INTERNATIONAL STANDARD

ISO 11615

First edition
2012-11-01

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 réglementées sur les médicaments

Reference number
ISO 11615:2012(E)

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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11615 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

This International Standard was developed in response to a worldwide demand for internationally harmonized specifications for Medicinal Products. It is one of five standards which together provide the basis for the unique Identification of Medicinal Products. The group of standards comprises:

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*;

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

ISO 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*.

These standards for the Identification of Medicinal Products (IDMP) support the activities of medicines regulatory agencies worldwide by jurisdiction. 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:

— regulator to regulator;

— pharmaceutical company to regulator;

— sponsor of clinical trial to regulator;

— regulator to other stakeholder;

— regulator 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 International Standard are to be applied for the concepts which are required to uniquely identify, characterize and exchange regulated Medicinal Products and associated information.

The terms and definitions adopted in this International Standard are intended to facilitate the interpretation and application of legal and regulatory requirements but they are without prejudice to any legally binding document. In case of doubt or potential conflict, the terms and definitions contained in legally binding documents prevail.

This International Standard has been developed in conjunction with the Common Product Model in HL7. It is anticipated that implementation will use HL7 V3 messaging to transmit information between stakeholders.

In the context of exchange of regulatory information, the purpose of this International Standard 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 International Standard in order to support successful related 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 International Standard 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, characterize and uniquely identify regulated Medicinal Products for human use during their entire life cycle, i.e. from development to authorization, post-marketing and renewal or withdrawal from the market, where applicable.

Furthermore, to support successful information exchange in relation to the unique identification and characterization of Medicinal Products, the use of other normative IDMP messaging standards is included, which are to be applied in the context of this International Standard.

2 Normative references

The following referenced documents are indispensable for the application 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 639-2, *Codes for the representation of names of languages — Part 2: Alpha-3 code*

ISO 3166-1, *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 11616, *Health informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

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 21090, *Health informatics — Harmonized data types for information interchange*

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

3 Terms, definitions and abbreviations

3.1 Terms and definitions

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

3.1.1
administrable dose form
pharmaceutical dose form for administration to the patient, after any necessary transformation of the manufactured dose form has been carried out

EXAMPLES Solution for injection, tablet for oral use, hard-capsule powder for inhalation.

NOTE 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).

3.1.2
administration device
equipment intended for correct administration of the Medicinal Product

EXAMPLES Applicator, oral syringe.

NOTE An administration device may be an integral part of an immediate container or a closure.

[ENV 12610:1997]

3.1.3
allergens
materials of concern
ingredients in a device capable of stimulating a type-I hypersensitivity or allergic reaction in atopic individuals

EXAMPLE Latex.

3.1.4
authorization date
date when the authorization was granted by a Medicines Regulatory Agency for a specific activity

EXAMPLE The date of the marketing authorization, which allows the Marketing Authorization Holder to put a Medicinal Product on the market.

3.1.5
authorization procedure
marketing authorization procedure
formal procedure applied by a Medicines Regulatory Agency to grant a marketing authorization, to amend an existing one, to extend its duration or to revoke it

EXAMPLE Revocation of a marketing authorization due to an unfavourable benefit/risk balance of the medicine.

NOTE The terms authorization procedure and marketing authorization procedure are synonymous.

3.1.6
authorization status
actual state of the marketing authorization

EXAMPLES Active, suspended, expired, revoked.

3.1.7
batch
specific manufacturing release of a Medicinal Product or item by the manufacturer

3.1.8
batch number
identifier assigned to a specific batch of a Medicinal Product or item resulting from a manufacturing process at a specific point of time

3.1.9
characteristic
abstraction of a property of an object

3.1.10
clinical trial
clinical study
any 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), 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 The terms clinical trial and clinical study are synonymous.

3.1.11
clinical trial authorization
authorization granted by a Medicines Regulatory Agency to conduct a clinical trial in a jurisdiction

3.1.12
combined pharmaceutical dose form
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, and that includes information on the manufactured dose form of each manufactured item and the administrable dose form of the pharmaceutical product

EXAMPLE Powder and solvent for solution for injection. The Medicinal Product contains two manufactured items: a powder for solution for injection and a solvent for solution for injection. The pharmaceutical product that is prepared from the two manufactured items is a solution for injection; the combined pharmaceutical dose form for the Medicinal Product is “powder and solvent for solution for injection”.

3.1.13
common name
generic name
international nonproprietary name recommended by the World Health Organization (WHO), or, if one does not exist, a nonproprietary name recommended by the jurisdiction within which the name is used

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

3.1.14
concept
unit of knowledge constructed through combining characteristics expressed in words

3.1.15
container
item of packaging that is part of a Medicinal Product and is used for storage, identification and/or transport of the components of the Medicinal Product

3.1.16
controlled vocabulary
finite set of values that represent the only allowed values for a data item

NOTE The allowed values can be codes, text or numeric.

[CDISC Clinical Research Glossary V8.0, 2009]

3.1.17
datatype
set of distinct values, characterized by properties of those values, and by operations on those values

[ISO 11404:2007, definition 3.12]

3.1.18
distributor
organization in possession of a licence covering the procuring, holding, supplying or exporting of Medicinal Products, apart from supplying Medicinal Products to the public

NOTE This is applicable to “wholesale distribution of Medicinal Products”.

3.1.19
dose
specified quantity of a medicine, to be taken at one time or at stated intervals

3.1.20
dose form
dosage form
pharmaceutical dose form
physical manifestation of a Medicinal Product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient

NOTE 1 Dose form, dosage form and pharmaceutical dose form are synonymous.

NOTE 2 "Pharmaceutical dose form" can refer to the administered dose form or the manufactured dose form.

3.1.21
Global Trade Identification Number
GTIN
GS1 unique identifier of items that are traded (e.g. pharmaceuticals, medical devices) in the supply chain

NOTE A GTIN is used to identify any item upon which there is a need to retrieve pre-defined 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.

3.1.22
identifier
ID
description that is sufficient to represent an object in a given environment

NOTE 1 In the context of this International Standard, this is a list of identifying characteristics that together unambiguously identify a Medicinal Product, pharmaceutical product, substance, specified substance, route of administration, pharmaceutical dose form or any other element which requires to be uniquely identified.

NOTE 2 Adapted from ENV 12610:1997.

3.1.23
immediate container
immediate packaging
packaging in which a manufactured item or pharmaceutical product is contained and with which it is in direct contact

EXAMPLES Ampoule, vial, prefilled syringe, bottle, blister.

NOTE 1 An immediate container can be fitted with or have integrated into it an administration device and/or closure.

NOTE 2 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.

NOTE 3 An alternative, compatible definition of immediate container ("immediate packaging") is given in Directive 92/27/EEC.

NOTE 4 Adapted from ENV 12610:1997.

3.1.24
ingredient
material used in the preparation of a medicinal/pharmaceutical product

NOTE The ingredient is part of a Medicinal Product, either alone or in combination with one or more ingredients. The ingredient is also a component of a pharmaceutical product. Ingredient is equal to the detailed description of a substance, a substance playing the role of an ingredient in a product.

3.1.25
international non-proprietary name
INN
official non-proprietary or generic name given to a pharmaceutical substance, as designated by the World Health Organization

3.1.26
intermediate packaging
container between the outer packaging and the immediate container

3.1.27
invented name
name for an innovative Medicinal Product as authorized by a Medicines Regulatory Agency in a jurisdiction

NOTE Synonym to “trade name” of a Medicinal Product.

3.1.28
Investigational Medicinal Product
pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorized form, used for an unauthorized indication, or used to gain further information about the authorized form

3.1.29
(Investigational) Medicinal Product Batch Identifier
(I)BAID_1
unique identifier allocated to a specific batch of an (Investigational) Medicinal Product, which appears on the outer packaging of the (Investigational) Medicinal Product

NOTE 1 It is constructed by using the batch number assigned by the manufacturer and the expiration date.

NOTE 2 This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of an (Investigational) Medicinal Product at the package level.

3.1.30
(Investigational) Medicinal Product Batch Identifier
(I)BAID_2
unique identifier allocated to a specific batch of an (Investigational) Medicinal Product, which appears on the immediate packaging, where this is not the outer packaging

NOTE 1 It is constructed by using the batch number assigned by the manufacturer and the expiration date.

NOTE 2 This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of an (Investigational) Medicinal Product based at the level of the immediate container.

3.1.31
Investigational Medicinal Product Identifier
IMPID
unique identifier allocated to an Investigational Medicinal Product supplementary to any existing identifier as ascribed by a Medicines Regulatory Agency in a jurisdiction or a sponsor of a clinical trial

NOTE This is for indexing purposes and to contribute to improving patient safety by allowing for the unique Identification of Medicinal Products worldwide.

3.1.32
Investigational Medicinal Product Package Identifier
IPCID
unique identifier allocated to an Investigational Medicinal Product at package level supplementary to any existing identifier as ascribed by a Medicines Regulatory Agency in a jurisdiction or a sponsor of a clinical trial

NOTE This is for indexing purposes and to contribute to improving patient safety by allowing for the unique Identification of Medicinal Products worldwide.

3.1.33
jurisdiction
geographical area or subject matter to which the Medicines Regulatory Agency applies

3.1.34
legal status of supply
jurisdictional rule as to whether a Medicinal Product is subject to a medical prescription before it may be supplied to a patient or consumer

3.1.35
manufactured dose form
pharmaceutical dose form of a manufactured item as manufactured and, where applicable, before transformation into the pharmaceutical product

EXAMPLE Powder for solution for injection.

NOTE The manufactured dose form is identical to the administrable 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).

3.1.36
manufactured item
qualitative and quantitative composition of a product as contained in the packaging of the Medicinal Product

NOTE 1 A Medicinal Product may contain one or more manufactured items.

NOTE 2 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.

NOTE 3 The manufactured item is not in direct contact with the outer packaging except where the outer packaging also serves as the immediate container.

3.1.37
manufacturing authorization
manufacture of the Medicinal Products within a jurisdiction subject to the holding of an authorization

NOTE Such authorization may be required for both total and partial manufacture and for the various processes of dividing up, packaging or presentation. However, such authorization 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 authorized in a jurisdiction to carry out such processes.

3.1.38
manufacturing authorization date
date when the manufacturing authorization was granted

3.1.39
manufacturing authorization holder
organization that holds the authorization for the manufacturing process

3.1.40
marketing authorization
authorization issued from a Medicines Regulatory Agency that a Medicinal Product may be placed on the market

3.1.41
Marketing Authorization Holder
organization that holds the authorization for marketing a Medicinal Product in a jurisdiction

3.1.42
marketing authorization number
identifier assigned by a Medicines Regulatory Agency to a Medicinal Product

3.1.43
marketing authorization procedure
authorization procedure
formal procedure applied by a Medicines Regulatory Agency to grant a marketing authorization, amend an existing one, extend its duration or to withdraw it

NOTE Marketing authorisation procedure and authorisation procedure are synonymous.

3.1.44
marketing start date
date when the authorized Medicinal Product is marketed in a jurisdiction

NOTE The date of actual marketing of a Medicinal Product is always after a marketing authorization has been granted by a Medicines Regulatory Agency.

3.1.45
marketing stop date
date when the marketing of the authorized Medicinal Product is stopped in a jurisdiction

3.1.46
material
substance or specified substance of which a certain component is made

NOTE This applies to a Medicinal Product package item (container), package (component) and device.

3.1.47
measurement point
physical location on an administration device where the quantity of the medication being delivered is measured

3.1.48
medical device
any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer 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.

[EC Directive on Medical Devices 2007/47]

3.1.49
Medicinal Product
any substance or combination of substances that may be administered to human beings (or animals) for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions

NOTE 1 A Medicinal Product may contain one or more manufactured items and one or more pharmaceutical products.

NOTE 2 In certain jurisdictions a Medicinal Product may also be defined as any substance or combination of substances which may be used to make a medical diagnosis.

NOTE 3 The provisions in this standard 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 authorized by a Medicines Regulatory Agency. However, the provisions do not apply to medicinal products prepared according to prescription, i.e. prepared in a pharmacy from a prescription intended for a specific patient; medicinal products prepared in accordance with an official formula, i.e. prepared in a pharmacy in accordance with the instructions in a pharmacopoeia and intended to be given direct to the patient by the pharmacy; medicinal products intended for research and development trials (see 3.1.28 Investigational Medicinal Product); intermediate products intended for subsequent processing by an authorized manufacturer.

[ENV 13607 and ENV 12610]

3.1.50
Medicinal Product Identifier
MPID
unique identifier allocated to a Medicinal Product supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction

NOTE This is for indexing purposes and to contribute to improved patient safety by allowing for the unique Identification of Medicinal Products worldwide.

3.1.51
Medicinal Product name
name as authorized by a Medicines Regulatory Agency

NOTE This may be either an invented name not liable to be confused with the common name, or a common or a scientific name accompanied by a trade mark or any other applicable descriptor.

