiction* (3.1.34) or a sponsor of a *clinical trial* (3.1.11)

Note 1 to entry: This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of *Medicinal Products* (3.1.50) worldwide.

3.1.34
jurisdiction
geographical area within a country/*region* (3.1.73) or subject matter to which the *Medicines Regulatory Agency* (3.1.56) applies

3.1.35
legal status of supply
regional/jurisdictional rule as to whether a *Medicinal Product* (3.1.50) is subject to a medical prescription before it may be supplied to a patient or consumer

3.1.36
manufactured dose form
pharmaceutical dose form of a *manufactured item* (3.1.37) as manufactured and, where applicable, before transformation into the pharmaceutical product

Note 1 to entry: The manufactured dose form is identical to the *administrable dose form* (3.1.2) in cases where no transformation of the manufactured item is necessary (i.e. where the manufactured item is equal to the pharmaceutical product).

3.1.37
manufactured item
qualitative (3.1.70) and *quantitative composition* (3.1.71) of a product as contained in the packaging of the *Medicinal Product* (3.1.50) as put on the market or *Investigational Medicinal Product* (3.1.31) as used in a *clinical trial* (3.1.11)

Note 1 to entry: A *Medicinal Product* (3.1.50) may contain one or more manufactured items. In many instances, the manufactured item is equal to the pharmaceutical product. However, there are instances where the manufactured item(s) undergo a transformation before being administered to the patient (as the pharmaceutical product) and the two are not equal.

3.1.38
manufacturer
organisation that holds the authorisation for the manufacturing process

Note 1 to entry: Establishment is a synonym of manufacturer.

3.1.39
manufacturing authorisation
authorisation provided by a *Medicines Regulatory Agency* (3.1.56) to manufacture *Medicinal Products* (3.1.50) within a *region* (3.1.73)

Note 1 to entry: Such authorisation may be required for both total and partial manufacture and for the various processes of dividing up, packaging or presentation. However, such authorisation may not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail supply, by pharmacists in dispensing pharmacies or by persons legally authorised in a region to carry out such processes.

3.1.40
marketing authorisation
authorisation issued from a *Medicines Regulatory Agency* (3.1.56) that allows a *Medicinal Product* (3.1.50) to be placed on the market

3.1.41
marketing authorisation holder
organisation that holds the authorisation for marketing a *Medicinal Product* (3.1.50) in a *region* (3.1.73)

3.1.42
marketing authorisation number
identifier (3.1.26) assigned by a *Medicines Regulatory Agency* (3.1.56) to a *Medicinal Product* (3.1.50)

3.1.43
marketing authorisation procedure
formal procedure applied by a *Medicines Regulatory Agency* (3.1.56) to grant a *marketing authorisation* (3.1.40), amend an existing one, extend its duration or to withdraw it

Note 1 to entry: Marketing authorisation procedure and *authorisation procedure* (3.1.6) are synonymous.

3.1.44
marketing start date
date when the authorised Medicinal Product is marketed in a *region* (3.1.73)

Note 1 to entry: The date of actual marketing of a *Medicinal Product* (3.1.50) is always after a *marketing authorisation* (3.1.40) has been granted by a *Medicines Regulatory Agency* (3.1.56).

3.1.45
marketing stop date
date when the marketing of the authorised Medicinal Product is stopped in a *region* (3.1.73)

3.1.46
marketing status
when a *Medicinal Product* (3.1.50) is actually put on the market or is no longer available in a country or *jurisdiction* (3.1.34)

3.1.47
material
substance (3.1.80) or *specified substance* (3.1.77) of which a certain packaging or device is made

Note 1 to entry: This applies to a Medicinal Product package item [*container* (3.1.16)], package (component) and device.

3.1.48
measurement point
physical location on an *administration device* (3.1.3) where the quantity of the medication being delivered is measured

3.1.49
medical device
instrument, apparatus, appliance, software, *material* (3.1.47) or other article, whether used alone or in combination, including the software intended by its *manufacturer* (3.1.38) to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

— investigation, replacement or modification of the anatomy or of a physiological process;

— control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[SOURCE: EC Directive on Medical Devices 2007/47]

Note 1 to entry: This definition is applicable for the purposes of this and related standards alone (see ISO 11238, ISO 11239, ISO 11240 and this document).

3.1.50
Medicinal Product
pharmaceutical product or combination of pharmaceutical products that may be administered to human beings (or animals) for treating or preventing disease, with the aim/purpose of making a medical diagnosis or to restore, correct or modify physiological functions

Note 1 to entry: A Medicinal Product may contain in the packaging one or more *manufactured items* (3.1.37) and one or more pharmaceutical products. In certain *regions* (3.1.73), a Medicinal Product may also be defined as any *substance* (3.1.80) or combination of substances which may be used to make a medical diagnosis.

Note 2 to entry: The provisions in this document apply to proprietary Medicinal Products for human use intended to be placed on the market and to industrially manufactured Medicinal Products, the marketing of which has been authorised by a *Medicines Regulatory Agency* (3.1.56). However, the provisions do not apply to: i) Medicinal Products prepared according to prescription (e.g. prepared in a pharmacy from a prescription intended for a specific patient), ii) Medicinal Products prepared in accordance with an official formula (e.g. prepared in a pharmacy in accordance with the instructions in a pharmacopoeia and intended to be given direct to the patient by the pharmacy), iii) Medicinal Products intended for research and development trials [see 11.2)] and to iv) intermediate products intended for subsequent processing by an authorised *manufacturer* (3.1.38).

[SOURCE: ENV 13607 and ENV 12610]

3.1.51
Medicinal Product Batch Identifier 1
unique *identifier* (3.1.26) allocated to a specific *batch* (3.1.8) of a *Medicinal Product* (3.1.50), which appears on the *outer packaging* (3.1.57) of the Medicinal Product

Note 1 to entry: It is constructed by using the *batch number* (3.1.9) assigned by the *manufacturer* (3.1.38) and the expiration date. This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of a Medicinal Product at the package level.

3.1.52
Medicinal Product Batch Identifier 2
unique *identifier* (3.1.26) allocated to a specific *batch* (3.1.8) of a *Medicinal Product* (3.1.50), which appears on the immediate packaging, where this is not the *outer packaging* (3.1.57)

Note 1 to entry: It is constructed by using the *batch number* (3.1.9) assigned by the *manufacturer* (3.1.38) and the expiration date. This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of a Medicinal Product based at the level of the *immediate container* (3.1.27).

3.1.53
Medicinal Product Identifier
unique *identifier* (3.1.26) allocated to a *Medicinal Product* (3.1.50) supplementary to any existing authorisation number as ascribed by a *Medicines Regulatory Agency* (3.1.56) in a *region* (3.1.73)

Note 1 to entry: This is an alphanumeric text field.

Note 2 to entry: This is for indexing purposes and to contribute to improved patient safety by allowing for the unique identification of Medicinal Products worldwide.

3.1.54
Medicinal Product name
name as authorised by a *Medicines Regulatory Agency* (3.1.56)

Note 1 to entry: This may be either an *invented name* (3.1.30) not liable to be confused with the *common name* (3.1.14), or a common or a scientific name accompanied by a trade mark or any other applicable descriptor.

3.1.55
Medicinal Product Package Identifier
unique *identifier* (3.1.26) allocated to a *Packaged Medicinal Product* (3.1.59) supplementary to any existing authorisation number as ascribed by a *Medicines Regulatory Agency* (3.1.56) in a *region* (3.1.73)

Note 1 to entry: This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of Medicinal Products worldwide.

3.1.56
medicines regulatory agency
institutional body that, according to the legal system under which it has been established, is responsible for the granting of *marketing authorisations* (3.1.40), *clinical trial authorisations* (3.1.12) and *manufacturing authorisations* (3.1.39) for *Medicinal Products* (3.1.50)

Note 1 to entry: In certain *regions* (3.1.73), the role of the institutional body, which according to the legal system grants the marketing authorisation of Medicinal Products, may be complemented by an additional institutional body responsible for the evaluation and supervision of Medicinal Products. For example, in the EU, the European Commission is the institutional body that grants the marketing authorisation of Medicinal Products and the European Medicines Agency is the body responsible for the evaluation and supervision of Medicinal Products.

3.1.57
outer packaging
external container in which a *Medicinal Product* (3.1.50) is supplied

Note 1 to entry: The *manufactured item* (3.1.37) or *pharmaceutical product* (3.1.60) is not in direct contact with the outer packaging except where the outer packaging also serves as the *immediate container* (3.1.27). An alternative, compatible definition of outer packaging is given in Directive 92/27/EEC.

3.1.58
package item
<container> individual, distinct item(s) contained in a *Packaged Medicinal Product* (3.1.59) which act as *containers* (3.1.16) for *manufactured item(s)* (3.1.37)

3.1.59
Packaged Medicinal Product
Medicinal Product (3.1.50) in a *container* (3.1.16) being part of a package, representing the entirety that has been packaged for sale or supply

3.1.60
pharmaceutical product
qualitative (3.1.70) and *quantitative composition* (3.1.71) of a *Medicinal Product* (3.1.50) in the dose form approved for administration in line with the regulated product information

Note 1 to entry: In many instances, the pharmaceutical product is equal to the *manufactured item* (3.1.37). However, there are instances where the manufactured item shall undergo a transformation before being administered to the patient (as the pharmaceutical product) and the two are not equal.

3.1.61
pharmaceutical product identifier
unique *identifier* (3.1.26) for a *pharmaceutical product* (3.1.60)

3.1.62
pharmacovigilance
process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines

Note 1 to entry: Pharmacovigilance is a key public health function which comprises:

— collecting and managing data on the safety of medicines;

— looking at the data to detect "signals" (any new or changing safety issue);

— evaluating the data and making decisions with regard to safety issues;

— acting to protect public health (including regulatory action);

— communicating with stakeholders;

— auditing of both the outcomes of action taken and the key processes involved.

Note 2 to entry: Those directly involved in pharmacovigilance include:

— patients as the users of medicines;

— doctors, pharmacists, nurses and all other healthcare professionals working with medicines and regulatory authorities responsible for monitoring the safety of medicines;

— pharmaceutical companies, and companies importing or distributing medicines.

3.1.63
physical characteristic
description of the height, weight, width, depth, volume, colour, shape, etc., of an item

3.1.64
primary identifier
each one of the unique IDMP *identifiers* (3.1.26)

Note 1 to entry: This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of *Medicinal Products* (3.1.50) worldwide.

3.1.65
procedure number
tracking or identification number assigned by a *Medicines Regulatory Agency* (3.1.56) in relation to a specific medicine's regulatory process

3.1.66
procedure type
type of legal process applied to authorise or maintain a Medicinal Product marketing authorisation

3.1.67
product classification
categorisation or grouping of *Medicinal Products* (3.1.50) based on specific properties

3.1.68
product labelling
Medicinal Product information as authorised by a *Medicines Regulatory Agency* (3.1.56) in a *region* (3.1.73)

Note 1 to entry: The product labelling content may not be changed except with the approval of the originating Medicines Regulatory Agency.

3.1.69
protocol number
identification or tracking number assigned to the clinical trial protocol

3.1.70
qualitative composition
composition of all the constituents of the investigational or authorised *Medicinal Product* (3.1.50), if applicable, before or after reconstitution and functioning of the constituents of:

— the *substance* (3.1.80) and *specified substance* (3.1.77) description;

— the excipients, whatever their nature or the quantity used, including colouring matter, preservatives, *adjuvants* (3.1.1), stabilisers, thickeners, emulsifiers, flavouring and aromatic substances, etc.

3.1.71
quantitative composition
amount of *substance* (3.1.80) and *specified substance* (3.1.77) constituents of the investigational or authorised *Medicinal Product* (3.1.50) expressed in a ratio scale

Note 1 to entry: It is necessary for the quantitative composition of the substance(s) or the specified substance descriptions of the finished investigational or authorised Medicinal Products (depending on the pharmaceutical form concerned) to specify the mass, or the number of units of biological activity, either per dosage unit or per unit of mass or volume, of each substance or specified substance. Substance or specified substance descriptions present in the form of compounds or derivatives are always designated quantitatively by their total mass and, if necessary or relevant, by the mass of active entity, or entities, of the molecule. The term strength is a synonym of quantitative composition.

3.1.72
reference strength
strength of an active *substance(s)* (3.1.80) and/or *specified substance(s)* (3.1.77) used as a reference from which the strength of an investigational or authorised *Medicinal Product* (3.1.50) is described

Note 1 to entry: The strength of the active substance(s) and/or specified substance(s) shall be described as a quantity of the *substance* (3.1.80) present in a given unit of the *pharmaceutical product* (3.1.60) or *manufactured item* (3.1.37).

3.1.73
region
area, especially part of a country or the world having definable *characteristics* (3.1.10) but not always fixed boundaries

3.1.74
registration number
identifier (3.1.26) assigned to a *clinical trial* (3.1.11) by a *Medicines Regulatory Agency* (3.1.56) in a *region* (3.1.73) for tracking purposes

3.1.75
regulated document
document issued in the context of the regulatory process to grant, maintain or update the authorisation of a *Medicinal Product* (3.1.50) or in the regulatory process of the authorisation and supervision of *clinical trials* (3.1.11)

3.1.76
route of administration
path by which the *pharmaceutical product* (3.1.60) is taken into or makes contact with the body

3.1.77
specified substance
substance (3.1.80) defined by groups of elements that describes multi-substance *materials* (3.1.47) or specifies further information on substances relevant to the description of *Medicinal Products* (3.1.50)

Note 1 to entry: This could include grade, units of measure, physical form, constituents, *manufacturer* (3.1.38), critical manufacturing processes (e.g. extraction, synthetic or recombinant processes), specification and the analytical methods used to determine whether a substance is in compliance with a specification. There are four different groups of elements that can be used to define a given specified substance and specific relationships between each group of elements.