3.1.52
Medicinal Product Package Identifier
PCID
unique identifier allocated to a packaged Medicinal Product supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction

NOTE This is for indexing purposes and to contribute to improving patient safety by allowing for the unique Identification of Medicinal Products worldwide.

3.1.53
Medicines Regulatory Agency
institutional body that, according to the legal system under which it has been established, is responsible for the granting of marketing authorization for Medicinal Products

NOTE In certain jurisdictions the role of the institutional body which according to the legal system grants the marketing authorization 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 authorization of Medicinal Products and the European Medicines Agency is the body responsible for the evaluation and supervision of Medicinal Products.

3.1.54
⟨**device**⟩ **listing number**
⟨**device**⟩ **model number**
type of information which identifies a specific device

3.1.55
outer packaging
external container in which a Medicinal Product is supplied

EXAMPLES Box, carton.

NOTE 1 The manufactured item or pharmaceutical product is not in direct contact with the outer packaging except where the outer packaging also serves as the immediate container.

NOTE 2 An alternative, compatible definition of outer packaging is given in Directive 92/27/EEC.

3.1.56
package item (container)
individual, distinct item(s) contained in a Packaged Medicinal Product which act as containers for manufactured item(s) for sale or distribution

3.1.57
Packaged Medicinal Product
Medicinal Product in a container being part of a package, representing the entirety that has been packaged for sale or supply

3.1.58
pharmaceutical product
qualitative and quantitative composition of a Medicinal Product in the dose form approved for administration in line with the regulated product information

NOTE 1 A Medicinal Product can contain one or more pharmaceutical products.

NOTE 2 In many instances, the pharmaceutical product is equal to the manufactured item. However, there are instances where the manufactured item must undergo a transformation before being administered to the patient (as the pharmaceutical product) and the two are not equal.

3.1.59
pharmacovigilance
process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines

NOTE 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.

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.

3.1.60
Pharmaceutical Product Identifier
PhPID
unique identifier for a pharmaceutical product

3.1.61
physical characteristics
description of the height, weight, width, depth, volume, colour and shape of an item

3.1.62
primary identifiers
set of unique IDMP identifiers allocated supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction

NOTE This is for indexing purposes and to contribute to improving patient safety by allowing for the unique Identification of Medicinal Products worldwide.

3.1.63
procedure number
tracking or identification number assigned by a Medicines Regulatory Agency in relation to a specific medicines regulatory process

3.1.64
procedure type
type of legal process applied to authorize or maintain a Medicinal Product marketing authorization

EXAMPLES Centralised, decentralised, national, mutual recognition.

3.1.65
product
short form for Medicinal Product or Investigational Medicinal Product

3.1.66
product classification
categorization or grouping of Medicinal Products based on specific properties

EXAMPLES Pharmacological classification, classification by therapeutic effect.

3.1.67
protocol number
⟨clinical trial⟩ identification or tracking number assigned to the clinical trial protocol

3.1.68
qualitative composition
composition of all the constituents of the investigational or authorized Medicinal Product, if applicable, after reconstitution and functioning of the constituents of:

— the substance and specified substance description;

— the constituent(s) of the excipients, whatever their nature or the quantity used, including colouring matter, preservatives, adjuvants, stabilizers, thickeners, emulsifiers, flavouring and aromatic substances, etc.

3.1.69
quantitative composition
amounts of substance and specified substance constituents of the investigational or authorized Medicinal Product expressed in a ratio scale

NOTE 1 It is necessary for the quantitative composition of the substance(s) or the specified substance descriptions of the finished investigational or authorized 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.

NOTE 2 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.

NOTE 3 See also strength (3.1.76).

3.1.70
reference strength
strength of substance(s) and/or specified substance(s) used as a reference from which the strength of an investigational or authorized Medicinal Product is described

EXAMPLE 1 Where an ingredient is present in the form of a salt or hydrate, the quantitative composition may be expressed in terms of the mass [or biological activity in International (or other) units where appropriate] of the active moiety (base, acid or anhydrous material), e.g. '60 mg toremifene (as citrate)' or 'toremifene citrate equivalent to 60 mg toremifene' will have 'toremifene citrate' as the active ingredient and 'toremifene' as the reference substance.

EXAMPLE 2 Where the active ingredient is an ester or pro-drug the quantitative composition may be stated in terms of the quantity of that ester or pro-drug; e.g. 75 mg of fosphenytoin, which is equivalent to 50 mg of phenytoin. 'Phenytoin' is therefore the reference substance.

NOTE The strength of the substance(s) and/or specified substance(s) shall be described as a quantity of the substance present in a given unit of the pharmaceutical product or manufactured item.

3.1.71
registration number
⟨clinical trial⟩ identifier assigned to a clinical trial by a Medicines Regulatory Agency in a jurisdiction for tracking purposes

3.1.72
regulated document
any document issued by a Medicines Regulatory Agency in the context of the regulatory process to grant, maintain or update the authorization of a Medicinal Product or in the regulatory process of the authorization and supervision of clinical trials

EXAMPLES Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL).

3.1.73
route of administration
path by which the pharmaceutical product is taken into or makes contact with the body

EXAMPLES Oral, intravenous, oromucosal, ocular.

3.1.74
specified substance
substance defined by groups of elements that describes multi-substance materials or specifies further information on substances relevant to the description of Medicinal Products

NOTE 1 This could include grade, units of measure, physical form, constituents, manufacturer, 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.

NOTE 2 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.

3.1.75
sponsor
individual, company, institution or organization, which takes responsibility for the initiation, management and/or financing of a clinical trial

3.1.76
strength
content of the substance(s) or specified substance(s), expressed quantitatively per dosage unit, unit of presentation, per unit of volume or mass, according to the dose form

NOTE See also quantitative composition (3.1.69).

3.1.77
substance
any matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical

NOTE 1 substances can be either single substances, mixture substances or one of a group of specified substances. Single substances are defined using a minimally sufficient set of data elements divided into five types: chemical, protein, nucleic acid, polymer and structurally diverse. substances may be salts, solvates, free acids, free bases, mixtures of related compounds that are either isolated or synthesized together. Pharmacopoeial terminology and defining characteristics will be used when available and appropriate. Defining elements are dependent on the type of substance.

NOTE 2 Discrete existence refers to the ability of a substance to exist independently of any other substance. substances can either be well-defined entities containing definite chemical structures, synthetic (i.e. isomeric mixtures) or naturally-occurring (i.e. conjugated oestrogens) mixtures of chemicals containing definite molecular structures, or materials derived from plants, animals, microorganisms or inorganic matrices for which the chemical structure may be unknown or difficult to define. substances may be salts, solvates, free acids, free bases, mixtures of related compounds that are either isolated or synthesized together.

3.1.78
Summary of Product Characteristics
SMPC
product labelling
Medicinal Product information as authorized by a Medicines Regulatory Agency in a jurisdiction

NOTE 1 The product labelling content may not be changed except with the approval of the originating Medicines Regulatory Agency. The Summary of Product Characteristics is the basis of information for health professionals on how to use the Medicinal Product safely and effectively.

NOTE 2 Summary of Product Characteristics and product labelling are synonymous.

3.1.79
target population
type of patients or consumers for which the indication of a Medicinal Product is authorized

3.1.80
therapeutic indication
intended use of the Medicinal Product as authorized by the Medicines Regulatory Agency in a jurisdiction

NOTE For clinical trials, this refers to the intended use under investigation and as described in the clinical trial protocol.

3.1.81
trademark
distinctive sign or indicator used by an individual, business organization 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

3.1.82
unit of presentation
qualitative term describing the discrete countable entity in which a pharmaceutical product or manufactured item is presented, in cases where strength or quantity is expressed referring to one instance of this countable entity

EXAMPLE 1 To describe strength: a puff, spray or tablet “contains 100 µg per spray” (unit of presentation = spray).

EXAMPLE 2 To describe quantity: a bottle, box or vial “contains 100 ml per bottle” (unit of presentation = bottle).

NOTE A unit of presentation can have the same name as another controlled vocabulary, such as a basic dose form or a container, but the two concepts are not equivalent, and each has a unique controlled vocabulary term identifier.

3.1.83
version
mechanism that takes into account that at the given effective date, some characteristics of the investigational or authorized Medicinal Product have changed and those changes may be traced during the entire life cycle of a product

3.1.84
vocabulary
terminological dictionary which contains designations and definitions from one or more specific subject fields

[ISO 1087-1:2000, definition 3.7.2]

3.2 Abbreviations

3.2.1
BAID_1
Medicinal Product Batch Identifier (outer packaging)

3.2.2
BAID_2
Medicinal Product Batch Identifier (immediate packaging)

3.2.3
BRIDG
The Biomedical Research Integrated Domain Group Model[1)]

3.2.4
DIBD
Development International Birth Date

3.2.5
DSUR
Development Safety Update Report

3.2.6
GTIN™
Global Trade Identification Number[2)]

3.2.7
IBAID_1
Investigational Medicinal Product Batch Identifier (outer packaging)

3.2.8
IBAID_2
Investigational Medicinal Product Batch Identifier (immediate packaging)

3.2.9
IBD
International Birth Date

3.2.10
ID
Identifier

3.2.11
IDMP
Identification of Medicinal Products

3.2.12
IMPID
Investigational Medicinal Product Identifier

3.2.13
INN
International non-proprietary name

3.2.14
IMDRF
International Medical Devices Regulators' Forum

3.2.15
IPCID
Investigational Medicinal Product Package Identifier

3.2.16
MPID
Medicinal Product Identifier

3.2.17
OID
Object identifier

1) For more information, see http://www.bridgmodel.org/.

2) Further information can be found at GS1: http://www.gs1.org/.

3.2.18
PBRER
Periodic Benefit-Risk Evaluation Report

3.2.19
PCID
Medicinal Product Package Identifier

3.2.20
PhPID
Pharmaceutical Product Identifier

3.2.21
PSUR
Periodic Safety Update Report

3.2.22
SPC/SmPC
Summary of Product Characteristics

3.2.23
UML
Unified Modeling Language [Object Management Group, Inc.][3)]

3.2.24
UDI
Unique Device Identification Code (IMDRF)

3.2.25
WHO
World Health Organization[4)]

4 Requirements

4.1 Concepts required for the unique Identification of Medicinal Products

4.1.1 General considerations

This International Standard 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).

Each jurisdiction already has systems for issuing marketing authorization numbers, package identifiers, batch numbers, bar codes and the like. The additional identifiers defined in this International Standard provide an indexing mechanism that is supplementary to these existing systems. It is not a replacement for them.

Such identification shall apply the principles described below.

4.1.2 Authorized Medicinal Products

The unique identification of authorized 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 recognize, monitor and trace the use of Medicinal Products;

3) For more information, see http://www.uml.org/.

4) For more information, see http://www.who.int.

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

c) the assignment of a unique **Medicinal Product Batch Identifier** (BAID_1) to reliably recognize 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 authorization;

d) the assignment of a unique **Medicinal Product Batch Identifier** (BAID_2) to reliably recognize 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 authorization.

The main characteristics that are associated with the MPID, PCID, BAID_1 and BAID_2 are:

— name of the Medicinal Product;

— legal status of supply;

— terms of the marketing authorization;

— marketing authorization (licence) holder;

— manufacturer(s);

— authorizing Medicines Regulatory Agency;

— qualitative and quantitative composition;

— ingredients, strength, pharmaceutical form, route of administration;

— device(s) as part of a Medicinal Product;

— clinical particulars;

— product classification(s);

— package description [e.g. container, administration device(s) and package quantity];

— regulated product information and documentation.

4.1.3 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 recognize, monitor and trace the use of Medicinal Products which are studied in clinical trials;

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

c) the assignment of a unique **Investigational Medicinal Product Batch Identifier** (IBAID_1) where applicable, to reliably recognize and trace a batch number which appears on the outer packaging of the Medicinal Product in compliance with the requirements of the clinical trial authorization;

d) the assignment of a unique **Investigational Medicinal Product Batch Identifier** (IBAID_2) where applicable, to reliably recognize and trace a batch number which appears on the immediate packaging of the Medicinal Product in compliance with the requirements of the clinical trial authorization.

The main characteristics that are associated with the IMPID, IPCID and IBAID_1 and IBAID_2 are:

— name(s) or code associated with the Investigational Medicinal Product;

— sponsor of the clinical trial;

— manufacturer(s);

— authorizing Medicines Regulatory Agency;

— qualitative and quantitative composition;

— strength (taking into account various stages during drug development and maximum dose allowed), pharmaceutical form, route of administration;

— device(s) as part of a Medicinal Product;

— clinical particulars;

— product classification(s);

— package description where applicable (e.g. container, administration device(s) and package quantity for the purpose of the clinical trial).

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

This International Standard defines the concepts required to associate regulated Medicinal Products (authorized 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 characterization 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 a Medicinal Product);

c) the description of the pharmaceutical product(s) in the pharmaceutical dose form approved for administration, where applicable, after reconstitution and as authorized 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).

4.1.5 Concepts required for the unique Identification of Medicinal Products and the association with the marketing authorization number

A marketing authorization number that is assigned to a Medicinal Product by a Medicines Regulatory Agency of a jurisdiction 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[5] - 250 mg-film-coated tablets 50 tablets – authorization number *15.2YZ*; Drug B - 250 mg -film-coated tablets 100 tablets – authorization 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 Capsules[6], Pharmacopoeia, for oral administration, containing 250 mg - authorization number (product level) 0XYZ1-20Z0; authorization 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 - authorization number (product level) 0XYZ1-20K0; authorization number (package level) 0XYZ1-20K0-01 for bottles of 100 and 0XYZ1-20K0-05 for bottles of 500).

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

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

c) To a Medicinal Product presentation - which means that for each product presentation a different authorization 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 – authorization 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 authorization number *V/00/1YX/003*).

NOTE Certain Medicinal Products may be distributed without a marketing authorization in a jurisdiction (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 International Standard defines the concepts required to associate the MPID and PCID(s) with the relevant marketing authorization number(s) as assigned by a Medicines Regulatory Agency in a jurisdiction. Such association shall use the following two principles.

— The MPID shall always be associated with the applicable marketing authorization number of the Medicinal Product (e.g. the MPID “*Country-055-0957*” shall be associated with the authorization 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 authorization 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*).*

4.1.6 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 pre-defined 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. The GS1 Healthcare User Group advocates the use of global standardization to aid compliance to the regulatory requirements of all countries. However, it shall be noted that national, federal or local regulations may apply and take precedence over any GS1 Standard.

The basic pre-defined 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 sub-packaging units, the nature of the grouping (carton, blister, blister-cell);

A modification to any of the basic elements that characterize 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.

5 Description of the information modelling principles and practices

5.1 General considerations

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

Like all languages, 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 International Standard 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. The following aims to explain the style that has been followed in this International Standard.

In addition, colour has been used in the diagrams to help visualize groups of associated entities together with one another.

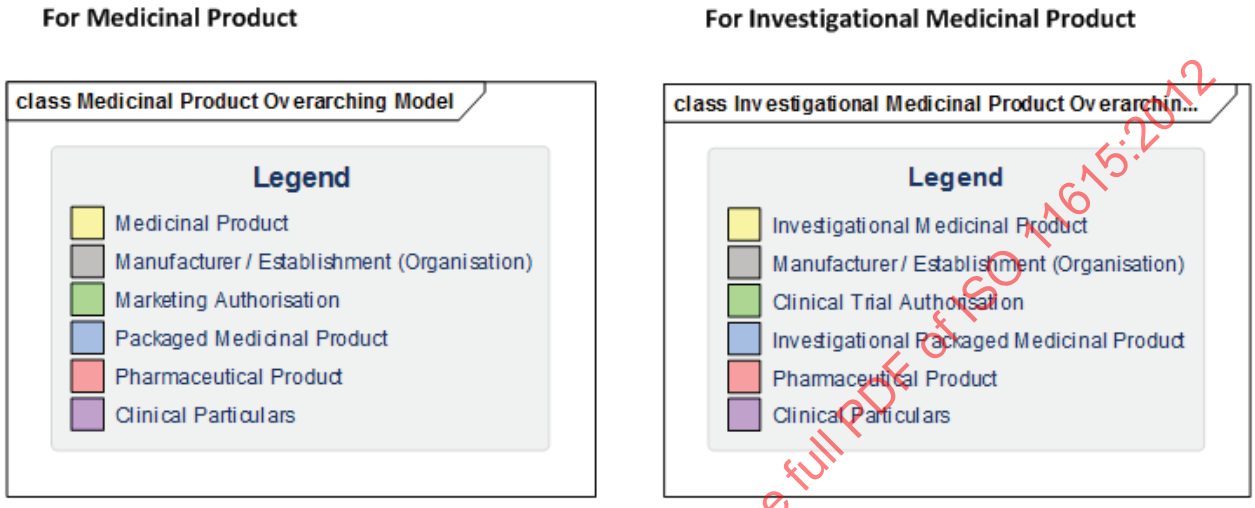

Figure 1 — Legend for colour coding of model classes

5.2 Conceptual overview diagrams

The two conceptual overview diagrams (one each for Medicinal Product and Investigational Medicinal Product) are provided to give a framework with which to view the more detailed descriptions of information.

These diagrams therefore 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 (Investigational) Medicinal Product and these core classes are shown, but none of the detailed entities, relationships or attributes is described.

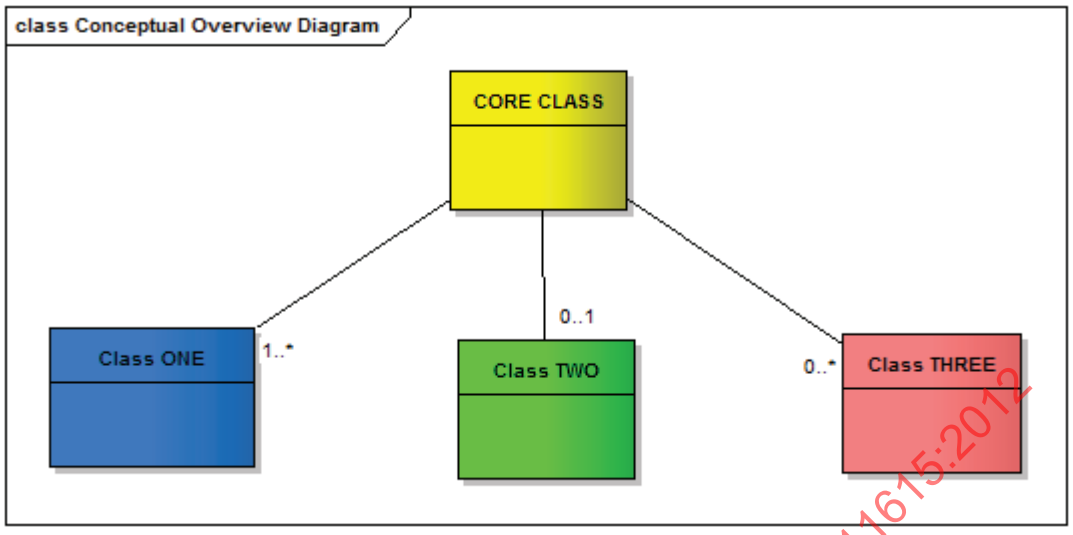

Figure 2 — Example conceptual overview diagram

5.3 Section high-level diagrams

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

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

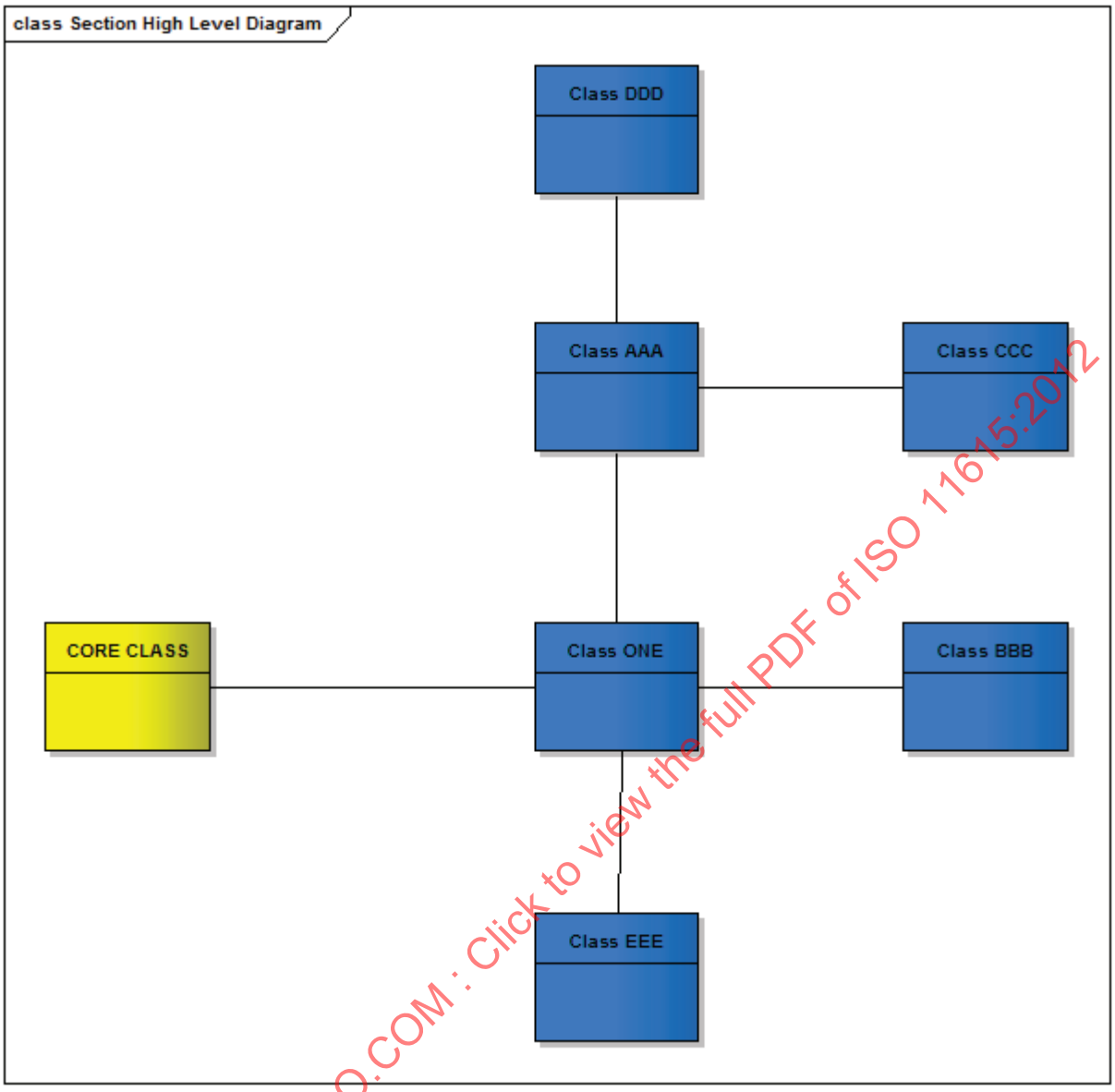

Figure 3 — Example section high-level diagram

5.4 Detailed description diagrams

5.4.1 General

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

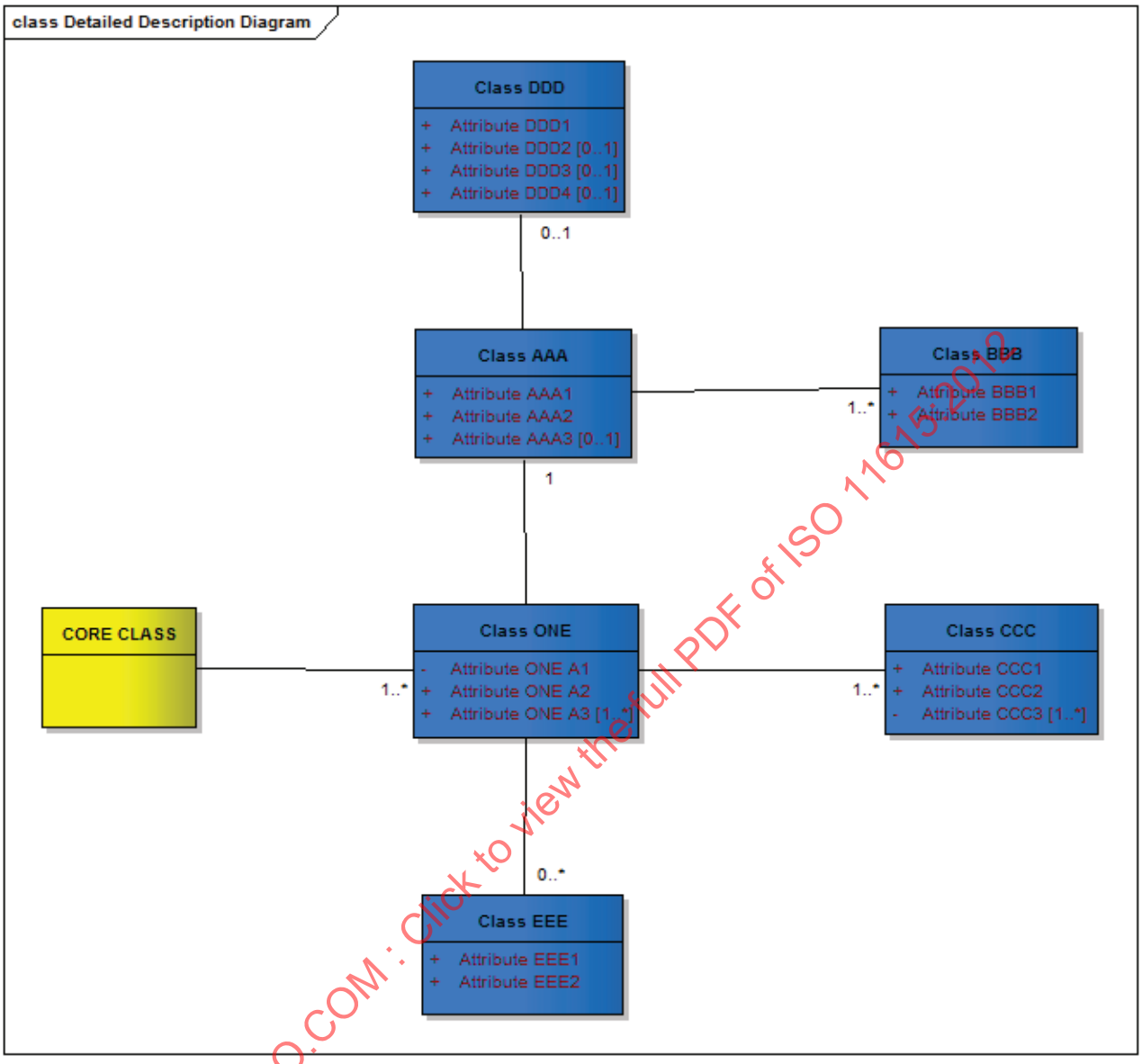

Figure 4 — Example detailed description diagram

5.4.2 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 (whereas in the BRIDG model, for example, the semantics of a relationship type, such as “has function” or “is performed by” are explicitly described).