3.1.78
sponsor
individual, company, institution or organisation, which takes responsibility for the initiation, management and/or financing of a *clinical trial* (3.1.11)

3.1.79
strength range
interval defined by a lower and an upper limit of the amounts of *substance* (3.1.80) and *specified substance* (3.1.77) constituents of the investigational or authorised *Medicinal Product* (3.1.50)

3.1.80
substance
matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical

Note 1 to entry: A substance can be a moiety. A moiety is an entity within a substance that has a complete and continuous molecular structure. The strength of a *pharmaceutical product* (3.1.60) is often based on what is referred to as the active moiety of the molecule, responsible for the physiological or pharmacological action of the drug substance. Chemically, the active moiety of a stoichiometric or non-stoichoimetrical substance molecule is considered that part of the molecule that is the base, free acid or ion molecular part of a salt, solvate, chelate, clathrate, molecular complex or ester.

3.1.81
target population
type of patients or consumers for which the indication of a *Medicinal Product* (3.1.50) is authorised or is under investigation

3.1.82
therapeutic indication
defines the target disease or condition for which the *Medicinal Product* (3.1.50) is authorised or under investigation

3.1.83
trademark
distinctive sign or indicator used by an individual, business organisation or other legal entity to identify that the associated products or services to consumers originate from a unique source, and to distinguish those products or services from those of other entities

3.1.84
unit of presentation
qualitative term describing the discrete countable entity in which a *pharmaceutical product* (3.1.60) or *manufactured item* (3.1.37) is presented, in cases where strength or quantity is expressed referring to one instance of this countable entity

Note 1 to entry: A unit of presentation can have the same name as another *controlled vocabulary* (3.1.18), such as a basic dose form or a *container* (3.1.16), but the two concepts are not equivalent, and each has a unique controlled vocabulary term *identifier* (3.1.26).

3.1.85
vocabulary
terminological dictionary which contains designations and definitions from one or more specific subject fields

[SOURCE: ISO 1087-1:2000, 3.7.2]

3.2 Abbreviated terms

BAID1	Medicinal Product Batch Identifier (outer packaging)
BAID2	Medicinal Product Batch Identifier (immediate packaging)
BRIDG	The Biomedical Research Integrated Domain Group Model
CV	Controlled Vocabulary
GTIN	Global Trade Item Number
IBAID1	Investigational Medicinal Product Batch Identifier (outer packaging)
IBAID2	Investigational Medicinal Product Batch Identifier (immediate packaging)
IBD	International Birth Date
ID	Identifier
IDMP	Identification of Medicinal Products
IMP	Investigational Medicinal Product
IMPID	Investigational Medicinal Product Identifier
INN	International non-proprietary name
IMDRF	International Medical Devices Regulators' Forum
IPCID	Investigational Medicinal Product Package Identifier
MPID	Medicinal Product Identifier
OID	Object Identifier
OMG	Object Management Group
PCID	Medicinal Product Package Identifier
PhPID	Pharmaceutical Product Identifier
SPC/SmPC	Summary of Product Characteristics
UML	Unified Modeling Language (Object Management Group, Inc.)
UDI	Unique Device Identification Code (IMDRF)
WHO	World Health Organization

4 Message exchange format

In the context of this document, the normative message exchange format to be utilised as reference in transactions is HL7 V3, Structured Product Labelling (SPL). Various solutions for creating SPL

files exist and range from basic software tools to comprehensive information management systems. SPL instances (code snippets) are provided in the ISO/TS 20443 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 nor in the ISO/TS 20443 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: http://www.hl7.org.

5 Conformance terminology and context as it relates to the ISO IDMP standards and corresponding IDMP 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 Concepts required for the unique identification of Medicinal Products

6.1 General considerations

This document defines the concepts required for the unique identification of Medicinal Products at an international level, wherever such recognition is required (e.g. in the area of pharmacovigilance, worldwide adverse event reporting and risk management).

Regions have systems for issuing marketing authorisation numbers, package identifiers, batch numbers, and bar codes. The additional identifiers defined in this document provide an indexing mechanism that is supplementary to these existing systems and shall not serve as a replacement for them.

Such identification shall apply the principles described below.

6.2 Authorised Medicinal Products

The unique identification of authorised Medicinal Products and the description of their main characteristics shall apply the following principles:

a) the assignment of a unique Medicinal Product Identifier (MPID) to reliably recognise, monitor and trace the use of Medicinal Products;

b) the assignment of a unique Medicinal Product Package Identifier (PCID) to reliably recognise and trace Medicinal Products as packaged for sale or supply;

c) the assignment of a unique Medicinal Product Batch Identifier (BAID1) to reliably recognise and trace a manufacturer's batch number, which appears on the outer packaging of the Medicinal Product, in compliance with the requirements of the marketing authorisation;

d) the assignment of a unique Medicinal Product Batch Identifier (BAID2) to reliably recognise and trace a batch number on the immediate packaging of the Medicinal Product, where this is not the outer packaging, in compliance with the requirements of the marketing authorisation.

6.3 Investigational Medicinal Products

The unique identification of Investigational Medicinal Products and the description of their main characteristics shall apply the following principles:

a) the assignment of a unique Investigational Medicinal Product Identifier (IMPID) to reliably recognise, monitor and trace the use of Investigational Medicinal Products which are studied in clinical trials;

b) the assignment of a unique Investigational Medicinal Product Package Identifier (IPCID), where applicable, to reliably recognise and trace the Investigational Medicinal Product as packaged for supply during clinical trials;

c) the assignment of a unique Investigational Medicinal Product Batch Identifier (BAID1), where applicable, to reliably recognise and trace a batch number which appears on the outer packaging of the Investigational Medicinal Product in compliance with the requirements of the clinical trial authorisation;

d) the assignment of a unique Investigational Medicinal Product Batch Identifier (BAID2), where applicable, to reliably recognise and trace a batch number which appears on the immediate packaging of the Investigational Medicinal Product, where this is not the outer packaging, in compliance with the requirements of the clinical trial authorisation.

6.4 Concepts required for the unique identification of a Medicinal Product and the association with PhPID(s)

This document defines the concepts required to associate regulated Medicinal Products (authorised or under investigation in a clinical trial) with the appropriate PhPID(s) as described in ISO 11616. Such an association shall apply all of the following principles:

a) a Medicinal Product may relate to one or more pharmaceutical products as part of a treatment regimen (e.g. a kit containing vaginal tablets 500 mg and a vaginal cream 10 %);

b) the characterisation of the pharmaceutical product(s) using the active substance(s) or specified substance(s), the (reference) strength thereof, the pharmaceutical (administrable) dose form(s) and any medical device being an integral part of the Medicinal Product (e.g. a scaffolding for cell-based Medicinal Product);

c) the description of the pharmaceutical product(s) in the pharmaceutical dose form approved for administration, where applicable, after reconstitution and as authorised in accordance with the regulated product information;

d) the association of the regulated (investigational) Medicinal Product and the pharmaceutical product(s) using the PhPID(s).

6.5 Concepts required for the unique identification of Medicinal Products and the association with the marketing authorisation number

A marketing authorisation number that is assigned to a Medicinal Product by a Medicines Regulatory Agency of a region may refer to the following main principles.

a) To a Medicinal Product — without specific discrimination between different pack sizes (e.g. Drug B - ursodeoxycholic acid[1)] - 250 mg film-coated tablets 50 tablets - authorisation number *15.2YZ*; Drug B - 250 mg film-coated tablets 100 tablets - authorisation number also *15.2YZ*).

b) To a Medicinal Product and one or more packages — allowing for discrimination at product and package level (e.g. Drug C - amoxicillin capsule, Pharmacopoeia, for oral administration, containing

1) This is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

250 mg - authorisation number (product level) 0XYZ1-20Z0; authorisation number (package level) 0XYZ1-20Z0-01 for bottles of 100 and 0XYZ1-20Z0-05 for bottles of 500. Drug C - amoxicillin capsules, Pharmacopoeia, for oral administration, containing 500 mg - authorisation number (product level) 0XYZ1-20K0; authorisation number (package level) 0XYZ1-20K0-01 for bottles of 100 and 0XYZ1-20K0-05 for bottles of 500).

c) To a Medicinal Product presentation — which means that for each product presentation, a different authorisation number is assigned (e.g. Drug A - 40 IU/ml - Suspension for injection - Subcutaneous use - Vial (glass) - 10 ml (1,4 mg/ml) - 1 vial - authorisation number V/00/1YX/001; Drug A - 100 IU/ml - Suspension for injection - Subcutaneous use - Vial (glass) - 10 ml (3,5 mg/ml) - 1 vial authorisation number V/00/1YX/003).

Certain Medicinal Products may be distributed without a marketing authorisation in a region (e.g. "grandfather drugs"). For these products, a distribution licensing number is assigned and appears on the package, the container or the package insert.

This document defines the concepts required to associate the MPID and PCID(s) with the relevant marketing authorisation number(s) as assigned by a Medicines Regulatory Agency in a region. Such association shall use the following two principles.

— The MPID shall always be associated with the applicable marketing authorisation number of the Medicinal Product (e.g. the MPID "*Country-055-0957*" shall be associated with the authorisation number *Country 15.2YZ* for Drug B -250 mg film-coated tablets, which comes in two pack sizes of 50 and 100 tablets).

— The PCID shall always be associated with the applicable marketing authorisation number for a specific package or presentation (e.g. PCID *Country-0787-2550-05* shall be associated with *0XYZ1-20Z0-05 for* amoxicillin capsules, Pharmacopoeia, for oral administration, containing 250 mg).

6.6 Concepts required for the unique identification of Medicinal Products and the association with data carrier identifiers

Data carrier identifiers uniquely identify items that are traded (e.g. pharmaceuticals, medical devices) in the supply chain. For example, a GTIN is used to identify any item upon which there is a need to retrieve predefined information and that may be priced, ordered or invoiced at any point in any supply chain. GTINs may be 8, 12, 13 or 14 digits in length. GS1 advocates the use of global standardisation to aid compliance to the regulatory requirements of all countries.

The basic predefined characteristics of a data carrier identifier can be:

— product name, product brand and product description;

— formulation (active ingredients);

— strength;

— dosage (or usage);

— net quantity (weight, volume, or other dimension impacting trade);

— packaging configuration;

— form, fit or function;

— for groupings, the number of elementary items contained and their subdivision in subpackaging units, the nature of the grouping (carton, blister, blister-cell).

A modification to any of the basic elements that characterise a trade item will usually lead to a change in the data carrier identifier. Additional data can be included with the data carrier such as batch number and expiration date.

NOTE Reference is made to ISO/TS 16791.

7 Description of the information modelling principles and practices

7.1 General considerations

The information modelling in this document uses the Unified Modeling 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 has been kept very simple, using classes, attributes and basic association relationships only; some constructs (such as stereotypes and complex relationships) have been avoided for this reason. In addition, colour has been used in the diagrams to help visualise groups of associated entities together with one another (see Figure 1).

The following aims to explain the style that has been followed in this document.

Figure 1 — Legend for colour coding of model classes

7.2 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 15) 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.

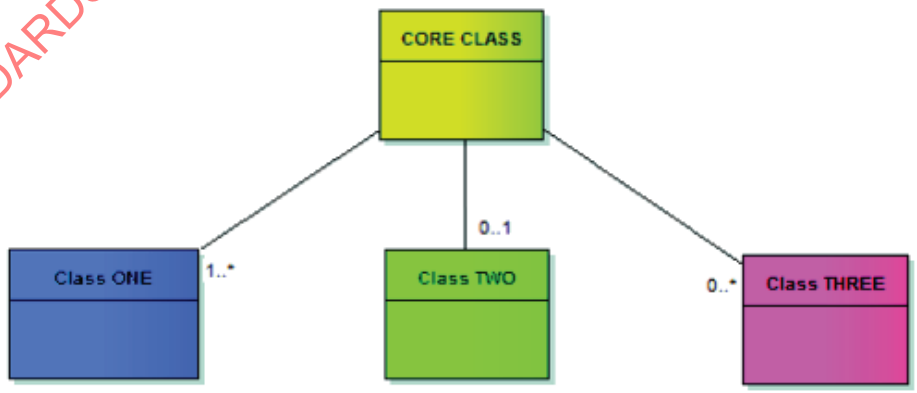

Figure 2 — Example conceptual overview diagram

7.3 High-level diagrams

The high-level diagrams (see Figure 3) provided at the start of each sublcause 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.