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 International Standard 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.

5.4.3 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.

A datatype for the data in each attribute is not specified directly in the model. However, the text description for each attribute indicates the form in which data should be specified.

In Annex F there is some guidance as to how these various forms or patterns for data described in text for each attribute could be implemented using the healthcare datatypes of ISO 21090.

5.4.4 Generalized classes and patterns

There is one use of a generalized 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 generalization/specialization relationships, but by using a specialized class name.

The detailed representation of an “Organization”, its “Contact Persons” and its “Other Locations” is described once in 7.4. Then, wherever information of type “Organization” with its “Contact Person(s)” and/or “Other Locations” is required, as for example in the class “Manufacturer/Establishment (Organization)” or the “Medicines Regulatory Agency (Organization)” class, the “(Organization)” in the class name indicates that the information shall be described as for the generalized “Organization” class.

There is also one generalized 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.

5.4.5 Translation and language

With the specific exception of Medicinal Product name information (see 7.2.2.5), there is no description of the translation of information described in this International Standard. It is acknowledged that, for global implementation, translation of the information will be required and will occur at implementation.

6 Identifying characteristics for authorized Medicinal Products

6.1 Primary identifiers

6.1.1 General considerations

To satisfy the requirements as described in 4.1, the following four identifiers shall be specified:

a) MPID – Medicinal Product Identifier;

b) PCID – Medicinal Product Package Identifier;

c) BAID_1 – Medicinal Product Batch Identifier, allocated to a specific batch of a Medicinal Product, which appears on the outer packaging of the Medicinal Product;

d) BAID_2 – Medicinal Product Batch Identifier, allocated to a specific batch of a Medicinal Product, which appears on the immediate packaging, where this is not the outer packaging.

In addition, there is an association with Pharmaceutical Product Identifiers (PhPIDs) as defined in ISO 11616.

Further details as regards the use of these identifiers can be provided in implementation guidance.

6.2 Medicinal Product Identifier (MPID)

6.2.1 General considerations

For each authorized Medicinal Product, a unique MPID shall be assigned. The MPID shall be allocated supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction. 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 Authorization Holder (Organization Identifier) code segment;

c) Medicinal Product code segment (Unique Medicinal Product Identifier).

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

6.2.2 MPID code segments

The MPID code segments shall be generated as described below:

6.2.2.1 Country code segment

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

6.2.2.2 Marketing Authorization Holder (Organization Identifier) code segment

This code segment shall reflect the unique identifier of the Marketing Authorization Holder (organization) of the Medicinal Product. An international coding system for unique Marketing Authorization Holders (organizations) identifiers can be applied, if available.

6.2.2.3 Medicinal Product code segment

This code segment shall reflect a unique Medicinal Product Identifier assigned to the Medicinal Product. It utilizes the following attributes to define a single Medicinal Product to which a code is assigned:

a) marketing authorization in relation to the jurisdiction;

b) legal status of supply (e.g. prescription only or “over the counter” sale);

c) Medicinal Product name;

d) the pharmaceutical dose form;

e) the ingredient substance(s) and their 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 authorized for the Medicinal Product.

A separate unique MPID shall be assigned whenever any of the above items of information for a Medicinal Product are different as applicable to a Medicines Regulatory Agency’s process.

EXAMPLE For a seasonal influenza vaccine, the strains can change with the season. This implies that a new MPID shall be assigned for this vaccine each time the strains are changed.

This process may result in changes to the MPID for a Medicinal Product when existing regulatory identifiers (e.g. marketing authorization number) would not change. This International Standard does not require such existing regulatory identifiers to be changed in step with the MPID. Each jurisdiction can continue with its existing working practices for existing identifiers.

6.3 Packaged Medicinal Product Identifier (PCID)

6.3.1 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 authorization/approval number at package level as ascribed by a Medicines Regulatory Agency in a jurisdiction.

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.

6.3.2 Package Description 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) — type, material(s) and alternate material(s);

— manufactured item(s) — 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 medicines regulatory process.

This process may result in changes to a PCID when existing regulatory identifiers, e.g. marketing authorization number, would not change. This International Standard does not require such existing regulatory identifiers to be changed in step with the PCID. Each jurisdiction may continue with its existing working practices for existing identifiers.

6.4 Medicinal Product Batch Identifier (BAID_1)

For each authorized Medicinal Product, a BAID_1 shall be assigned. The BAID_1 shall use the batch number and the expiration date together with the PCID. The BAID_1 shall use the batch number as it appears on the outer packaging of a specific batch of the Medicinal Product.

The BAID_1 shall use a common attribute set related to a packaged Medicinal Product, which when all of them have a value, define a specific BAID_1 concept:

a) PCID;

b) batch number (outer packaging);

c) expiration date (month/year) using the ISO 8601 date format.

6.5 Medicinal Product Batch Identifier (BAID_2)

For each authorized Medicinal Product, a BAID_2 can be assigned. The BAID_2 shall use the batch number and the expiration date together with the PCID. The BAID_2 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 BAID_2 shall use a common attribute set related to a packaged Medicinal Product, which when all of them have a value, define a specific BAID_2 concept:

a) PCID attribute set;

b) batch number (immediate packaging, when not the outer packaging);

c) expiration date (month/year) using the ISO 8601 date format.

7 Information for an authorized Medicinal Product

7.1 Authorized Medicinal Product — Information overview

7.1.1 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 characterize an authorized Medicinal Product which itself is identified by the MPID.

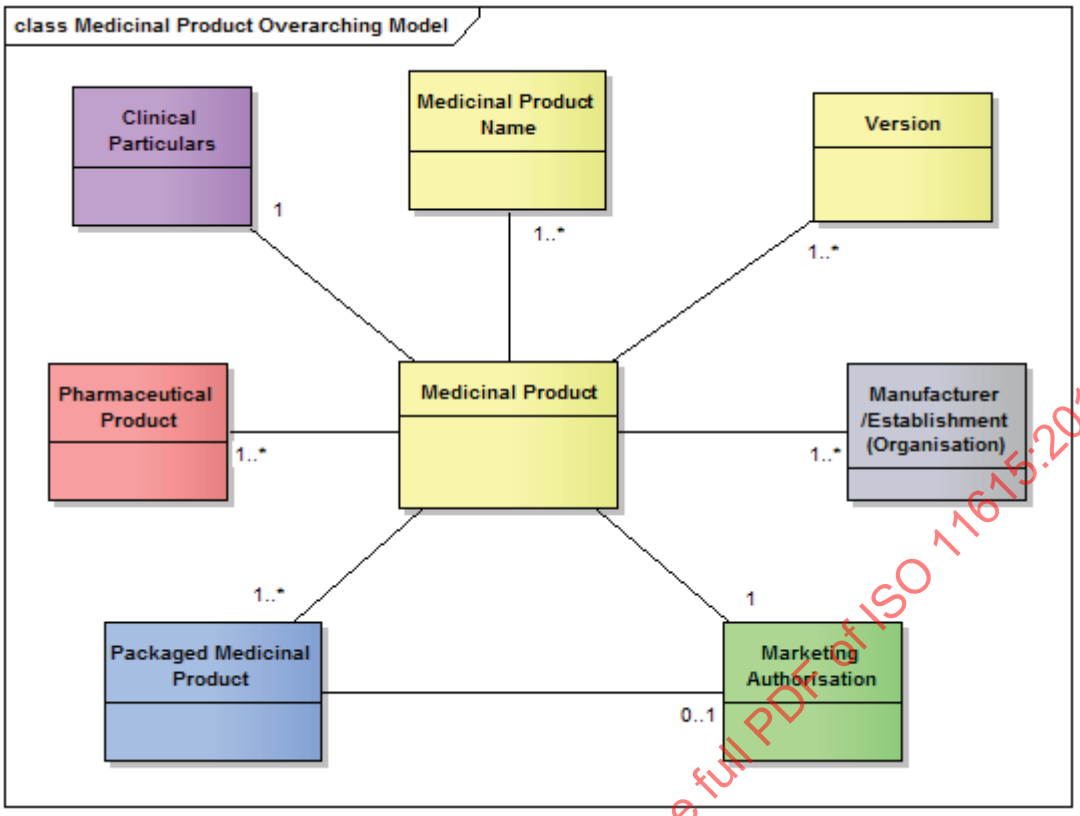

Figure 5 — Medicinal Product overarching model

7.1.2 Medicinal Product

This section specifies the MPID together with the information that uniquely identifies and characterizes a Medicinal Product as authorized by a Medicines Regulatory Agency in a jurisdiction.

7.1.3 Medicinal Product Name

This section specifies the name of the Medicinal Product as authorized by a Medicines Regulatory Agency in a jurisdiction, together with an analysis of the name into various parts.

7.1.4 Version

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

7.1.5 Marketing Authorization

This section specifies the information about the marketing authorization as issued by a Medicines Regulatory Agency, which grants permission to a pharmaceutical company to place a Medicinal Product on the market in a jurisdiction.

7.1.6 Manufacturer/Establishment

This section specifies the characteristics of the manufacturing process and other associated operations and their authorizations 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 jurisdiction.

7.1.7 Packaged Medicinal Product

This section 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).

7.1.8 Pharmaceutical Product

This section 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).

7.1.9 Clinical Particulars

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

7.2 Medicinal Product

7.2.1 General

This section specifies the MPID together with the information that uniquely identifies and characterizes a Medicinal Product as authorized by a Medicines Regulatory Agency in a jurisdiction.

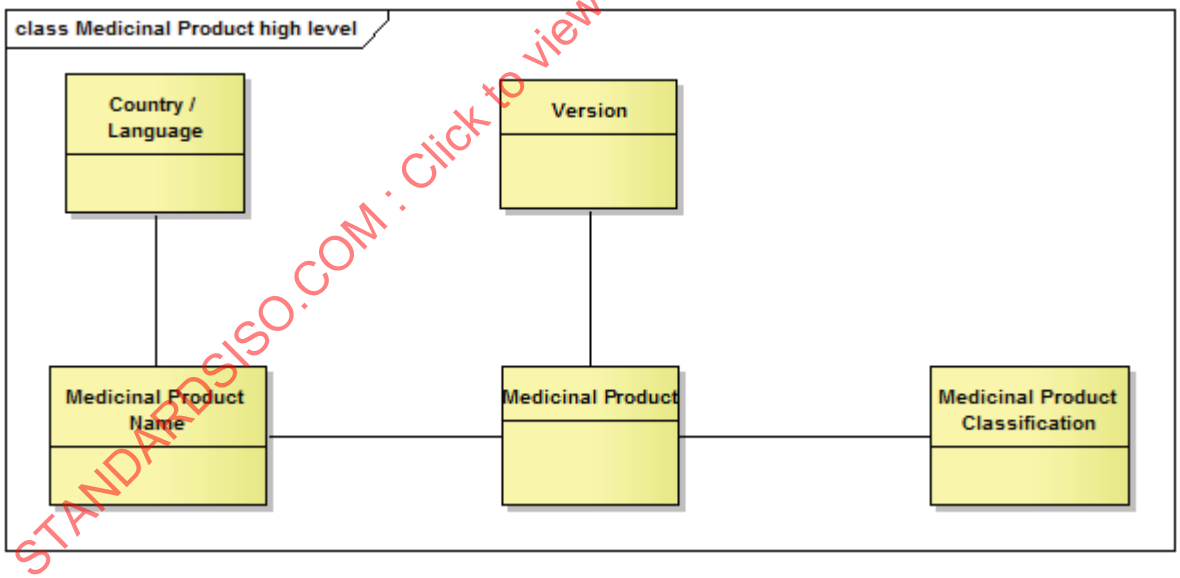

Figure 6 — Medicinal Product section high-level diagram

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.

7.2.2 Detailed description of Medicinal Product Information

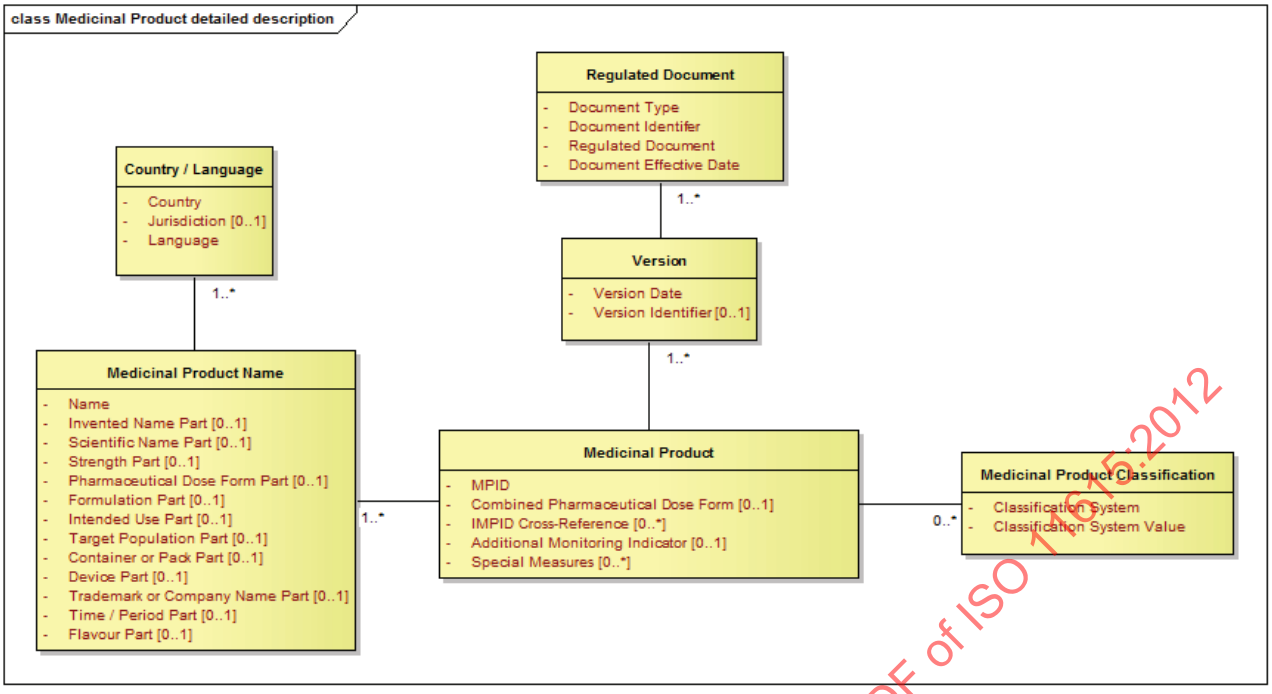

Figure 7 — Medicinal Product section detailed description diagram

7.2.2.1 Medicinal Product

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

7.2.2.1.1 MPID

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

7.2.2.1.2 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.

EXAMPLE Powder and solvent for solution for injection. The Medicinal Product contains two manufactured items: a powder for solution for injection and a solvent for solution for injection. The pharmaceutical product that is prepared from the two manufactured items is a solution for injection; the authorized pharmaceutical dose form for the Medicinal Product is “powder and solvent for solution for injection”.

7.2.2.1.3 IMPID Cross-Reference

There can be a cross-reference between the MPID of the authorized Medicinal Product and the related IMPID(s) assigned during the development phase and clinical investigation of that Medicinal Product. The related IMPIDs can be specified as text.

7.2.2.1.4 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.

EXAMPLE “Black triangle” monitoring.

7.2.2.1.5 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.

EXAMPLE Requirement to conduct post-authorization studies.

7.2.2.2 Version

The characteristics of an authorized Medicinal Product as defined in this International Standard shall be versioned. This refers to the fact that at a given version date 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 the “Identifying Characteristics for Authorized Medicinal Products” section but the difference(s) are required to be recorded and tracked against the MPID.

7.2.2.2.1 Version Date

The date of the authorization or the latest update of the regulated product information (e.g. elements related to the Summary of Product Characteristics or Product Labelling, which serve as the reference for the unique Identification of Medicinal Products and their characteristics) shall be specified. A complete point in time date consisting of day, month and year shall be specified using the ISO 8601 date format.

7.2.2.2.2 Version Identifier

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

7.2.2.3 Regulated Document

The document(s) as approved by a Medicines Regulatory Agency in a jurisdiction that supports a version increment of an MPID shall be specified.

NOTE A jurisdiction may further refine the requirements in relation to the regulated document at implementation such that this information is to be specified only if required.

7.2.2.3.1 Document 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.

EXAMPLES Summary of Product Characteristics (SmPC), package leaflet, regulatory decision document, approval letter, content of labelling, package insert.

7.2.2.3.2 Document Identifier

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

7.2.2.3.3 Regulated Document

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

7.2.2.3.4 Document Effective Date

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

7.2.2.4 Product Classification

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

7.2.2.4.1 Classification System

The classification system itself shall be specified using an appropriate identification system.

7.2.2.4.2 Classification 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.

EXAMPLES Classification System: WHO Anatomical Therapeutic Chemical (ATC) Classification System

Classification Value: A10BA02 – Metformin

Classification System: VHA National Drug File Reference Terminology (NDF-RT)

Classification Value: N0000000072 - 14-alpha Demethylase Inhibitors

7.2.2.5 Medicinal Product Name

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 jurisdictions. As a general principle, a marketing authorization is granted to a single Marketing Authorization Holder who is responsible for placing the Medicinal Product on the market. The marketing authorization 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 authorized, an analysis of the name parts shall be provided in a structured format. Depending on the jurisdiction, 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 above, this is the one part of this International Standard where translation of information is explicitly described and modelled, showing the language of the information (and the jurisdictions where it is appropriate).

7.2.2.5.1 Name

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

7.2.2.5.2 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.

EXAMPLE For the Medicinal Product Name “Drug XYZ® Precisehaler 200 mg for adults” the invented (trade) name part is “Drug XYZ”.

7.2.2.5.3 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.

EXAMPLE For the Medicinal Product Name “Irbesartan/Hydrochlorothiazide Pharma KK” the common (generic) name part is “Irbesartan/Hydrochlorothiazide”.

7.2.2.5.4 Strength part

The strength, if reflected in the Medicinal Product Name, shall be specified as text, where applicable. This strength name part can differ from the concept of “Strength” as described in 7.7. The use of decimal points shall be accommodated, if required.

EXAMPLE 1 For the Medicinal Product Name “Drug K Forte Tablets”, the strength name part is “Forte”.

EXAMPLE 2 For the Medicinal Product Name “SoothingMed 2,5 % Cream”, the strength name part is “2,5 %”.

7.2.2.5.5 Pharmaceutical Dose Form part

The pharmaceutical dose form, if reflected in the Medicinal Product Name, shall 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 7.8.2.1.1 and 7.6.2.10.2 respectively.

EXAMPLE For the Medicinal Product Name “Novo-Drug X EASY-TO-SWALLOW CAPLETS”, the pharmaceutical dose form name part is “EASY-TO-SWALLOW CAPLETS”.

7.2.2.5.6 Formulation part

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

EXAMPLE For the Medicinal Product Name “SpecialMed Sugar Free Cough Syrup”, the formulation name part is “Sugar Free”.

7.2.2.5.7 Intended Use part

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

EXAMPLE For the Medicinal Product Name “Drug-BI Caplets - Heartburn Relief”, the intended use part is “Heartburn Relief”.

7.2.2.5.8 Target Population part

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

EXAMPLE For the Medicinal Product Name “Broncho-Drug 3,5 mg-capsules for children”, the target population part is “children”.

7.2.2.5.9 Container or Pack part

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

EXAMPLE 1 For the Medicinal Product Name “LXA 10 mg/ml Solution for injection Subcutaneous use Vial (glass) - 4 ml - 1 Vial”, the container or pack part is “Vial (glass)”.

EXAMPLE 2 For the Medicinal Product Name “HeartDrug Titration Pack”, the container or pack part is “titration pack”.

EXAMPLE 3 For the Medicinal Product Name “BaccVac Multidose Vial”, then container or pack part is “multidose vial”.

7.2.2.5.10 Device part

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

EXAMPLE For the Medicinal Product Name “Drug XYZ® Precisehaler 200 mg for adults”, the device part is “Precisehaler”.

7.2.2.5.11 Trademark or Company Name part

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

EXAMPLE For the Medicinal Product Name “Clopidrogel Pharma®”, the trademark or company name part is “Pharma®”.

7.2.2.5.12 Time/Period part

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

EXAMPLE For an influenza vaccine with the Medicinal Product Name “Drug-FLU season 2008/2009”, the time/period part is “2008/2009”.

7.2.2.5.13 Flavour part

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

EXAMPLE For the Medicinal Product Name “CoughCure Linctus Orange Flavour”, the flavour part is “Orange”.

7.2.2.6 Country/Language

The country and optionally the jurisdiction where the Medicinal Product Name of a Medicinal Product is authorized shall be specified in the official language as applicable.

7.2.2.6.1 Country

The country where the Medicinal Product Name is applicable shall be described using ISO 3166-1 alpha-2 or alpha-3 codes.

7.2.2.6.2 Jurisdiction

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

EXAMPLE For the country of Canada, the jurisdiction of Quebec province may be specified.

7.2.2.6.3 Language

The language of the Medicinal Product Name as applicable in the specified country and jurisdiction if appropriate shall be specified using the ISO 639-2 language code.

7.3 Marketing Authorization

7.3.1 General

This section specifies the marketing authorization information for a Medicinal Product.

The marketing authorization is issued by the appropriate Medicines Regulatory Agency in a jurisdiction. In line with the laws and regulations applicable in a jurisdiction, an authorization 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 authorized Medicinal Products shall be applied as outlined in this section. Where no formal Marketing Authorization Holder is established, the distributor shall be specified.

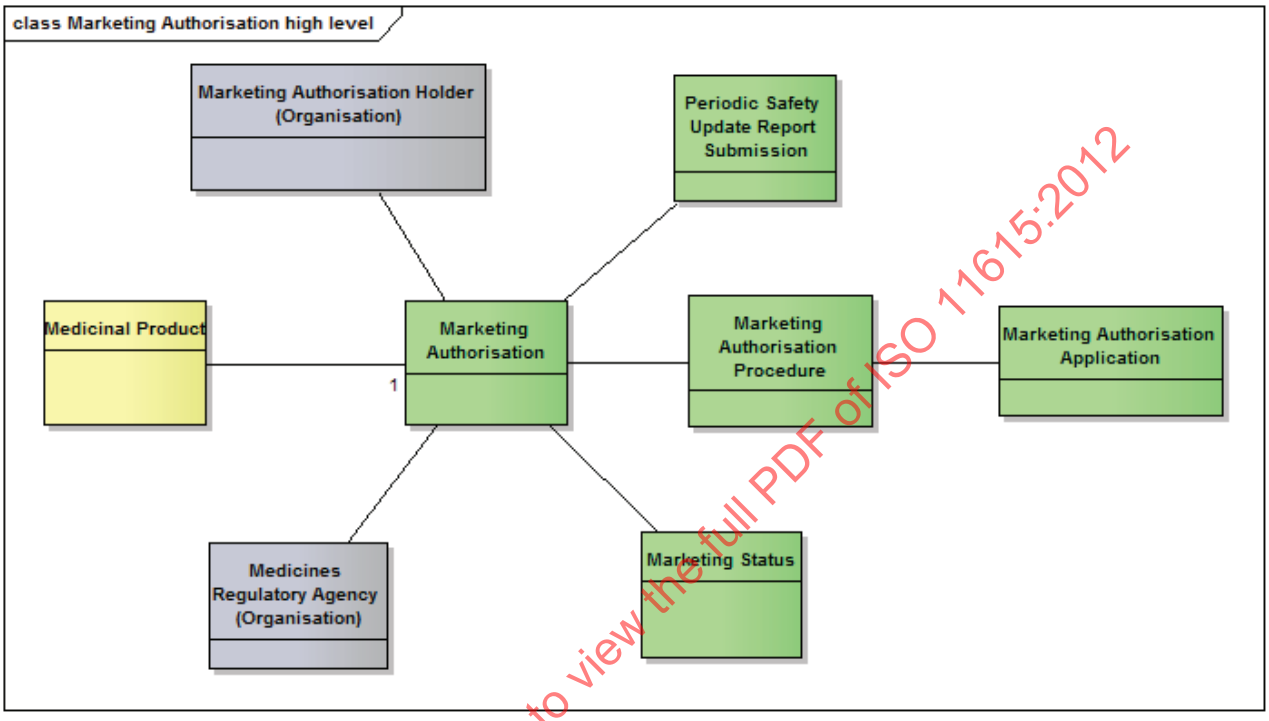

Figure 8 — Marketing Authorization section high-level diagram

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

This marketing authorization is issued by a Medicines Regulatory Agency to an organization referred to as Marketing Authorization Holder. Within the Marketing Authorization 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 authorization, renewal, variation to and revocation of a marketing authorization is managed on the basis of a marketing authorization procedure, which itself is supported by a marketing authorization application.