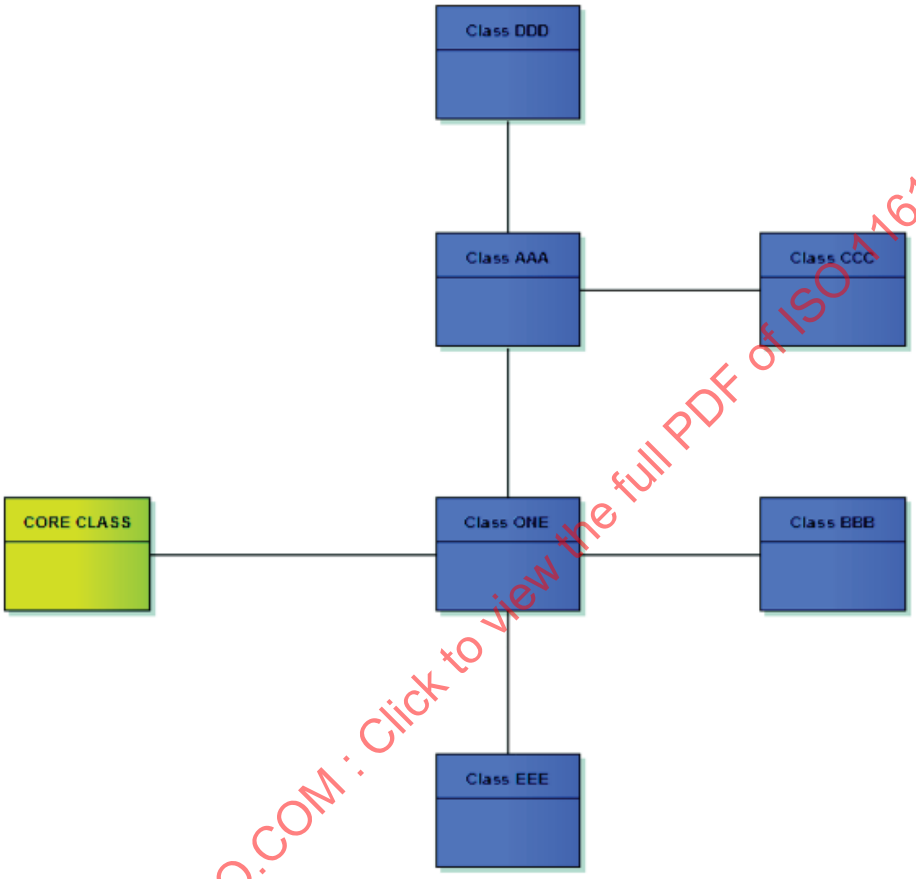

Figure 3 — Example high-level diagram

7.4 Detailed description diagrams

7.4.1 General

The detailed description diagrams (see Figure 4) for each subclause 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.

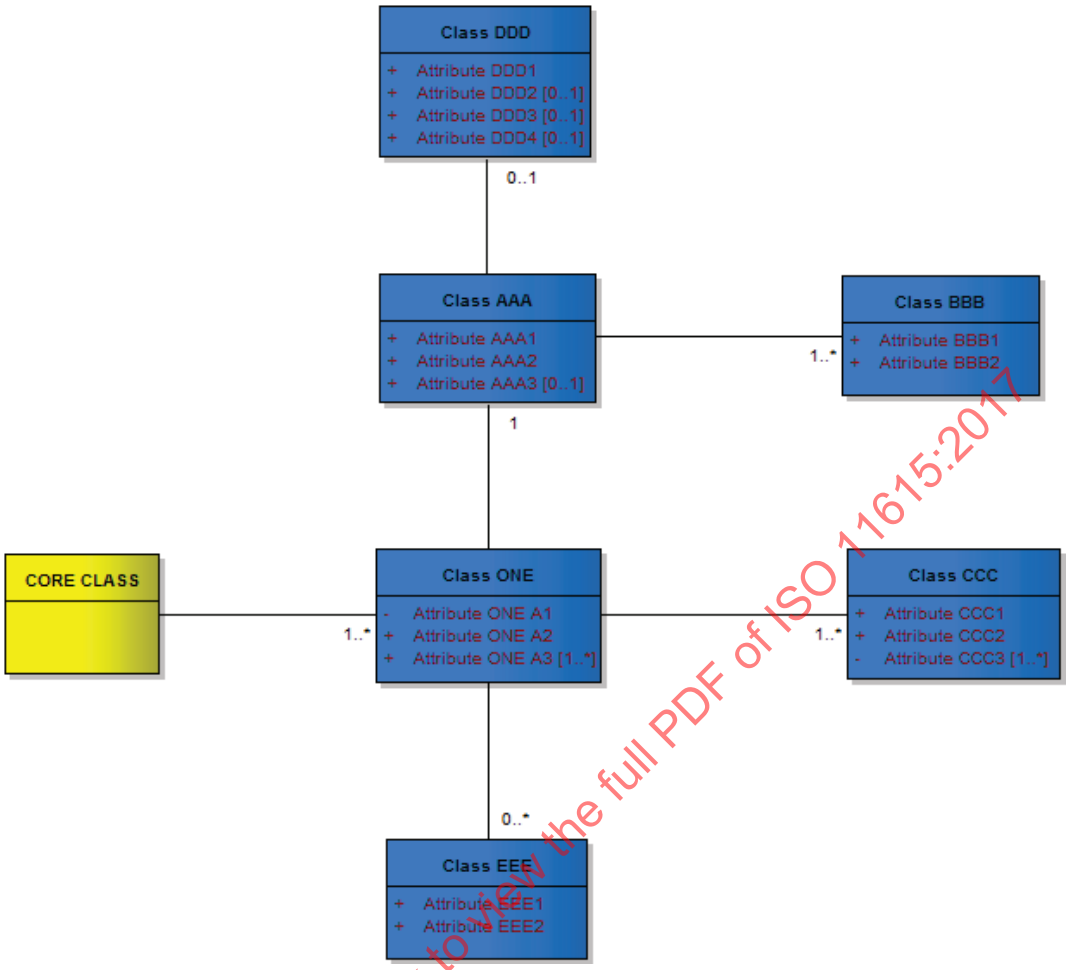

Figure 4 — Example detailed description diagram

7.4.2 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 entities can be elevated to mandatory if some conditions are met. See Clause 5.

Refer to ISO 21090 for more information on composition of attributes.

7.4.3 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...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.

Some optional attributes can be elevated to mandatory if some conditions are met. See Clause 5.

See ISO 21090 for more information on composition of attributes.

7.4.4 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 once in 7.4. Then, 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 for the generalised "Organisation" class.

There is also one generalised pattern used several times in the diagrams, whereby somewhat generic classes provide the ability to describe something using (unspecified) classification or 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 (be that a classification, nomenclature or identification system), and the second, to describe the applicable term or value from that system.

7.4.5 Translation and language

With the specific exception of Medicinal Product name information, there is no description of the translation of information described in this document. It is acknowledged that, for global implementation, translation of the information will be required and will occur at implementation according to regional guidance.

8 Identifying characteristics for authorised Medicinal Products

8.1 Primary identifiers — General considerations

To satisfy the requirements as described in Clause 6, the following five identifiers shall be specified:

a) Medicinal Product Identifier (MPID);

b) Medicinal Product Package Identifier (PCID);

c) Medicinal Product Batch Identifier (BAID1), allocated to a specific batch of a Medicinal Product, which appears on the outer packaging of the Medicinal Product;

d) Medicinal Product Batch Identifier (BAID2), allocated to a specific batch of a Medicinal Product, which appears on the immediate packaging, where this is not the outer packaging;

e) 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 In addition, there is an association with pharmaceutical product identifiers (PhPIDs) as defined in ISO 11616 and ISO/TS 20451.

NOTE 2 Refer to regional guidance for serialisation requirements, as the Falsified Medicines Directive (Directive 2011/62/EU).

8.2 Medicinal Product Identifier (MPID)

8.2.1 General considerations

For each authorised Medicinal Product, a unique MPID shall be assigned. The MPID shall be allocated supplementary to any existing authorisation number as ascribed by a Medicines Regulatory Agency in a region. This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of Medicinal Products worldwide.

The MPID shall use a common segment pattern related to a Medicinal Product, which when each segment is valued shall define a specific MPID concept. The pattern is:

a) country code segment (ISO 3166-1 alpha-2 code elements);

b) marketing authorisation holder (organisation identifier) code segment;

c) Medicinal Product code segment.

Any change of the values related to these three code segments shall result in the assignment of a new MPID.

8.2.2 MPID code segments

8.2.2.1 General

The MPID code segments shall be generated as described below.

8.2.2.2 Country code segment

This code segment shall reflect the country code of that region, where the Medicinal Product is authorised. The ISO 3166-1 alpha-2 code elements shall be used.

8.2.2.3 Marketing authorisation holder (organisation identifier) code segment

This code segment shall reflect the unique identifier of the marketing authorisation holder (organisation) of the Medicinal Product. An international coding system for unique marketing authorisation holders (organisations) identifiers can be applied, if available.

8.2.2.4 Medicinal Product code segment

This code segment shall reflect a Medicinal Product code assigned to the Medicinal Product. It utilises defining attributes to determine a single Medicinal Product to which a code is assigned. A different

Medicinal Product code segment shall be assigned, leading to a unique MPID, (subject also to the notes below) whenever any of the following items of information for a Medicinal Product are modified, as applicable, per a Medicines Regulatory Agency process(es):

a) marketing authorisation indicated in a region;

NOTE The change of a marketing authorization (MA), depending on regional requirements, might not lead to a change of MPID.

b) legal status of supply as a value/attribute (e.g. prescription only or "over the counter" sale);

Legal status of supply may be considered a defining element for Medicinal Product identification per regional requirements as this supports regulatory compliance and pharmacovigilance activities.

c) Medicinal Product name;

d) pharmaceutical dose form;

e) active ingredient(s)/active moieties and their corresponding strength;

f) device(s) 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 Medicinal Product;

g) therapeutic indication(s) as authorised for the Medicinal Product.

Depending on the regional requirements of a Medicines Regulatory Agency, therapeutic indications such as age, or related therapeutic indications within a given pharmacological class upon where the mechanism of action or clinical significance is identical, may not warrant a different MPID. Refer to regional implementation requirements for specific guidance.

Excipients may cause a unique MPID to be assigned depending on its significance to the qualitative/quantitative composition of the product or any known sensitivities. Refer to regional guidance/implementation for regulatory practices within a respective region.

Regional implementation guides will provide more information on how to identify the appropriate pharmaceutical dose form(s) that should be used.

For a seasonal influenza vaccine, new formulations are introduced every year regardless of whether there is a strain change. This implies that a new MPID shall be assigned by a Medicines Regional Agency for this vaccine for each given year of formulation. If year of formulation is not a defining criteria for new MPID assignment within a region, then it shall be necessary for any strain change from year to year to be utilised as the defining input for Medicinal Product identification and the assignment of an MPID. Refer to regional implementation requirements for specific guidance.

This process may result in changes to the MPID for a Medicinal Product when existing regulatory identifiers (e.g. marketing authorisation number) would not change. This document does not require such existing regulatory identifiers to be changed in step with the IDMP requirements for MPID assignment. Each region may elect to continue with its existing working practices for existing identifiers rather than adopt a new process for MPID assignment in accordance with this document. In this instance, it is required that the regional authority on the matter incorporate a Medicinal Product identification process in addition to existing practices to be in conformance with this document.

8.3 Packaged Medicinal Product Identifier (PCID)

8.3.1 General considerations

For each Packaged Medicinal Product, a unique Package Identifier (PCID) shall be assigned. The PCID shall be allocated in addition to any existing authorisation/approval number at package level as ascribed by a Medicines Regulatory Agency in a region.

The PCID shall use a common segment pattern related to a package of a Medicinal Product, which when each segment is valued, shall define a specific PCID concept. The pattern is:

a) MPID for the Medicinal Product;

b) package description code segment, which refers to a unique identifier for each package.

Any change of the values related to these code segments shall result in the assignment of a new PCID.

The PCID code segment shall use the defining attribute sets as described below.

8.3.2 Package description (PCID) code segment

This code segment shall reflect a code assigned to each package presentation of a Medicinal Product. It shall use the following defining attribute set:

— packaged item (container/s): the type, quantity (items per package), material(s) and alternate material(s);

— package component(s): the type, material(s) and alternate material(s);

— manufactured item(s): the manufactured dose form, unit of presentation, quantity (items per package).

A separate unique PCID shall be assigned whenever any of the aforementioned attribute sets of a Packaged Medicinal Product are different in any way that is relevant to the medicine's regulatory process.

This process may result in changes to a PCID when existing regulatory identifiers (e.g. marketing authorisation number) would not change. This document does not require such existing regulatory identifiers to be changed in step with the IDMP requirements for PCID assignment. Each region may elect to continue with its existing working practices for existing identifiers rather than adopt a new process for PCID assignment in accordance with this document. In this instance, it is required that the regional authority on the matter incorporate a Packaged Medicinal Product identification process consistent with this document in addition to existing practices to be in conformance with ISO IDMP.

8.4 Medicinal Product Batch Identifier (BAID1)

For each authorised Medicinal Product, a BAID1 shall be assigned. The BAID1 shall use the batch number together with the PCID. The BAID1 shall use the batch number as it appears on the outer packaging of a specific batch of the Medicinal Product.

The BAID1 shall use a common attribute set related to a Packaged Medicinal Product, which when all of them have a value, define a specific BAID1 concept:

a) PCID;

b) batch/lot number (outer packaging);

c) expiration date.

8.5 Medicinal Product Batch Identifier (BAID2)

For each authorised Medicinal Product, a BAID2 can be assigned. The BAID2 shall use the batch number and the expiration date together with the PCID. The BAID2 shall use the batch number as it appears on the immediate packaging, where this is not the outer packaging, of a specific batch of the Medicinal Product.

The BAID2 shall use a common attribute set related to a Packaged Medicinal Product, which when all of them have a value, define a specific BAID2 concept:

a) PCID;

b) batch number/lot (immediate packaging, when not the outer packaging).

c) expiration date.

9 Information for an authorised Medicinal Product

9.1 Authorised Medicinal Product — Information overview

9.1.1 General

In addition to the primary identifiers described above, the main concepts modelled in Figure 5 and described below shall apply in order to identify and characterise an authorised Medicinal Product which itself is identified by the MPID/PCID.

NOTE Each box present in Figure 5 does not represent an individual class, but represents all the classes related to the area named in the box. For instance, the box Packaged Medicinal Products represents all the classes related to Packaged Medicinal Products, e.g. batch identifier, package item (container), etc.