During the lifetime of a Medicinal Product, its marketing authorization is likely to have had a variety of changes. Therefore, the status of a marketing authorization 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).

The Periodic Safety Update Report Submission describes information regarding the timing of submissions for Periodic Safety Update Reports or Periodic Benefit-Risk Evaluation Reports for the Medicinal Product.

NOTE 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 authorization number.

7.3.2 Detailed description of marketing authorization information

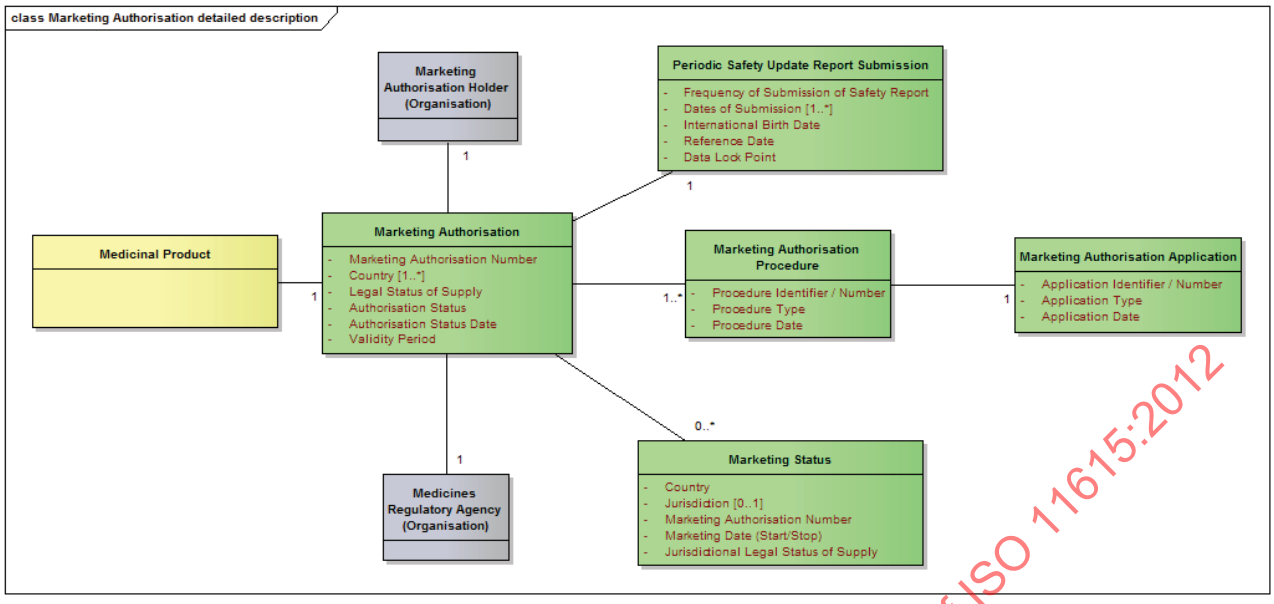

Figure 9 — Marketing Authorization section detailed description diagram

Each Medicinal Product shall have the relevant marketing authorization information specified.

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

7.3.2.1 Marketing authorization

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

7.3.2.1.1 Marketing authorization 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 authorization by legislation, the licensing number as appearing on the package, the container or the package insert shall be specified in the absence of a formal marketing authorization number (e.g. for “grandfather” drugs in the US.)

7.3.2.1.2 Country

The country in which the marketing authorization has been granted shall be provided in accordance with the ISO 3166-1 alpha-2 or alpha-3 codes.

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

7.3.2.1.3 Legal status of supply

The legal status of supply of the Medicinal Product as classified by the Regulatory Medicines 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.

EXAMPLE 1 Medicinal product subject to medical prescription.

EXAMPLE 2 Medicinal product not subject to medical prescription.

7.3.2.1.4 Authorization status

The status of the marketing authorization changes throughout the lifecycle of a Medicinal Product depending on the regulatory process applicable in a jurisdiction. This shall be specified using an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

EXAMPLES Active/valid, expired, renewed, not renewed, withdrawn.

7.3.2.1.5 Authorization status date

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

EXAMPLE The marketing authorization expired on 2011-01-01.

7.3.2.1.6 Validity period

The time period, described in terms of a beginning and end date of the marketing authorization for the relevant status shall be specified. Complete interval of time dates consisting of day, month and year shall be specified using the ISO 8601 date format.

EXAMPLE The marketing authorization is valid from 2011-01-01 to 2015-01-01.

7.3.2.2 Marketing Authorization Holder

Details in relation to the Marketing Authorization Holder to which a marketing authorization in a jurisdiction was granted shall be specified using an Organization class as described in 7.4.

For Medicinal Products which allow for distribution without a marketing authorization under 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 Authorization Holder.

7.3.2.3 Medicines Regulatory Agency

Details in relation to the Medicines Regulatory Agency that granted the marketing authorization for a Medicinal Product shall be specified using an Organization class as described in 7.4.

7.3.2.4 Marketing authorization procedure

The regulatory procedure applied to grant or amend a marketing authorization for a Medicinal Product shall be specified.

NOTE A jurisdiction may further refine the requirements in relation to the marketing authorization procedure (and the associated marketing authorization application) at implementation such that this information is to be specified only if required.

7.3.2.4.1 Procedure identifier/number

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

7.3.2.4.2 Procedure type

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

EXAMPLES Centralised, decentralised, national, mutual recognition.

7.3.2.4.3 Procedure date

The dates when the procedure commenced and was completed shall be described. Complete interval of time dates consisting of day, month and year shall be specified using the ISO 8601 date format.

7.3.2.5 Marketing authorization application

A marketing authorization will be supported by an application, as will any change of an existing marketing authorization (e.g. to renew, vary or withdraw).

Details of the marketing authorization application shall be described using this class.

7.3.2.5.1 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.

7.3.2.5.2 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.

EXAMPLES New, renewal, variation, line extension.

7.3.2.5.3 Application date

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

7.3.2.6 Marketing status

The marketing status refers to the date when the Medicinal Product is actually put on the market or the date as of which it is no longer available. It also indicates the legal status of supply (e.g. prescription only or non-prescription).

NOTE There may be circumstances where additional information (legal status of supply or a marketing authorization number) is specific to local provisions within a jurisdiction (e.g. states, provinces or territories). Marketing status allows these circumstances to be indicated as well, where this is specifically applicable.

7.3.2.6.1 Country

The country in which the marketing authorization has been granted shall be specified. It should be specified using the ISO 3166-1 alpha-2 or alpha-3 codes.

NOTE EU can be used for the name European Union. This is not an official ISO 3166-1 country code. The European Union is not a country but rather an organization with Member States, which are by themselves countries. As such, EU is not eligible to be formally included in ISO 3166-1. Recognizing, however, that many users of ISO 3166-1 have a practical need to encode that name EU, the ISO 3166 Maintenance Agency reserved the two-letter combination EU for the purpose of identifying the European Union within the framework of ISO 3166-1.

7.3.2.6.2 Jurisdiction

Where a Medicines Regulatory Agency has granted a marketing authorization 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.

EXAMPLE The legal status of supply of a Medicinal Product can differ in the various provinces in Canada. While the country of marketing authorization is Canada, the names of the provinces can be specified (as jurisdictions) and the legal status of supply applicable in each province also specified.

7.3.2.6.3 Jurisdictional marketing authorization number

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

7.3.2.6.4 Marketing date (start/stop)

The date when the Medicinal Product is placed on the market by the Marketing Authorization Holder (or where applicable, the manufacturer/distributor) in a country and/or jurisdiction shall be provided, as shall the date when the Medicinal Product is "no longer available on that market". Complete point in time dates 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. "No longer available on the market" can refer to the fact that the Marketing Authorization Holder has taken a decision to no longer market the Medicinal Product or that the marketing authorization is no longer valid.

7.3.2.6.5 Legal status of supply

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

EXAMPLES POM – Prescription only medicine,

P – Pharmacy only medicine,

GSL – General sales list medicine.

7.3.2.7 Periodic safety update report submission (PSUR)

Periodic safety update reports and Periodic Benefit-Risk Evaluation Reports refer to a summary and evaluation of the benefit risk profile of the Medicinal Product by the Marketing Authorization Holder at defined time intervals, which can be specified in the marketing authorization and/or by legislation.

NOTE A jurisdiction may further refine the requirements in relation to the periodic safety update report submission information at implementation such that this information is to be specified only if required.

7.3.2.7.1 Frequency of submission of PSUR

The frequency of the submission of a PSUR or PBRER can be defined by legislation or as part of a marketing authorization in a jurisdiction. The frequency shall be described using a numerical value for the repeating interval 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.

EXAMPLE PSUR submission frequency is defined as every six months during the first two years following the initial placing on the market and once a year for the following two years.

7.3.2.7.2 Dates of submission

The dates of submission of PSURs or PBRERs in line with the defined frequency of submission of PSURs or PBRERs shall be presented. Complete point in time dates consisting of day, month and year shall be specified using the ISO 8601 date format.

7.3.2.7.3 International birth date

The international birth date (IBD) refers to the date of the first marketing authorization for the product granted to any company in any country in the world. A complete point in time date consisting of day, month and year shall be specified using the ISO 8601 date format.

7.3.2.7.4 Reference date

Where Medicinal Products that are subject to different marketing authorizations contain the same active substance or the same combination of active substances, the frequency and dates of submission of the PSURs or PBRERs may be amended and harmonized by a Medicines Regulatory Agency in a jurisdiction e.g. to enable a single assessment to be made in the context of PSUR or PBRER work-sharing procedures and to set a reference date from which the dates of submission are calculated. A complete point in time date consisting of day, month and year shall be specified using the ISO 8601 date format.

7.3.2.7.5 Data lock point

The data lock point is the date designated as the cut-off for data to be included in a PSUR or PBRER. A complete point in time date consisting of day, month and year shall be specified using the ISO 8601 date format.

7.4 Organization

7.4.1 General

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

7.4.2 Detailed description of organization information

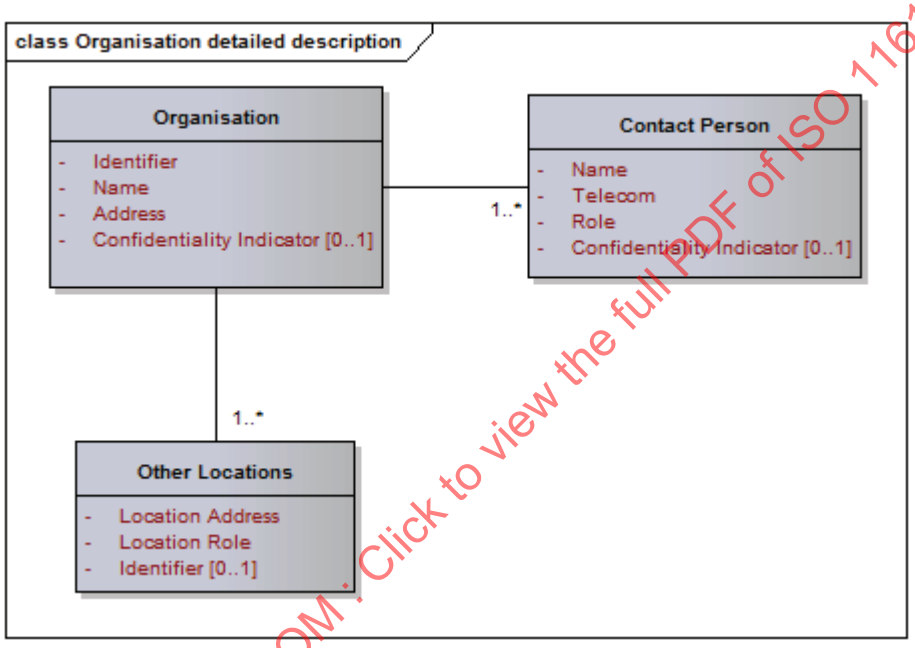

Figure 10 — Organization detailed description diagram

7.4.2.1 Organization

7.4.2.1.1 Identifier

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

7.4.2.1.2 Name

The name of the organization shall be provided in text.

7.4.2.1.3 Address

The address of the organization shall be provided using a standardised structured address format.

7.4.2.1.4 Confidentiality indicator

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

EXAMPLES Confidential, no restriction.

7.4.2.2 Contact person

This class is used to specify a contact person from within the organization and the role of that person.

NOTE 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.

7.4.2.2.1 Name

The name of the contact person shall be provided using a standardized structured person name description format.

7.4.2.2.2 Telecom

The telecom information (telephone, e-mail, etc.) of the contact person shall be provided using a standardized structured telecoms description format.

7.4.2.2.3 Role

The role of the contact person within the organization 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.

EXAMPLE 1 Qualified Person Responsible for Pharmacovigilance (organization context: Marketing Authorization Holder).

EXAMPLE 2 Person responsible for batch release (organization context: manufacturer).

EXAMPLE 3 Legal representative of sponsor (organization context: sponsor).

7.4.2.2.4 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.

EXAMPLES Confidential, no restriction.

7.4.2.3 Other locations

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

NOTE 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.

7.4.2.3.1 Location address

The address of the location of the organization shall be provided using a standardized structured address format.

7.4.2.3.2 Location role

The role of the location within the organization 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.

EXAMPLE Location of the pharmacovigilance system master file (organization context: Marketing Authorization Holder).

7.4.2.3.3 Identifier

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

7.5 Manufacturer/Establishment

7.5.1 General

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

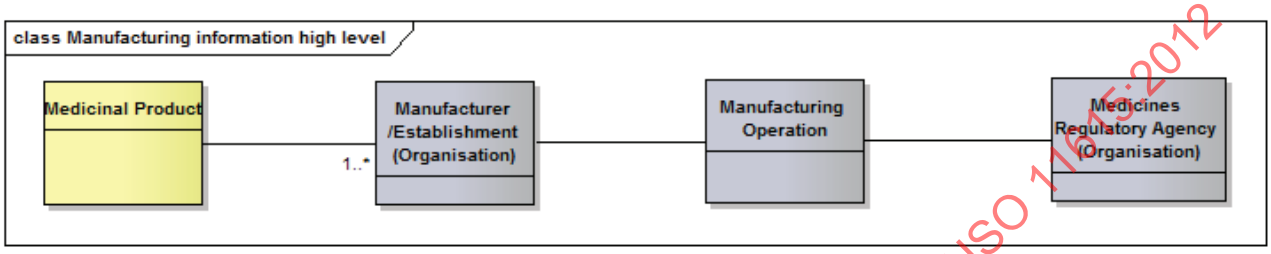

Figure 11 — Manufacturer/Establishment section high-level diagram

The Medicinal Product is associated with organization information for one or more manufacturers or establishments which undertake various manufacturing operations in order to produce a Medicinal Product. These are overseen by an appropriate Medicines Regulatory Agency.

7.5.2 Detailed description of Manufacturer/Establishment information

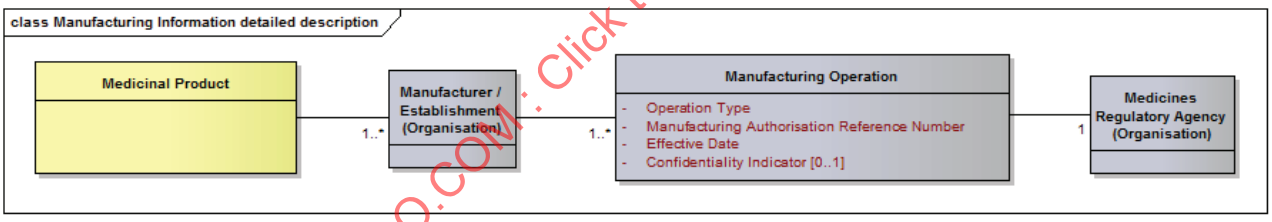

Figure 12 — Manufacturer/Establishment section detailed description diagram

A Medicinal Product shall be associated with one or more manufacturers/establishments.

NOTE 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.

7.5.2.1 Manufacturer/Establishment (Organization)

The information related to the manufacturer/establishment for the organization undertaking the particular manufacturing operation shall be described using the pattern for organization described in 7.4.

EXAMPLE 1 For the operation of “batch release”, the manufacturer is “Company ABC”.

EXAMPLE 2 For the operation of “re-labelling”, the establishment is “Company DEF”.

7.5.2.2 Manufacturing operation

The manufacturing operation being undertaken by the particular manufacturer/establishment organization shall be specified.

7.5.2.2.1 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.

EXAMPLES Re-labelling, re-packaging, batch release.

7.5.2.2.2 Manufacturing authorization reference number

The reference number of the authorization for manufacturing or equivalent shall be specified in text.

7.5.2.2.3 Effective date

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

7.5.2.2.4 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.

EXAMPLES Confidential, no restriction.

7.5.2.3 Medicines Regulatory Agency (Organization)

The Medicines Regulatory Agency which oversees a specific manufacturing operation shall be described using the pattern for organization described in 7.4.

7.6 Packaged Medicinal Product, including Manufactured Item and Device

7.6.1 General

This section 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 the one or more items contained within, and then to the actual description of the individual item(s).

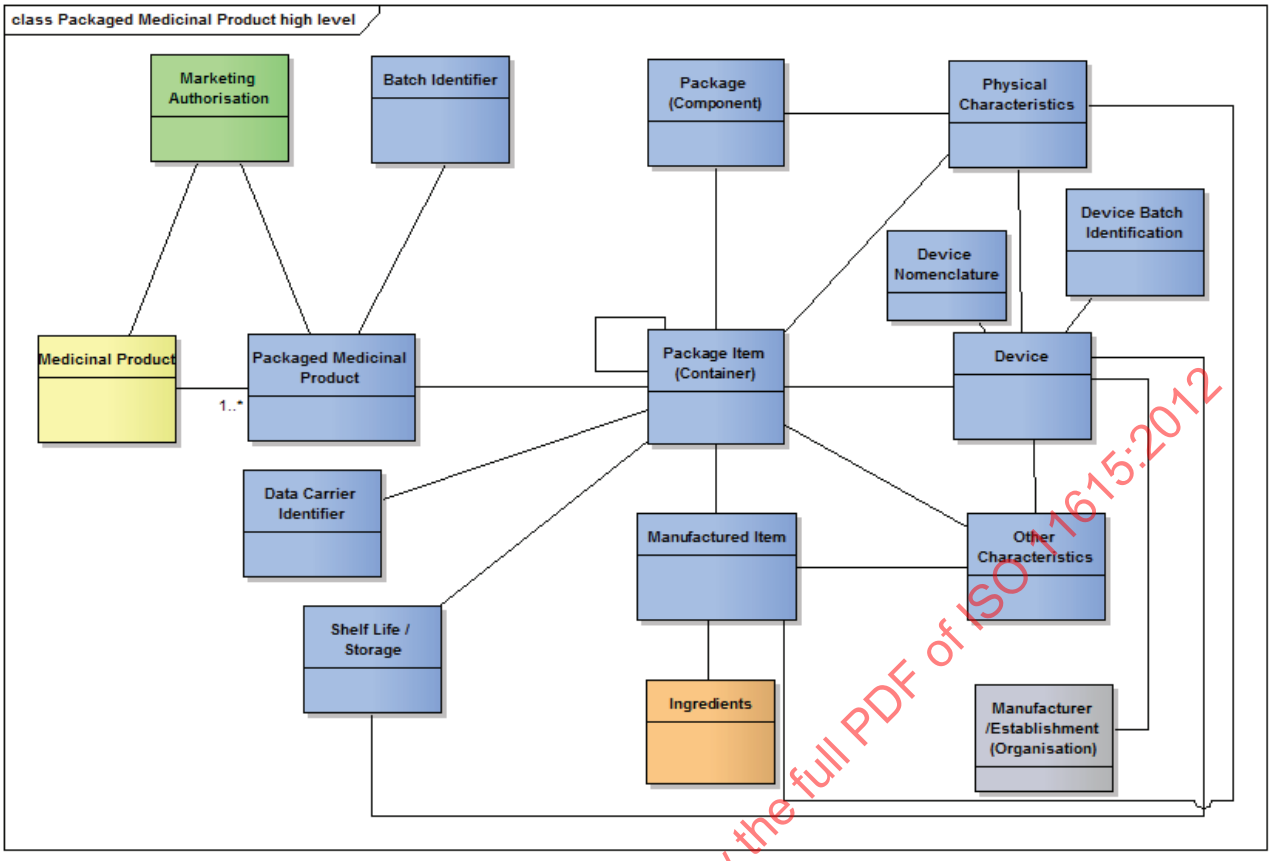

Figure 13 — Packaged Medicinal Product section high-level diagram

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 recursing 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 7.7.

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 the device may be described using the Manufacturer/Establishment (Organization) structures described in 7.5.

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 Item Part 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 Medicinal Product, the Device and the Manufactured Item may have a set of Other Characteristics associated with them.

Batch identifiers, i.e. the BAID_1 and BAID_2, can be presented in relation to the Packaged Medicinal Product as appropriate.

There are instances where Marketing Authorization 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 Authorization information can be described directly for the Packaged Medicinal Product, using the structures described in 7.3.

7.6.2 Detailed description of Packaged Medicinal Product Information

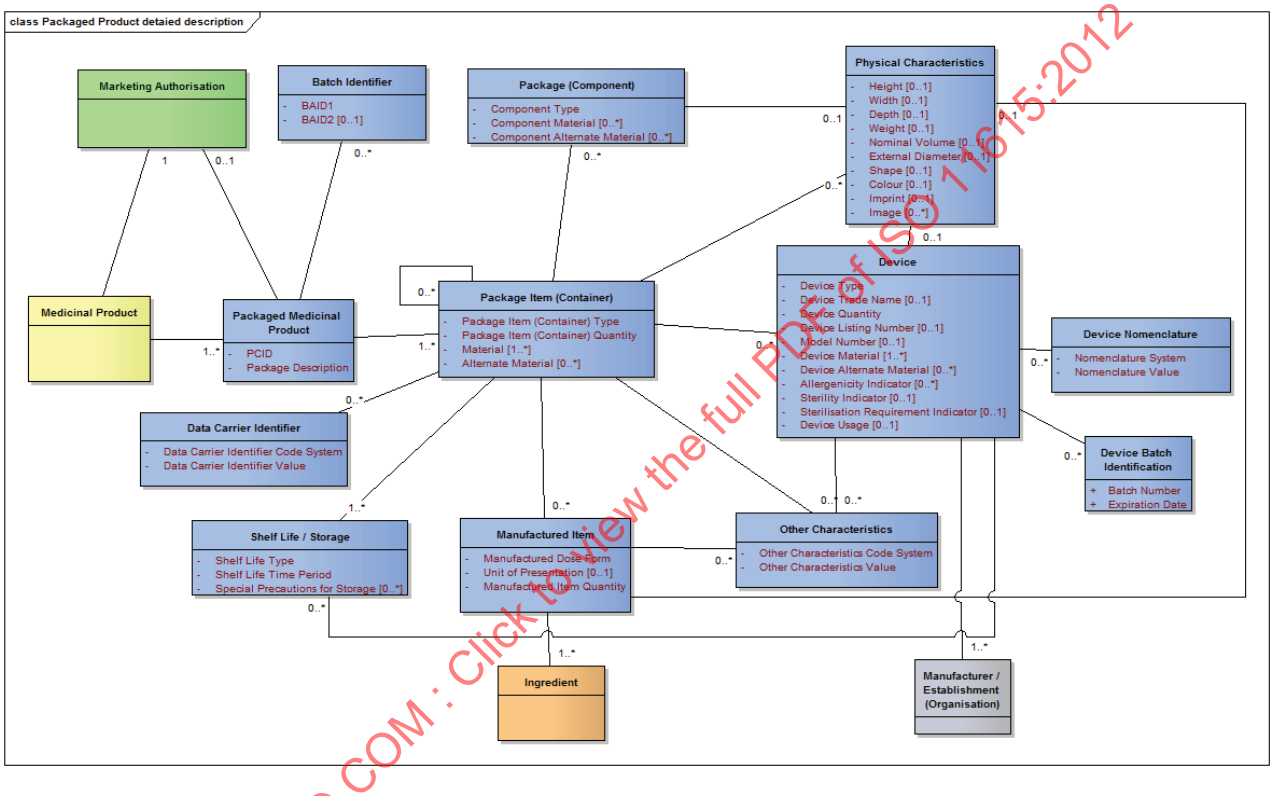

Figure 14 — Packaged Medicinal Product section detailed description diagram

7.6.2.1 Packaged Medicinal Product

7.6.2.1.1 PCID

This is the unique identifier for the packaged Medicinal Product, constructed as described in 6.3 above.

7.6.2.1.2 Package description

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

7.6.2.2 Package Item (Container)

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.

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

EXAMPLE 2 A Medicinal Product presented as a packaged Medicinal Product with an outer package with inner packaging (a box containing two blister sleeves containing 20 capsules or a carton containing 4 vials of solution for injection) will have two recursed package items: the parent package item to describe the box or carton and the child package item to describe the blister sleeve or the vial (the latter then related to the manufactured item).

EXAMPLE 3 A Medicinal Product "kit" presented as a packaged Medicinal Product with an outer package containing more than one type of content, for example, a box containing a tube (of cream) and a blister sleeve containing a tablet, will have a recursed parent package item to describe the box and two child package items to describe the tube and the blister (each then related to an manufactured item).