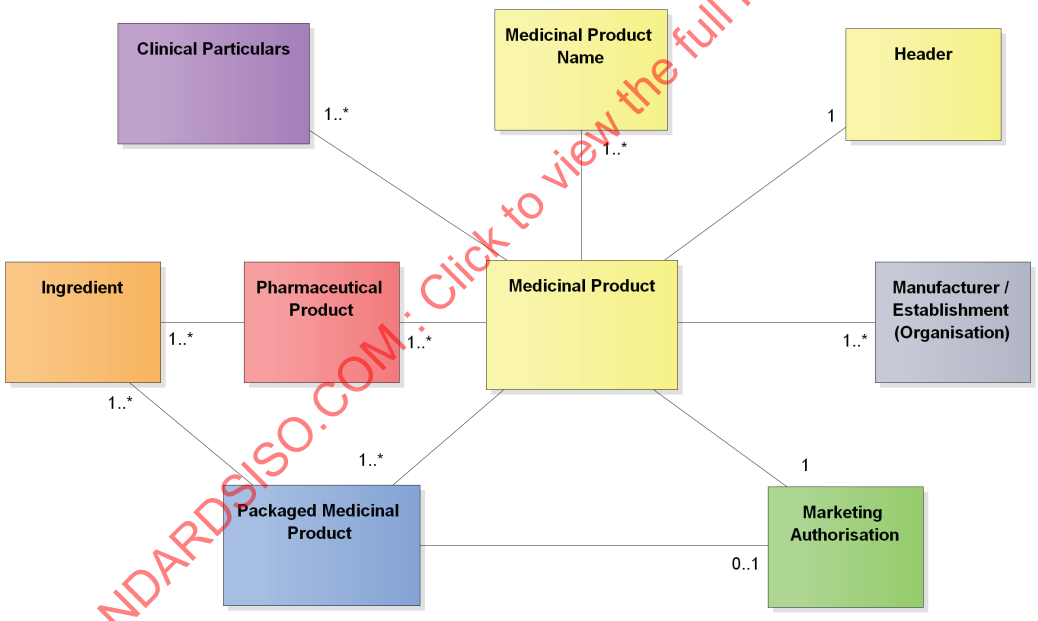

Figure 5 — Medicinal Product overarching model

9.1.2 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 region.

9.1.3 Medicinal Product name

This subclause specifies the name of the Medicinal Product as authorised by a Medicines Regulatory Agency in a region, together with an analysis of the name into various parts.

9.1.4 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.

9.1.5 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.

9.1.6 Marketing authorisation

This subclause specifies the information about the marketing authorisation as issued by a Medicines Regulatory Agency, which grants permission to an organisation to place a Medicinal Product on the market in a region.

9.1.7 Packaged Medicinal Product

This subclause specifies information about the packaging and container(s) of a Medicinal Product and any associated device(s) which are 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).

9.1.8 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).

9.1.9 Ingredient

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

9.1.10 Clinical particulars

This subclause specifies information about the clinical particulars of the Medicinal Product as described in line with the regulated product information (e.g. SmPC).

9.2 Medicinal Product

9.2.1 General

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 region.

A Medicinal Product has a Medicinal Product name, which will 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.

9.2.2 Detailed description of Medicinal Product information

9.2.2.1 General

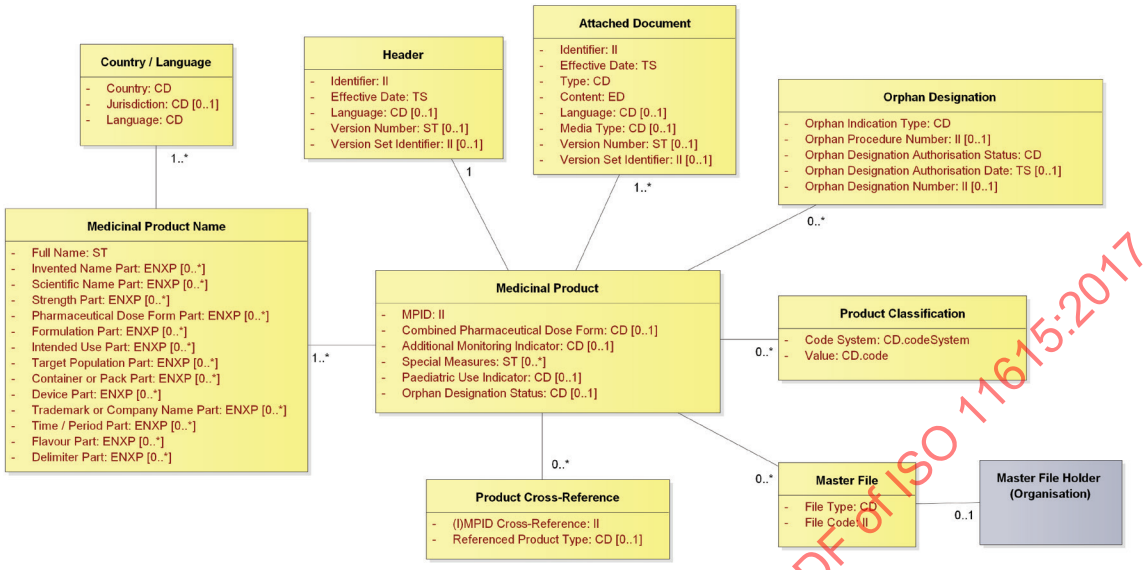

Figure 6 — Medicinal Product section detailed description diagram

9.2.2.2 Medicinal Product

9.2.2.2.1 General

This represents the Medicinal Product as authorised by a Medicines Regulatory Agency in a region and has the following attributes.

9.2.2.2.2 MPID

This is the MPID for the Medicinal Product, which shall be always specified. It is specified as text.

9.2.2.2.3 Combined pharmaceutical dose form

The combined pharmaceutical dose form is a single term to describe two or more manufactured items that are intended to be combined in a specific way to produce a single pharmaceutical product. It includes information on the manufactured dose form of each manufactured item and the administrable dose form of the pharmaceutical product. If the Medicinal Product requires description of a combined pharmaceutical dose form, it can be specified here using a term and a term identifier as defined in ISO 11239 and the resulting terminology.

9.2.2.2.4 Additional monitoring indicator

If the Medicinal Product is subject to additional monitoring, this can be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.2.2.2.5 Special measures

If the Medicinal Product is subject to specific special measures, these can be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.2.2.2.6 Paediatric use indicator

This is a flag that indicates if the Medicinal Product is also authorised for use in children.

9.2.2.2.7 Orphan designation status

The description if the Medicinal Product is subject to orphan designation and intended for the treatment of a rare disease.

9.2.2.3 Orphan designation

9.2.2.3.1 General

This class includes several attributes required to have all the information related to a product with an orphan designation status.

9.2.2.3.2 Orphan indication type

This attribute is for the type of intended use of the Medicinal Product, for instance disease prevention, treatment or diagnostic.

9.2.2.3.3 Orphan procedure number

This attribute is the procedure number for the orphan designation authorisation application.

9.2.2.3.4 Orphan designation authorisation status

This attribute is for describing the status of the orphan designation authorisation, for instance granted, pending, expired or withdrawn.

9.2.2.3.5 Orphan designation authorisation date

This attribute is for the date in which the orphan designation status was granted.

9.2.2.3.6 Orphan designation number

This field is to indicate the orphan designation decision number.

9.2.2.4 Product classification

9.2.2.4.1 General

The Medicinal Product can be classified according to various classification systems, which may be regional or international. One or more of these various classifications of the product can be specified in this subclause.

9.2.2.4.2 Code system

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 shall be specified using an appropriate identification system; the controlled term and the controlled term identifier shall be specified.

9.2.2.4.3 Value

The individual value from the classification system that applies to the Medicinal Product shall be specified using a controlled term and a controlled term identifier.

9.2.2.5 Master file

9.2.2.5.1 General

This class is used to identify any type of master file related to the Medicinal Product, for instance Pharmacovigilance System Master File.

9.2.2.5.2 File type

This attribute is to define which kind of master file is indicated

9.2.2.5.3 File code

This attribute is for a code to uniquely identify a master file.

9.2.2.6 Master file holder (organisation)

This is a set of classes that are used to describe the custodian organisation of the master file and the location where the master file is located. Use the same set of classes as used for describing organisations (see 9.4).

9.2.2.7 Product cross-reference

9.2.2.7.1 General

There can be a cross-reference between the MPIDs/PCIDs of the authorised Medicinal Product(s) and the related IMPIDs/IPCIDs 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 their corresponding identifiers. The related Medicinal Products and Investigational Medicinal Products can be specified with their corresponding identifiers.

9.2.2.7.2 (I)MPID cross-reference

This is an attribute used to reference other IMPID(s) or MPID(s) related to the medicinal.

See more information and examples on the use of this attribute in ISO/TS 20443.

9.2.2.7.3 Referenced product type

This attribute is to identify which kind of Medicinal Product is cross-referenced. See more information and examples on the use of this attribute in ISO/TS 20443.

9.2.2.8 Medicinal Product name

9.2.2.8.1 General

The Medicinal Product name, represented in one or more languages, is one of the defining characteristics of a Medicinal Product and its MPID.

The convention applied for naming a Medicinal Product can differ between Medicines Regulatory Agencies in 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 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 full and complete Medicinal Product name as authorised, an analysis of the name parts can be provided in a structured format. Depending on the region, the Medicinal Product name shall be specified in all official languages that apply.

NOTE 1 This is to facilitate the creation of a Medicinal Product name index and the coding of Medicinal Product names, which are often incomplete in spontaneous adverse reaction reports.

NOTE 2 Due to the business requirement for the Medicinal Product name index as described in the NOTE 1 above, this is the one part of this document where translation of information is explicitly described and modelled, showing the language of the information (and the regions where it is appropriate).

9.2.2.8.2 Full name

The full and complete Medicinal Product name as approved by the Medicines Regulatory Agency in a regions shall be specified, as text.

9.2.2.8.3 Invented name part

The invented name (i.e. trade name) of the Medicinal Product without the trademark or any other similar designations reflected in the Medicinal Product name can be specified as text, where applicable.

9.2.2.8.4 Scientific name part

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

9.2.2.8.5 Strength part

The strength, if reflected in the Medicinal Product name, can be specified as text, where applicable. This strength name part can differ from the concept of “Strength” as described in 9.7.

9.2.2.8.6 Pharmaceutical dose form part

The pharmaceutical dose form, if reflected in the Medicinal Product name, can 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 ISO/TS 20443.

9.2.2.8.7 Formulation part

The formulation, if reflected in the Medicinal Product name, can be specified as text, where applicable.

9.2.2.8.8 Intended use part

The intended use, if reflected in the Medicinal Product name, can be specified as text, where applicable.

9.2.2.8.9 Target population part

The target population, if reflected in the Medicinal Product name, can be specified as text, where applicable.

9.2.2.8.10 Container or pack part

The container or pack, if reflected in the Medicinal Product name, can be specified as text, where applicable.

9.2.2.8.11 Device part

The device, if reflected in the Medicinal Product name, can be specified as text, where applicable.

9.2.2.8.12 Trademark or company name part

The trademark, if reflected in the Medicinal Product name, can be specified as text, where applicable.

9.2.2.8.13 Time/period part

The time/period, if reflected in the Medicinal Product name, can be specified as text, where applicable.

9.2.2.8.14 Flavour part

The flavour, if reflected in the Medicinal Product name, can be specified as text, where applicable.

9.2.2.8.15 Delimiter part

A delimiter separates one composite in a segment from another or separates one subcomposite from another.

9.2.2.9 Country/Language

9.2.2.9.1 General

The country and optionally the region where the Medicinal Product name of a Medicinal Product is authorised shall be specified in the official language as applicable.

9.2.2.9.2 Country

The country where the Medicinal Product name is applicable shall be described using ISO 3166-1 alpha-2 code elements.

9.2.2.9.3 Jurisdiction

The jurisdiction within the country where the Medicinal Product name is applicable can be described using an appropriate controlled vocabulary, if appropriate. The controlled term and the controlled term identifier shall be specified.

9.2.2.9.4 Language

The language of the Medicinal Product name as applicable in the specified country and jurisdiction if appropriate shall be specified using ISO 639-1.

9.2.2.10 Header

9.2.2.10.1 General

The characteristics of an authorised Medicinal Product as defined in this document shall be versioned within a regulated document, 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 Clause 8. However, the difference(s) are required to be recorded and tracked against the MPID/PCID.

9.2.2.10.2 Identifier

This attribute is for the unique code identifying the regulatory information submission.

9.2.2.10.3 Effective date

The date specified in the regulatory decision document by which the authorisation or the updates to the regulated product information become effective shall be specified. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.2.2.10.4 Language

This attribute defines the language used for the information related to the regulatory submission.

9.2.2.10.5 Version number

This is a number identifying a specific version of the regulatory information submission.

9.2.2.10.6 Version set identifier

This is a number used to group together a set of specific versions of the regulatory information submission.

9.2.2.11 Attached document

9.2.2.11.1 General

Any document(s) officially submitted to a medicines regulatory agency shall be specified as a regulated document.

9.2.2.11.2 Identifier

The reference to the regulatory decision document related to the granting of the authorisation or the latest update of the regulated product information shall be specified in text.

9.2.2.11.3 Effective date

The date corresponding to a version of a regulated document containing regulated 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 Document version date corresponds to the tracking versions of a regulated document. It does not correspond to the actual revisions or regulatory timelines that may be captured within a regulated document.

9.2.2.11.4 Type

The type of document that is supporting a version increment shall be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.2.2.11.5 Content

The actual document that is supporting a version increment shall be attached. The format of the document attachment shall be specified by regional implementations.

9.2.2.11.6 Language

This attribute defines the language used for the information related to the regulatory submission.

9.2.2.11.7 Media type

This attributes is used to define the graphic media type of the attached document.

9.2.2.11.8 Version number

This is a number identifying a specific version of the attached regulatory document.

9.2.2.11.9 Version set identifier

This is a number used to group together a set of specific versions of the same regulatory document.

9.3 Marketing authorisation

9.3.1 General

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

The marketing authorisation is issued by the appropriate Medicines Regulatory Agency in a region. In line with the laws and regulations applicable in a region, an authorisation is usually required before a Medicinal Product is placed on the market. For some categories of Medicinal Products, specific exemptions may be applicable (e.g. "grandfather" drugs). For these types of medicines, the same principles of information provision as for authorised Medicinal Products shall be applied as outlined in this subclause. Where no formal marketing authorisation holder is established, the distributor shall be specified.

A Medicinal Product has a marketing authorisation (even if, as for "grandfather drugs" this is not a formal marketing authorisation, but serves as a proxy).

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. in the EU, this is the "Qualified Person Responsible for Pharmacovigilance").

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).

There may be circumstances where Medicinal Product additional information on marketing status is specific to local provisions within a jurisdiction (e.g. states, provinces or territories). This refers particularly to the legal status of supply or a marketing authorisation number.

9.3.2 Detailed description of marketing authorisation information

9.3.2.1 General

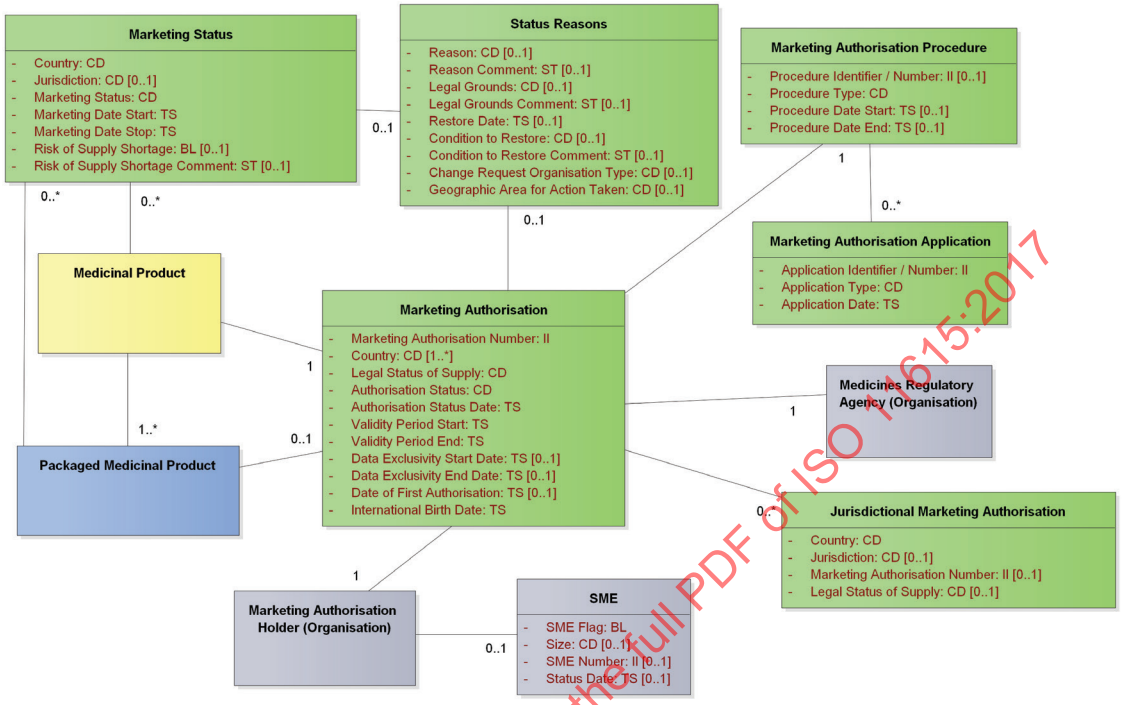

Figure 7 — Marketing authorisation section detailed description diagram

Each Medicinal Product shall have the relevant marketing authorisation information specified (see Figure 7).

The marketing authorisation information shall also be appropriately specified for a Packaged Medicinal Product, where applicable (see 9.3.2.2). In those situations, the information structure as follows shall be used, with the exception that the Medicines Regulatory Agency and the marketing authorisation holder information is not required to be specified again, as it is inherited from the marketing authorisation information of the Medicinal Product.

9.3.2.2 Marketing authorisation

9.3.2.2.1 General

A Medicinal Product is placed on the market when a marketing authorisation or equivalent has been issued by a Medicines Regulatory Agency.

9.3.2.2.2 Marketing authorisation number

The number as assigned to a Medicinal Product by the Regulatory Medicines Agency of a country or jurisdiction shall be specified in text. For Medicinal Products which allow distribution without a marketing authorisation by legislation, the licensing number as it appears on the package, the container or the package insert shall be specified in the absence of a formal marketing authorisation number (e.g. for "grandfather" drugs in the US).

9.3.2.2.3 Country

The country in which the marketing authorisation has been granted shall be provided in accordance with the ISO 3166-1 alpha-2 code elements.

9.3.2.2.4 Legal status of supply

The legal status of supply of the Medicinal Product as classified by the Medicines Regulatory Agency shall be specified (e.g. subject to medical prescription or not). The legal status of supply shall be described using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified. Legal status of supply may be a defining element for the Medicinal Product within a region to support regulatory, compliance and pharmacovigilance activities.

9.3.2.2.5 Authorisation status

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 using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.3.2.2.6 Authorisation status date

The date at which the given status has become applicable shall be specified. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.2.2.7 Validity period start

The beginning of the time period in which the marketing authorisation is in the specific status shall be specified. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.2.2.8 Validity period end

The end of the time period in which the marketing authorisation is in the specific status shall be specified. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.2.2.9 Data exclusivity start date

The "data exclusivity period" is a period of time 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 beginning of the data exclusivity period for the relevant status shall be specified. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.2.2.10 Data exclusivity end date

The end of the data exclusivity period for the relevant status shall be specified. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.2.2.11 Date of first authorisation

The date when the first authorisation was granted by a Medicines Regulatory Agency.

9.3.2.2.12 International birth date

This is the date of first marketing authorisation for a company's new Medicinal Product in any country in the world.

9.3.2.3 Marketing authorisation holder (organisation)

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 9.4.

For Medicinal Products which allow for distribution without a marketing authorisation under regional/jurisdictional law, 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.

9.3.2.4 Small to medium enterprise (SME)

9.3.2.4.1 SME flag

This is a flag to indicate if the organisation is an SME.

9.3.2.4.2 Size

The size of the SME needs to be specified, i.e. micro, small or medium.

For the definition of the values, refer to ISO/TS 20443.

9.3.2.4.3 SME number

This is a unique number that it is uniquely identifying an SME.

9.3.2.4.4 Status date

This is the date when the SME status was granted.

9.3.2.5 Medicines Regulatory Agency (organisation)

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 9.4.

9.3.2.6 Marketing authorisation procedure

9.3.2.6.1 General

The regulatory procedure applied to grant or amend a marketing authorisation for a Medicinal Product shall be specified. A region may further refine the requirements in relation to the marketing authorisation procedure (and the associated marketing authorisation application) at implementation such that this information is to be specified only if required.

9.3.2.6.2 Procedure identifier/number

The unique identifier for the specific instance of a procedure undertaken shall be provided in text.

9.3.2.6.3 Procedure type

The type of procedure that is followed to grant or update a marketing authorisation shall be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.3.2.6.4 Procedure date start

The initial date when the procedure commenced shall be described. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.2.6.5 Procedure date end

The end date when the procedure completed shall be described. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.2.7 Marketing authorisation application

9.3.2.7.1 General

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).

9.3.2.7.2 Application identifier/number

A unique identifier for the specific instance of an application shall be provided in text. The application identifier/number is usually assigned by a Medicines Regulatory Agency.

9.3.2.7.3 Application type

The type of the application shall be described using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.3.2.7.4 Application date

The date on which the marketing authorisation application was made shall be specified. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.2.8 Marketing status

9.3.2.8.1 General

This class provides information on the status of the marketing of the Medicinal Product.

9.3.2.8.2 Country

The country in which the marketing authorisation has been granted shall be specified. It should be specified using the ISO 3166-1 alpha-2 code elements.

9.3.2.8.3 Jurisdiction

Where a Medicines Regulatory Agency has granted a marketing authorisation for which specific provisions within a jurisdiction apply, the jurisdiction can be specified using an appropriate controlled terminology. The controlled term and the controlled term identifier shall be specified.

9.3.2.8.4 Marketing status

This attribute provides information on the status of the marketing of the Medicinal Product. See ISO/TS 20443 for more information and examples.

9.3.2.8.5 Marketing start date

The date when the 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. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

NOTE “Placed on the market” refers to the release of the Medicinal Product into the distribution chain.

9.3.2.8.6 Marketing stop date

The date when the Medicinal Product is no longer available on the market in a country and/or jurisdiction shall be provided. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

NOTE "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 Medicinal Product or that the marketing authorisation is no longer valid.

9.3.2.8.7 Risk of supply shortage

Indication on whether there is a risk of a product shortage in a region.

9.3.2.8.8 Risk of supply shortage comment

Any additional comment on supply shortage.

9.3.2.9 Status reasons

9.3.2.9.1 General

This class can describe the reason for a legal action taken on the marketing or on the marketing authorisation and in reference to the status of these elements.

9.3.2.9.2 Reason

The reason for a legal action taken on the marketing or on the marketing authorisation can be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.3.2.9.3 Reason comment

Additional comment(s) on the reason for a legal action taken on the marketing or on the marketing authorisation.

9.3.2.9.4 Legal grounds

The legal grounds of the action taken on the marketing or on the marketing authorisation can be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.3.2.9.5 Legal grounds comment

Any additional description of the action taken on the marketing or on the marketing authorisation.

9.3.2.9.6 Restore date

The date when the marketing or the marketing authorisation of the product is anticipated to be restored. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.2.9.7 Condition to restore

The condition under which the marketing authorisation or the marketing is restored can be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.3.2.9.8 Condition to restore comment

Additional comments on the condition to restore the marketing or the marketing authorisation of the product.

9.3.2.9.9 Change request organisation type

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) can be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.3.2.9.10 Geographic area for action taken

The geographic area where the legal action taken on the marketing or the on marketing authorisation is having effect can be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.3.2.10 Jurisdictional marketing authorisation

9.3.2.10.1 General

This class is used to provide more information when a marketing activity is undertaken in multiple subdivisions within a country.

9.3.2.10.2 Country

This attribute defines the country to which the jurisdictional marketing authorisation refers to.

9.3.2.10.3 Jurisdiction

This attribute indicates which jurisdiction the jurisdictional marketing authorisation is related to.

9.3.2.10.4 Marketing authorisation number

The number for the marketing authorisation assigned by a Medicines Regulatory Authority in the jurisdiction can be specified in text.

9.3.2.10.5 Legal status of supply

The legal status of supply for the Medicinal Product as applicable in a region/jurisdiction can be described using a suitable controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.4 Organisation

9.4.1 General

Whenever a class is described as an “organisation”, the following general set of information shall be specified for the appropriate instance of the organisation.

9.4.2 Detailed description of organisation information

9.4.2.1 General

Figure 8 shows a detailed description of organisation information.

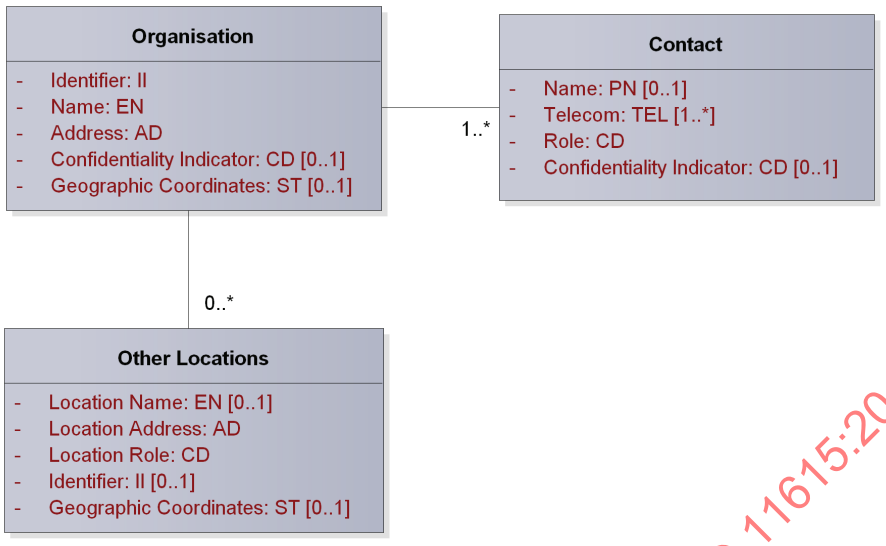

Figure 8 — Organisation detailed description diagram

9.4.2.2 Organisation

9.4.2.2.1 General

This is a class that is used to define organisations.

9.4.2.2.2 Identifier

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

9.4.2.2.3 Name

The name of the organisation shall be provided in text.

9.4.2.2.4 Address

The address of the organisation shall be provided using a standardised structured address format. The format is specified in ISO/TS 20443.

9.4.2.2.5 Confidentiality indicator

The confidentiality level of the organisation information can be specified using an appropriate controlled vocabulary. The controlled term and a term identifier shall be specified.

9.4.2.2.6 Geographic coordinates

These are coordinates that identify precisely the location where the organisation is set.

See ISO/TS 20443 for more information and example.

9.4.2.3 Other locations

9.4.2.3.1 General

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

A jurisdiction may further refine the requirements in relation to the other locations information at implementation so that this information is to be specified only if required.

9.4.2.3.2 Location name

This is to identify uniquely a location linked to a specific organisation.

9.4.2.3.3 Location address

The address of the location of the organisation shall be provided using a standardised structured address format. The format is specified in ISO/TS 20443.

9.4.2.3.4 Location role

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

9.4.2.3.5 Identifier

The unique identifier of the location can be provided. An international coding system for unique organisation identifiers can be used.

9.4.2.3.6 Geographic coordinates

These are coordinates that identify precisely the location where the organisation is set.

See ISO/TS 20443 for more information and example.

9.4.2.4 Contact

9.4.2.4.1 General

This class is used to specify one or more contact persons from within the organisation and the role of each person. A jurisdiction may further refine the requirements in relation to the contact person information at implementation so that this information is to be specified only if required.

9.4.2.4.2 Name

The name of the contact person shall be provided using a standardised structured person name description format. The format will be specified in regional implementation guides.

9.4.2.4.3 Telecom

The telecom information (telephone, e-mail, etc.) of the contact person shall be provided using a standardised structured telecoms description format. The format is specified in ISO/TS 20443.

9.4.2.4.4 Role

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

9.4.2.4.5 Confidentiality indicator

The confidentiality level of the contact person's information can be specified using an appropriate controlled vocabulary. The controlled term and a term identifier shall be specified.

9.5 Manufacturer/Establishment (organisation)

9.5.1 General

This subclause describes the manufacturer and/or establishment information for a Medicinal Product (see Figure 9).

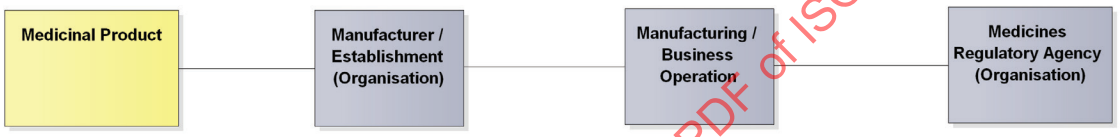

Figure 9 — Manufacturer/establishment (organisation) section high-level diagram

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 may be overseen by an appropriate Medicines Regulatory Agency.

9.5.2 Detailed description of manufacturer/establishment (organisation) information

9.5.2.1 General

Figure 10 shows a detailed description of the manufacturer/establishment section.

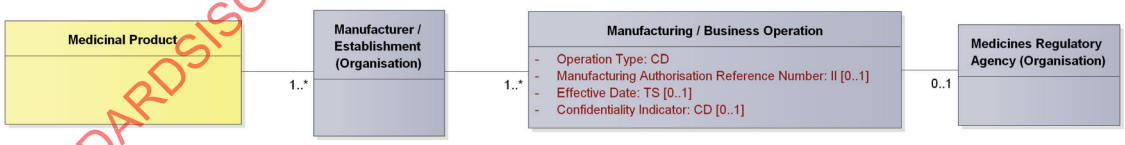

Figure 10 — Manufacturer/establishment section detailed description diagram

A Medicinal Product shall be associated with one or more manufacturers/establishments (see Figure 10).

A jurisdiction may further refine the requirements in relation to the manufacturer/establishment information at implementation so that this information is to be specified only if required.

9.5.2.2 Manufacturer/establishment (organisation)

The information related to the manufacturer/establishment for the organisation undertaking the particular manufacturing operation shall be described using the pattern for organisation described in 9.4.

9.5.2.3 Manufacturing/business operation

9.5.2.3.1 General

The manufacturing/business operation being undertaken by the particular manufacturer/establishment (organisation) shall be specified.

9.5.2.3.2 Operation type

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

9.5.2.3.3 Manufacturing authorisation reference number

The reference number of the authorisation for manufacturing or equivalent can be specified in text.

9.5.2.3.4 Effective date

The effective date of the manufacturing authorisation stated in the attribute above can be specified. The complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.5.2.3.5 Confidentiality indicator

The level of confidentiality of the manufacturing operation can be specified using an appropriate controlled vocabulary. The controlled term and a term identifier shall be specified.

9.5.2.4 Medicines Regulatory Agency (organisation)

The Medicines Regulatory Agency which oversees a specific manufacturing operation shall be described using the pattern for organisation described in 9.4.

9.6 Packaged Medicinal Product, including manufactured item and device

9.6.1 General

This subclause describes the Medicinal Product in terms of it being a Packaged Medicinal Product as presented for sale or supply.

The description of a Packaged Medicinal Product shall cater for the description of the entire packaging from the outer layers down through intermediate packaging to one or more items contained within, and then to the actual description of the individual item(s).

The Packaged Medicinal Product class acts as a collector class for more descriptive classes. In particular, there is one instance of the "package item" class for each separate item packaged.

The package item class has a recursive relationship with itself; this complexity is necessary to describe situations where there are packages within packages, for example, cartridges within a blister sleeve within a box. A package item can be identified by one or more data carrier identifiers.

The package item can have component parts such as closures; this is facilitated by the package (component) class.

The lowest level package item (container), when any recursion has been unrolled, is that which is in contact with the physical Medicinal Product represented in manufactured item. Manufactured items are described in terms of their ingredients, which are discussed in greater detail in ISO/TS 20443.

A Packaged Medicinal Product can be accompanied by a device. This may be an administration device such as an oral syringe. This device is described using the device class (with type "administration device"). Where a device forms an integrated part of the Packaged Medicinal Product, such as a pre-

filled syringe, this is also described using the device class (with type “integrated device”). The device as it is described by the various device coding systems can be specified using the device nomenclature class and batch information can be specified using the device batch identification class.

Any manufacturing operations associated with Packaged Medicinal Product, package item, package component or devices may be described using the manufacturer/establishment structures described in 9.4.

The shelf life/storage of a Packaged Medicinal Product or a device can also be described.

A package item (and most particularly the outermost packaging) or a package component, as well as a device and a manufactured item, can have their physical characteristics described, including an image of the item as required.

In addition, the packaged item (container), the device and the manufactured item may have a set of other characteristics associated with them.

Batch identifiers, i.e. the BAID1 and BAID2, can be presented in relation to the Packaged Medicinal Product as appropriate.

There are instances where marketing authorisation information is specific to a Packaged Medicinal Product, for example, when the legal status of supply of particular packages of a Medicinal Product differ (a pack size of five tablets is not subject to a prescription whereas the pack size of 30 tablets is). In these instances, marketing authorisation information can be described directly for the Packaged Medicinal Product using the structures described in 9.4.

9.6.2 Detailed description of Packaged Medicinal Product information

9.6.2.1 General

Figure 11 shows a detailed description of the Packaged Medicinal Product section.

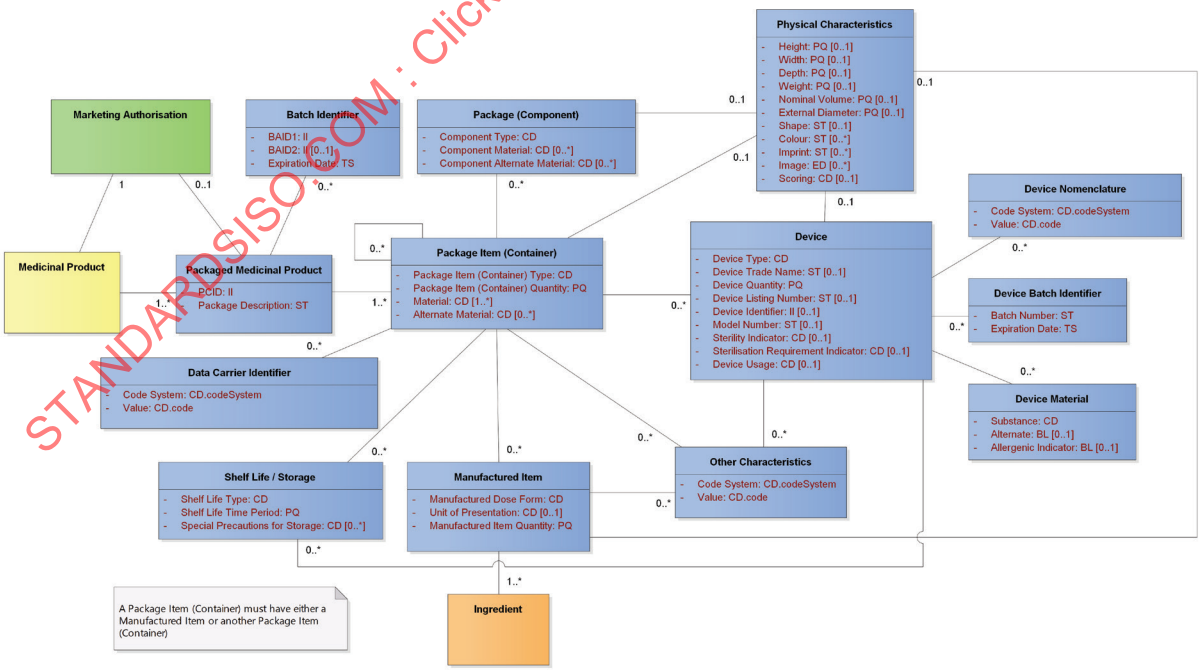

Figure 11 — Packaged Medicinal Product section detailed description diagram

9.6.2.2 Packaged Medicinal Product

9.6.2.2.1 PCID

This is the unique identifier for the Packaged Medicinal Product, constructed as described in 8.3.

9.6.2.2.2 Package description

A textual description of the Packaged Medicinal Product shall be provided.

9.6.2.3 Package item (container)

9.6.2.3.1 General

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.

There shall be at least one package item for each distinct kind of packaged item in a Packaged Medicinal Product. Where there are several identical package items, the number of them shall be given.

Subsequent, more detailed, descriptions in related classes shall be related to the single item only.

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

9.6.2.3.2 Package item (container) type

The package item (container) type shall be specified to describe the physical type of the container of the medicine in accordance with ISO 11239 and ISO/TS 20440 and its resulting terminology. A term and a term identifier shall be specified.

9.6.2.3.3 Package item (container) quantity

The quantity (or count number) of the package item shall be specified.

Because the package item class recurses to describe containers within containers, the first (outermost) container shall always have a quantity of "1".

9.6.2.3.4 Material

The material(s) of the package item shall be described in accordance with ISO 11238 and ISO/TS 19844 and its resulting terminology as applicable. A term and a term identifier shall be specified.

9.6.2.3.5 Alternate material

The alternate material(s) of the package item shall be described in accordance with ISO 11238 and ISO/TS 19844 and its resulting terminology as applicable. A term and a term identifier shall be specified. 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 plastic for a blister sleeve).

9.6.2.4 Data carrier identifier

9.6.2.4.1 General

Data carrier identifiers such as barcodes can be presented at each packaging level. Regional regulatory requirements can specify the data carrier(s) to be used. The data carrier identifier shall be specified as required.

9.6.2.4.2 Code system

The data carrier identification system itself shall be specified using an appropriate identification system.

9.6.2.4.3 Value

The individual value from the identification system that applies to the Packaged Medicinal Product shall be specified.

9.6.2.5 Shelf life/storage information for a package item (container)

The shelf life/storage information for a package item (container) can be described using shelf life/storage class (see 9.6.2.11).

9.6.2.6 Physical characteristics of a package item (container)

The physical characteristics (height, width, depth, weight, shape, etc.) of a package item (container) can be described using the physical characteristics class (see 9.6.2.20).

9.6.2.7 Other characteristics of a package item (container)

Other characteristics of a package item (container) can be described using the other characteristics class (see 9.6.2.21).

9.6.2.8 Batch identifier

9.6.2.8.1 BAID1

The BAID1, which appears on the outer packaging of a specific batch of the Medicinal Product, shall be specified. Since there will be many different batches of any one Packaged Medicinal Product, and since the specification of batch identification might not always be required for each type of Packaged Medicinal Product, the cardinality of the relationship between the Packaged Medicinal Product and the batch identifier is given as 0..*. 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.

9.6.2.8.2 BAID2

The BAID2, which appears on the immediate packaging and is not the outer packaging, shall be specified.

9.6.2.8.3 Expiration date

This is the date the manufacturer guarantees the full potency and safety of a particular batch/lot of Medicinal Product. The complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.6.2.9 Package (component)

9.6.2.9.1 General

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.

9.6.2.9.2 Component type

The type of component whose material is being described may be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.6.2.9.3 Component material

The material(s) of the component can be specified. Materials may be described in accordance with ISO 11238 and its resulting terminology as applicable. A controlled term and a controlled term identifier shall be specified.

9.6.2.9.4 Component alternate material

Alternative materials for the component can be specified. Materials shall be described in accordance with ISO 11238 and its resulting terminology as applicable. A controlled term and a controlled term identifier shall be specified.

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).

9.6.2.9.5 Physical characteristics of a package (component)

The physical characteristics (height, width, depth, weight, shape, etc.) of the package (component) can be described using the physical characteristics class (see 9.6.2.20). One or more images of the device can be included, if required.

9.6.2.10 Manufacturer of a package (component)

The manufacturer of a package (component) can be described using the manufacturer/establishment (organisation) set of classes (see 9.5).

9.6.2.11 Shelf life/storage

9.6.2.11.1 General

The shelf life/storage information can be described using the shelf life/storage class.

9.6.2.11.2 Shelf life type

This describes the shelf life, taking into account various scenarios such as shelf life of the Packaged Medicinal Product itself, shelf life after transformation, where necessary, and shelf life after the 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.

9.6.2.11.3 Shelf life time period

The shelf life time period can be specified using a numerical value for the period of time and its unit of time measurement. 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.

9.6.2.11.4 Special precautions for storage

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.

9.6.2.12 Device

9.6.2.12.1 General

Medicinal Products may be authorised with a device(s), which may be described using the device class. Devices may be of several types 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.

9.6.2.12.2 Device type

The type of device shall be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.6.2.12.3 Device trade name

This can be used to specify the trade name of the device, where applicable, as text.

9.6.2.12.4 Device quantity

The quantity of the device present in the pack shall be specified.

9.6.2.12.5 Device listing number

This can be used to specify the listing number of the device, where applicable, in text.

9.6.2.12.6 Device identifier

A unique device identifier needs to be specified.

9.6.2.12.7 Device model number

This can be used to specify the device model or reference number, where applicable, in text.

9.6.2.12.8 Sterility indicator

Where applicable, this can be used to specify whether the device is supplied as sterile using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.6.2.12.9 Sterilisation requirement indicator

Where applicable, this can be used to specify whether the device shall be sterilised before use based on an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.6.2.12.10 Device usage

The number of times that the device may be used as described in the regulated product information may be specified.

9.6.2.13 Device material

9.6.2.13.1 General

This class is used to list the substances that are used to create the material(s) of which the device is made and also for indicating if the substance is representing an alternate material and if the substance is a known allergen.

9.6.2.13.2 Substance

The substance that compose the material of the device shall be described in accordance with ISO 11238 as applicable and its resulting terminology.

9.6.2.13.3 Alternate

This flag indicates if the substance represents an alternative material of the device.

NOTE Alternate is used 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).

9.6.2.13.4 Allergenic indicator

This flag indicates if the substance is a known or suspected allergen.

9.6.2.14 Device nomenclature

9.6.2.14.1 General

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

9.6.2.14.2 Code system

The device nomenclature system shall be specified using an appropriate identification system.

9.6.2.14.3 Value

The term for the device from the specified nomenclature system shall be specified.

9.6.2.15 Device batch identifier

9.6.2.15.1 General

This class can be used to describe the batch number and/or expiry date of a device in a Packaged Medicinal Product.

At implementation, any batch number and expiry date for a device in a Packaged Medicinal Product will be related to a particular batch or batches of that Packaged Medicinal Product (as described using the BAID1), but for simplification at a conceptual level, the “many-to-many” relationship that this would give has been omitted.

9.6.2.15.2 Batch number

Where applicable, the batch number for the device can be specified, in text.

9.6.2.15.3 Expiration date

Where applicable, the expiration date for the batch can be specified.

9.6.2.16 "Shelf life/storage" information for a device

The shelf life/storage information for a device can be described using the shelf life/storage class (see 9.6.2.11).

9.6.2.17 "Physical characteristics" of a device

The physical characteristics (height, width, depth, weight, shape, etc.) of a device can be described using the physical characteristics class (see 9.6.2.20). One or more images of the device can be included, if required.

9.6.2.18 "Other characteristics" of a device

Other characteristics of a device can be described using the other characteristics class (see 9.6.2.21).

9.6.2.19 "Manufacturer" of a device

The manufacturer of a device can be described using the manufacturer/establishment (organisation) set of classes (see 9.5).

9.6.2.20 Manufactured item

9.6.2.20.1 General

The manufactured item(s) as contained in the Packaged Medicinal Product shall be described. This is the actual manufactured item (the tablet, liquid, 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.

NOTE The relationship between a package item (container) and a manufactured item is 0...* despite the fact that every Packaged Medicinal Product will have at least one manufactured item. The "zero" is present because the package item (container) class recurses, and, in the common situation where there is an outer and immediate package item, the outer package item does not immediately relate to a manufactured item. The multiplicity is present for the rare cases where a single immediate package item holds more than one manufactured item, as is the case, for example, for phased combined oral contraceptives and some hormone replacement therapies.

9.6.2.20.2 Manufactured dose form

This describes the pharmaceutical dose form of the manufactured item, where applicable, before transformation into the pharmaceutical product. The manufactured dose form shall be specified in accordance with ISO 11239 and ISO/TS 20440 and its resulting terminology. The controlled term and the controlled term identifier shall be specified.

A Medicinal Product may have two package items, e.g. 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 transformed to a solution for injection before the medicine can be administered to a patient. Powder and solvent for solution for injection is the "combined pharmaceutical dose form", which is an attribute of "Medicinal Product" and solution for injection is the "administrable dose form", which is an attribute of "pharmaceutical product".

9.6.2.20.3 Unit of presentation

This specifies the "real world" units in which the quantity of the manufactured item is described. The unit of presentation can be specified in accordance with ISO 11239 and ISO/TS 20440 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.

9.6.2.20.4 Manufactured item quantity

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 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.

9.6.2.20.5 Physical characteristics of a manufactured item

The physical characteristics (height, width, depth, weight, shape, etc.) of a manufactured item can be described using the physical characteristics class (see 9.6.2.20). One or more images of the manufactured item can be included, if required.

9.6.2.20.6 Other characteristics of a manufactured item

Other characteristics of a manufactured item can be described using the other characteristics class (see 9.6.2.21).

9.6.2.20.7 Ingredients of a manufactured item

The ingredient(s) of a manufactured item shall be described using the ingredient class (see 9.7).

9.6.2.21 Physical characteristics

9.6.2.21.1 General

Where applicable for a package item (container), package (component), manufactured item or device, its physical characteristics can be specified. One or more images can be provided as applicable.

9.6.2.21.2 Height

Where applicable, the height can be specified using a numerical value and its unit of measurement. 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.

9.6.2.21.3 Width

Where applicable, the width can be specified using a numerical value and its unit of measurement. 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.

9.6.2.21.4 Depth

Where applicable, the depth can be specified using a numerical value and its unit of measurement. 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.

9.6.2.21.5 Weight

Where applicable, the weight can be specified using a numerical value and its unit of measurement. 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.

9.6.2.21.6 Nominal volume

Where applicable, the nominal volume can be specified using a numerical value and its unit of measurement. 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.

9.6.2.21.7 External diameter

Where applicable, the external diameter can be specified using a numerical value and its unit of measurement. 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.

9.6.2.21.8 Shape

Where applicable, the shape can be specified. An appropriate controlled vocabulary shall be used. The term and the term identifier shall be used.

9.6.2.21.9 Colour

Where applicable, the colour can be specified. An appropriate controlled vocabulary shall be used. The term and the term identifier shall be used.

9.6.2.21.10 Imprint

Where applicable, the imprint can be specified as text.

9.6.2.21.11 Image

Where applicable, the image can be provided. The format of the image attachment shall be specified by regional implementations.

9.6.2.21.12 Scoring

Where applicable, the scoring can be specified. An appropriate controlled vocabulary shall be used. The term and the term identifier shall be used.

9.6.2.22 Other characteristics

9.6.2.22.1 General

Where applicable for a package item, a manufactured item or a device, other characteristics can be specified. This facility is useful for capturing unusual details not explicitly catered for in the other attributes.

9.6.2.22.2 Code system

The code system that is used to describe the characteristic shall be specified using an appropriate identification system.

9.6.2.22.3 Value

The individual value from the characteristics code system that applies shall be specified using a controlled term and a controlled term identifier.

9.7 Ingredient, substance and strength

9.7.1 General

This describes the ingredients of the Medicinal Product through its representations as the manufactured item(s) and the pharmaceutical product(s), based on ISO 11238 and ISO/TS 19844, ISO 11239 and ISO/TS 20440, ISO 11240 and their resulting terminologies.

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.

Any substance or specified substance shall have its strength specified in accordance with the regulated 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 product information.

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

9.7.2 Detailed description of ingredients, substance and strength information

9.7.2.1 General

Figure 12 shows a description of the ingredients, substance and strength section.

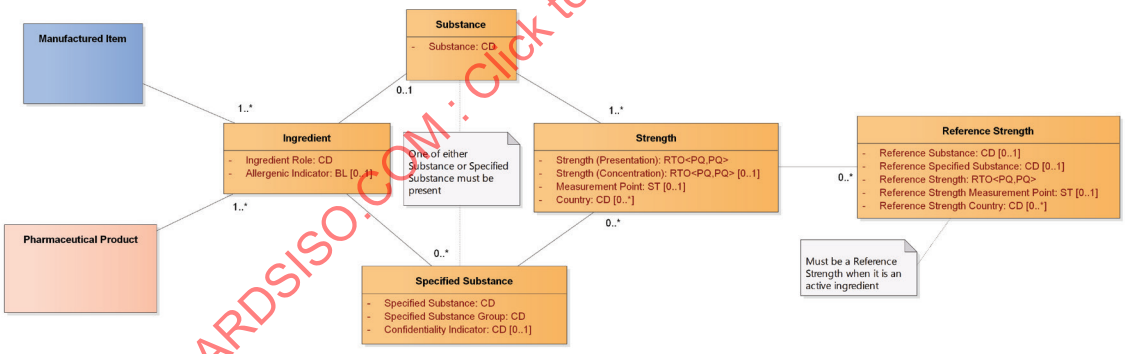

Figure 12 — Ingredients, substance and strength section detailed description diagram

9.7.2.2 Ingredient

9.7.2.2.1 General

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

9.7.2.2.2 Ingredient role

The role of the ingredient as part of the manufactured item/pharmaceutical product shall be specified using an appropriate controlled vocabulary. The controlled term and a term identifier shall be specified.

9.7.2.2.3 Allergenic indicator

This flag indicates if the ingredient is a known or suspected allergen.

9.7.2.3 Substance

9.7.2.3.1 General

This class is for allowing the specification of one or more substances.

9.7.2.3.2 Substance

A substance can be specified for an ingredient in the role described.

The substance shall be described in accordance with ISO 11238 and ISO/TS 19844 and its resulting terminology. A term and a term identifier shall be used.

9.7.2.4 Specified substance

9.7.2.4.1 General

One or more specified substances shall be associated to a substance.

9.7.2.4.2 Specified substance

When a specified substance is described, it shall be presented in accordance with ISO 11238 and ISO/TS 19844 and its resulting terminology. A term and a term identifier shall be used.

9.7.2.4.3 Specified substance group

The group to which a specified substance is assigned in accordance with ISO 11238 and ISO/TS 19844 and its resulting terminology can be used. A term and a term identifier shall be used.

9.7.2.4.4 Confidentiality indicator

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 used.

9.7.2.5 Strength

9.7.2.5.1 General

The strength of the substance 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 used.

Strength can be expressed in two ways: strength (presentation) and strength (concentration).

When the strength of a pharmaceutical product that has undergone a transformation (e.g. reconstitution) is to be specified, it shall be specified using the strength resulting from transformation undertaken exactly in accordance with the regulated product information.

9.7.2.5.2 Strength (presentation)

The strength (presentation) shall be specified. It is defined as the quantity or range of quantities of the substance/specified substance present in the unit of presentation of or in the volume (or mass) of the single pharmaceutical product or manufactured item.

When required for expression of strength, the unit of presentation shall be specified in accordance with ISO 11239 and ISO/TS 20440 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.

For strength expressed using standard units, the unit of measure symbol and the symbol identifier as defined in ISO 11240 and its resulting controlled vocabulary shall be specified.

9.7.2.5.3 Strength (concentration)

The strength (concentration) can be specified. It is defined as a quantity or range of quantities of the substance/specified substance present per unitary volume (or mass).

This attribute is only required when the strength (presentation) attribute is valued with the denominator as a non-unitary amount.

For solid dose forms, strength (concentration) is generally the same as strength (presentation) and therefore is not required to be expressed separately; the strength (presentation) only is required.

When required for expression of strength, 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. For strength expressed using standard units, the unit of measure symbol and the symbol identifier as defined in ISO 11240 and its resulting controlled vocabulary shall be specified.

9.7.2.5.4 Measurement point

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

9.7.2.5.5 Country

The country or countries for which the strength range (presentation) and (concentration) and associated measurement point are valid can be specified using values from the ISO 3166-1 alpha-2 codes.

If a measurement point is specified, one or more countries shall be described as applicable.

9.7.2.6 Reference strength

9.7.2.6.1 General

Strength can be further described by a reference strength with respect to a reference substance (i.e. active moiety). In case of an active substance, the reference strength shall be specified.

A reference strength is an expression of the strength in terms of either a reference substance or a reference specified substance or both.

9.7.2.6.2 Reference substance

If a reference strength substance needs to be specified based on the regulated product information, it shall be described in accordance with ISO 11238 and its controlled vocabulary. A controlled term and a controlled term identifier shall be used. In case of active substances a reference substance shall be specified.

9.7.2.6.3 Reference specified substance

If a reference strength specified substance needs to be described 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.

9.7.2.6.4 Reference strength

The reference strength shall be specified. A numerator value and numerator unit, as well as a denominator value and denominator unit shall be specified. The reference strength can be expressed in two ways: strength (presentation) and strength (concentration).

9.7.2.6.5 Reference strength measurement point

The reference strength measurement point, if applicable, can be described as in 9.7.2.5.4.

9.7.2.6.6 Reference strength country

Where a reference strength country is applicable, it shall be specified based on ISO 3166-1 alpha-2 code elements. See 9.7.2.5.4

9.8 Pharmaceutical product and device

9.8.1 General

This 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. See 9.8.2.5.

A Medicinal Product is associated with the pharmaceutical product class, describing the product in terms of its qualitative and quantitative composition and the pharmaceutical dose form approved for administration in line with the regulated product information. It is the pharmaceutical product therefore that has route of administration information for the administration process.

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”. In this case, the device is in effect an “ingredient” of the pharmaceutical product. 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. The pharmaceutical product is associated with a set of PhPIDs, as documented in ISO 11616 and ISO/TS 20451.

9.8.2 Detailed description of pharmaceutical product and device information

9.8.2.1 General

Figure 13 shows a description of the pharmaceutical product and device section.

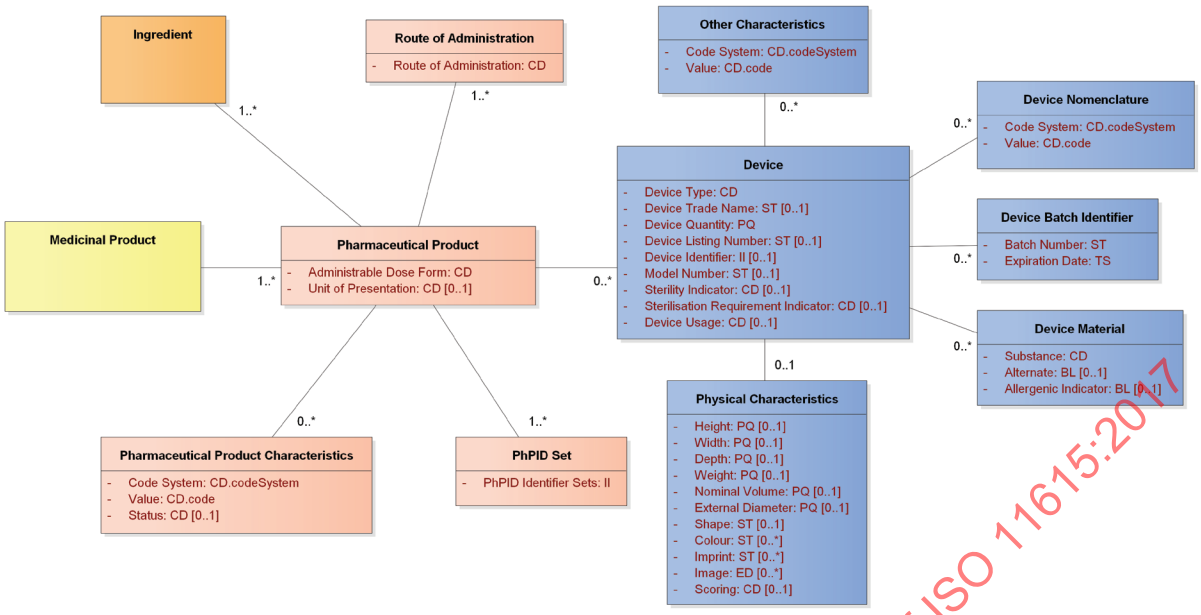

Figure 13 — Pharmaceutical product and device section detailed description diagram

9.8.2.2 Pharmaceutical product

9.8.2.2.1 General

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.

9.8.2.2.2 Administrable dose form

This shall describe the administrable dose form in accordance with the regulated product information. This is after it has undergone any necessary reconstitution, where applicable. The administrable dose form shall be specified in accordance with ISO 11239 and ISO/TS 20440 and the resulting terminology. The term and the 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.

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 correspond to the administrable dose form “solution for injection”.

9.8.2.2.3 Unit of presentation

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 ISO 11239 and ISO/TS 20440 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 shall be “1 unit” and the unit of presentation shall be the item that is counted, specified as a term and a term identifier as defined in ISO 11239 and ISO/TS 20440 and the resulting terminology.

9.8.2.3 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.

The route of administration shall be specified using terms and a term identifier as defined in ISO 11239 and ISO/TS 20440 and its resulting terminology.

9.8.2.4 Pharmaceutical product characteristics

9.8.2.4.1 General

This class can be used to describe various characteristics of the pharmaceutical product, such as its onset of action.

9.8.2.4.2 Code system

The code system being used to describe the type of characteristic shall be specified using an appropriate identification system.

9.8.2.4.3 Value

The individual value from the code system that describes the actual characteristic shall be specified using a controlled term and a controlled term identifier.

9.8.2.4.4 Status

The status of the pharmaceutical product characteristic should be listed here, e.g. assigned, not assigned or pending.

9.8.2.5 "Device" for pharmaceutical product

For pharmaceutical products, only those situations 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 shall be described using the device, physical characteristics and other characteristics classes. For products where this occurs (e.g. the skin scaffold situation), the device is in effect being considered as an "ingredient" of the pharmaceutical product, and is therefore described here, because it will be referenced in the PhPID identification of the pharmaceutical product.

9.8.2.6 PhPID set

This class shall carry 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.

9.9 Clinical particulars

9.9.1 General

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

A region/jurisdiction may further refine the requirements in relation to the clinical particulars information at implementation so that this information is to be specified only if required.

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), its undesirable effect(s) and its interactions.

Both indication(s) and contraindication(s) can be qualified by information about a specific population that any particular indication or contraindication refers to and by information about other therapy specifics, i.e. the use of the Medicinal Product in relation to other medication.

Undesirable effects are associated directly to the Medicinal Product or associated to the Medicinal Product but linked to a specific indication or to a specific population.

The clinical particulars class itself is a conceptual "parent" class, drawn into the high-level drawings for ease of visualisation (see 9.1.1); it does not hold information in and of itself, and therefore it is not realised in the detailed description attribute model (see Figure 14).

9.9.2 Detailed description for clinical particulars information

9.9.2.1 General

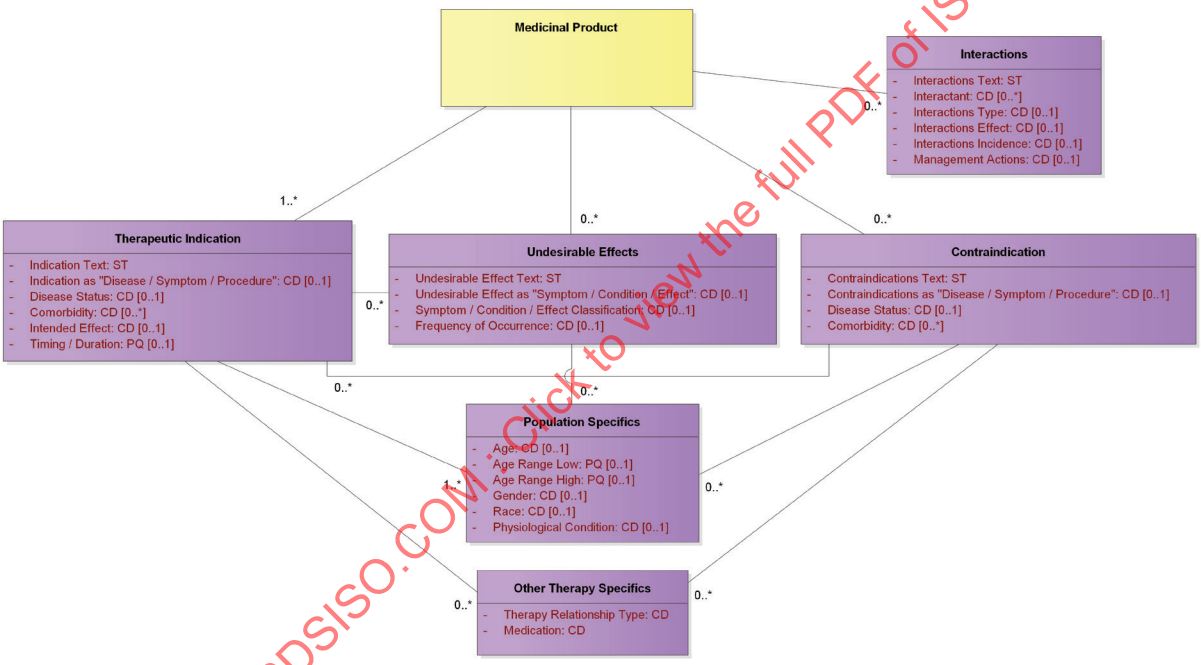

Figure 14 — Clinical particulars section detailed description diagram

9.9.2.2 Therapeutic indication

9.9.2.2.1 General

This class shall be used to describe the authorised indication(s) for the Medicinal Product in accordance with the regulated product information.

A region may further refine the requirements in relation to the therapeutic indication(s) information at implementation so that this information is to be specified only if required.

9.9.2.2.2 Indication text

The authorised therapeutic indication(s) shall be described in text.

9.9.2.2.3 Indication as “disease/symptom/procedure”

The underlying disease, symptom or procedure that is the indication for treatment 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 shall be specified.

9.9.2.2.4 Disease status

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 shall be specified.

9.9.2.2.5 Comorbidity

If there is any comorbidity (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 vocabulary. The controlled term and the controlled term identifier shall be specified.

9.9.2.2.6 Intended effect

The intended effect, aim or strategy to be achieved by 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 shall be specified.

NOTE 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.

9.9.2.2.7 Timing/Duration

If there is timing or duration information described as part of the indication as it is referenced in the regulated product information, it can be specified here.

9.9.2.3 Contraindication

9.9.2.3.1 General

This class shall be used to describe the authorised contraindication(s) for the Medicinal Product as described in the regulated product information.

A jurisdiction may further refine the requirements in relation to the contraindications information at implementation so that this information is to be specified only if required.

9.9.2.3.2 Contraindications text

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

9.9.2.3.3 Contraindications as “disease/symptom/procedure”

The underlying disease, symptom or procedure 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 shall be specified.

9.9.2.3.4 Disease status

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 shall be specified.

9.9.2.3.5 Comorbidity

The comorbidity (concurrent condition) or coinfection shall be specified.

9.9.2.4 Undesirable effects

9.9.2.4.1 General

This class shall be used to describe the undesirable effects of the Medicinal Product as described in the regulated product information. A jurisdiction may further refine the requirements in relation to the undesirable effects information at implementation so that this information is to be specified only if required.

9.9.2.4.2 Undesirable effect text

The text of the undesirable effect shall be given.

9.9.2.4.3 Undesirable effect as "symptom/condition/effect"

The symptom, condition or effect in relation to the undesirable effect as described in the regulated product information can be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.9.2.4.4 Symptom/condition/effect classification

The classification of the "symptom/condition/effect" can be specified. The controlled term and the controlled term identifier shall be specified using an appropriate controlled vocabulary.

9.9.2.4.5 Frequency of occurrence

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.

9.9.2.5 Population specifics

9.9.2.5.1 General

This class can be used to describe the population for which a particular indication or contraindication applies as authorised for the Medicinal Product in accordance with the regulated product information.

9.9.2.5.2 Age

The age of the specific population for an indication or a contraindication as authorised for the Medicinal Product in accordance with the regulated product information can be specified.

Either age or age range should be specified for a single indication/contraindication; both should not be specified.

9.9.2.5.3 Age range low

The lower limit of the age range of the specific population for an indication or a contraindication as authorised for the Medicinal Product in accordance with the regulated product information can be specified.

Either age or age range should be specified for a single indication/contraindication; both should not be specified.

9.9.2.5.4 Age range high

The upper limit of the age range of the specific population for an indication or a contraindication as authorised for the Medicinal Product in accordance with the regulated product information can be specified.

Either age or age range should be specified for a single indication/contraindication; both should not be specified.

9.9.2.5.5 Gender

The gender of the specific population for an indication or a contraindication in accordance with the regulated product information shall be specified using ISO/IEC 5218.

9.9.2.5.6 Race

The race of the specific population for an indication or a contraindication in accordance with the regulated product information can be specified using an appropriate controlled terminology. The controlled term and the controlled term identifier shall be specified.

9.9.2.5.7 Physiological condition

Various aspects of the physiological conditions of the specific population for an indication or 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.

9.9.2.6 Other therapy specifics

9.9.2.6.1 General

If there is information about the use of the Medicinal Product in relation to other therapies described as part of the indication or contraindication in accordance with the regulated product information, this can be specified using this class.

9.9.2.6.2 Therapy relationship type

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

9.9.2.6.3 Medication

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

9.9.2.7 Interactions

9.9.2.7.1 General

This class can be used to describe the interactions of the Medicinal Product (with other Medicinal Products) and other forms of interactions as described in the regulated product information.

9.9.2.7.2 Interactions text

The text of the interaction in accordance with the regulated product information shall be provided.

9.9.2.7.3 Interactant

This element can 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.

For more information, refer to regional implementation guides.

9.9.2.7.4 Interactions type

The type of interaction in line with the regulated product information can be described using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.9.2.7.5 Interactions effect

The effect of the interaction in line with the regulated product information can be described using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.9.2.7.6 Interactions incidence

The incidence of the interaction in accordance with the regulated product information can be described using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

9.9.2.7.7 Management actions

The actions to provide management of the interaction in accordance with the regulated product information can be described using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

10 Identifying characteristics for Investigational Medicinal Products

10.1 General

This subclause describes Investigational Medicinal Products (IMPs) that do not have a marketing authorisation and which are subject to an investigation in one or more clinical trials. The subclause also applies to authorised Medicinal Products that are subject to investigation in a clinical trial but are used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication.

"Investigational Medicinal Product" refers to a Medicinal Product being tested in a clinical trial, including the trial medication(s), each comparator and each placebo as defined in the clinical trial protocol.

10.2 Primary identifiers

10.2.1 General considerations

To satisfy the requirements as described in 6.4, the following four identifiers shall be specified:

a) Investigational Medicinal Product Identifier (IMPID);

b) Investigational Medicinal Product Package Identifier (IPCID);