7.6.2.2.1 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 its resulting terminology. A term and a term identifier shall be specified.

EXAMPLES Box, vial, blister sleeve, pre-filled syringe.

7.6.2.2.2 Package Item (Container) quantity

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

NOTE Because the Package Item class recurses to describe containers within containers, the first (outermost) container will always have a quantity of "1".

7.6.2.2.3 Material

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

7.6.2.2.4 Alternate material

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

NOTE 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).

7.6.2.3 Data carrier identifier

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

EXAMPLE 1 Data carrier identifier for one tablet in the blister cell (primary packaging).

EXAMPLE 2 Data carrier identifier for one box containing two blister sleeves (secondary packaging).

EXAMPLE 3 Data carrier identifier for a multi-pack of four boxes (tertiary packaging).

7.6.2.3.1 Data carrier identifier code system

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

7.6.2.3.2 Data carrier identifier value

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

EXAMPLE Data carrier identification code system: GTIN.

Data carrier identification value: 123459876511.

The **shelf-life and storage** information for a package item (container) can be described using the Shelf Life/Storage class (see 7.6.2.6 below).

The **physical characteristics** (height, width, depth, weight, shape, etc.) of the package item (container) can be described using the Physical Characteristics class (see 7.6.2.11). One or more images of the package item (container) can be also included as applicable.

Other characteristics of the package item (container) can be described using the Other Characteristics class (see 7.6.2.12).

7.6.2.4 Batch Identifier

7.6.2.4.1 BAID_1

The BAID_1 as described in 6.4, which appears on the outer packaging of a specific batch of the Medicinal Product, can 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.

7.6.2.4.2 BAID_2

The BAID_2 as described in 6.5, which appears on the immediate packaging, where this is not the outer packaging, can be specified.

7.6.2.5 Package (Component)

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.

7.6.2.5.1 Component type

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

EXAMPLES Child-resistant cap, vial, bung.

7.6.2.5.2 Component material

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

7.6.2.5.3 Component alternate material

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

NOTE 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).

The **physical characteristics** (height, width, depth, weight, shape, etc.) of the package (component) can be described, as documented in 7.6.2.11. One or more images of the package (component) can be included if required.

7.6.2.6 Shelf life/storage

The shelf life and storage information can be described using the Shelf Life/Storage class.

7.6.2.6.1 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.

EXAMPLES After first opening, unopened, after transformation.

7.6.2.6.2 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.

EXAMPLES Three years unopened, 28 days after opening.

7.6.2.6.3 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.

EXAMPLE Do not store above 25 °C or below 2 °C, store in the original package in order to protect from light.

7.6.2.7 Device

Medicinal products may be authorized with accompanying devices, which may be described using the Device class. Devices may be of several types (see 7.6.2.7.1) 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 Medicinal Product.

7.6.2.7.1 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.

EXAMPLES Administration device (e.g. vaginal applicator, dropper pipette), integrated device (e.g. pre-filled syringe, aerosol inhaler), medical device (e.g. cell scaffold), other device (e.g. sundry swabs).

7.6.2.7.2 Device trade name

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

7.6.2.7.3 Device quantity

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

EXAMPLE 1 A pack containing five sterile pre-injection swabs: Quantity = 5.

EXAMPLE 2 A pack containing a single 5 ml medicine spoon: Quantity = 1.

7.6.2.7.4 Device listing number

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

7.6.2.7.5 Model number

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

7.6.2.7.6 Device material

The material(s) of the device shall be described in accordance with ISO 11238 and its resulting terminology. A term and a term identifier shall be specified for each material.

7.6.2.7.7 Device alternate material

The alternative material(s) of the device can be described in accordance with ISO 11238 and its resulting terminology. A term and a term identifier shall be specified for each material.

NOTE 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 spoon).

7.6.2.7.8 Allergenicity indicator

Where applicable, this can be used to specify whether the device contains allergens and/or materials of concern. The allergens and/or materials of concern shall be described in accordance with ISO 11238 and the resulting terminology.

7.6.2.7.9 Sterility indicator

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

7.6.2.7.10 Sterilization requirement indicator

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

7.6.2.7.11 Device usage

The number of times that the device may be used as described in the regulated product information may be specified. An appropriate controlled terminology shall be applied and the controlled term and the controlled term identifier specified.

EXAMPLES For single use only, multiple use.

7.6.2.8 Device nomenclature

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

7.6.2.8.1 Nomenclature system

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

EXAMPLE 1 Global Medical Device Nomenclature (GMDN) based on ISO 15225.

EXAMPLE 2 Unique Device Identification (UDI) System from the International Medical Device Regulators' Forum (IMDRF).

7.6.2.8.2 Nomenclature value

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

7.6.2.9 Device Batch Identification

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

NOTE 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 BAID_1), but for simplification at a conceptual level, the “many-to-many” relationship that this would give has been omitted.

7.6.2.9.1 Batch number

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

7.6.2.9.2 Expiration date

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

The shelf life and storage information for a device can be described using the **Shelf Life/Storage** class (see 7.6.2.6).

The physical characteristics (height, width, depth, weight, shape, etc.) of the device can be described using the **Physical Characteristics** class (see 7.6.2.11). One or more images of the device can be included, if required.

Other characteristics of the device can be described using the Other Characteristics class (see 7.6.2.12).

The manufacturer of the device can be described using the **Manufacturer/Establishment** set of classes (see 7.5).

7.6.2.10 Manufactured Item

7.6.2.10.1 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 inner 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.

7.6.2.10.2 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 its resulting terminology. A term and a term identifier shall be used.

EXAMPLES Tablet, capsule, oral solution, powder for solution for injection.

NOTE A Medicinal Product may have two package items, one with a manufactured dose form of powder for solution for injection and the other with a manufactured dose form of solvent for solution for injection. These are then to be transformed to a solution for injection before the medicine can be administered to a patient. Solution for injection is the “administrable dose form”, which is an attribute of “pharmaceutical product”.

7.6.2.10.3 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 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.

EXAMPLES Tablet, capsule, pessary.

7.6.2.10.4 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.

The **physical characteristics** (height, width, depth, weight, shape, etc.) of the manufactured item can be described using the Physical Characteristics class (see 7.6.2.11). One or more images of the manufactured item can be included, if required.

Other characteristics of the manufactured item can be described using the Other Characteristics class (see 7.6.2.12).

The **ingredient(s)** of the manufactured item shall be described using the Ingredient class described in 7.7.

7.6.2.11 Physical characteristics

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.

7.6.2.11.1 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.

7.6.2.11.2 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.

7.6.2.11.3 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.

7.6.2.11.4 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.

7.6.2.11.5 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.

7.6.2.11.6 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.

7.6.2.11.7 Shape

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

7.6.2.11.8 Colour

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

7.6.2.11.9 Imprint

Where applicable, the imprint can be specified as text.

7.6.2.11.10 Image

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

7.6.2.12 Other characteristics

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.

7.6.2.12.1 Other Characteristics code system

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

7.6.2.12.2 Other Characteristics value

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

7.7 Ingredient, Substance and Strength

7.7.1 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, ISO 11239 and ISO 11240 and their resulting terminology.

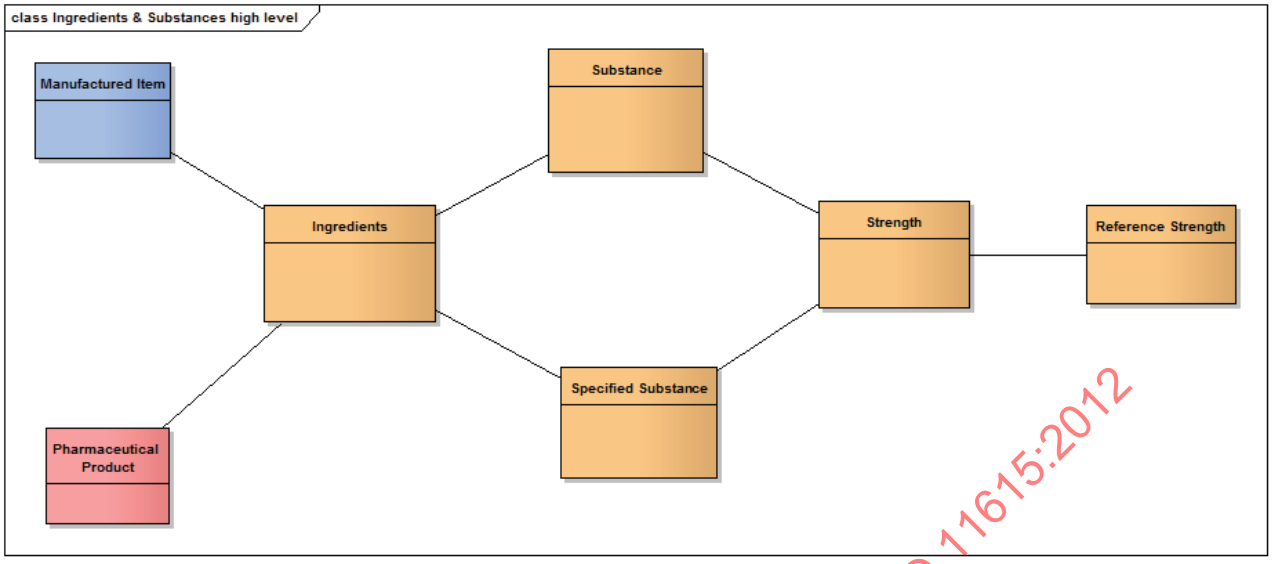

Figure 15 — Ingredients, Substance and Strength section high-level diagram

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.

7.7.2 Detailed description of Ingredients, Substance and Strength information

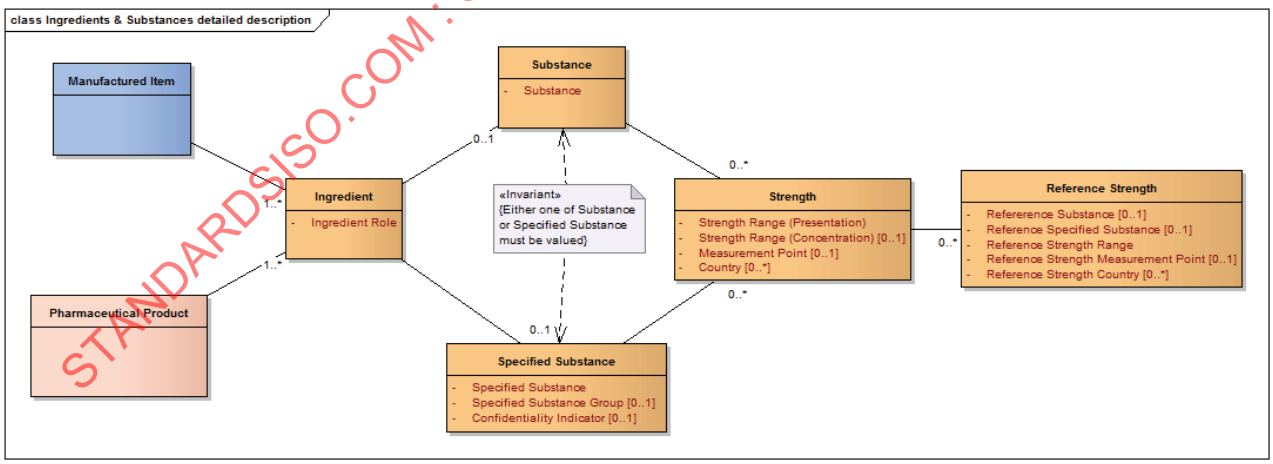

Figure 16 — Ingredients, Substance and Strength section detailed description diagram

7.7.2.1 Ingredient

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

7.7.2.1.1 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.

EXAMPLES Active substance, adjuvant, excipient.

NOTE There is a constraint that each ingredient shall be further described as either a substance or a specified substance.

7.7.2.2 Substance

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

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

EXAMPLES Insulin human, amoxicillin trihydrate.

7.7.2.3 Specified Substance

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

7.7.2.3.1 Specified Substance

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

EXAMPLE 1 Specified substance group 1: simeticone.

EXAMPLE 2 Specified substance group 2: insulin human crystalline - rDNA manufacturer A.

EXAMPLE 3 Specified substance group 3: Water for Injection [USP].

7.7.2.3.2 Specified Substance group

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

EXAMPLES Specified substance group 1,

Specified substance group 2.

7.7.2.3.3 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 specified.

EXAMPLES Confidential, no restriction.

7.7.2.4 Strength

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 specified.

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

NOTE 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.

7.7.2.4.1 Strength Range (Presentation)

The strength range (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.

EXAMPLE 1 20 mg (per tablet).

EXAMPLE 2 10 mg/5 ml.

EXAMPLE 3 3,1 g/5 ml to 3,7 g/5 ml.

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. The representation of this information is further described above in 7.6.2.10.3 for manufactured item or 7.8.2.1.2 for 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.

7.7.2.4.2 Strength Range (Concentration)

The strength range (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).

EXAMPLE 1 2 mg/ml.

EXAMPLE 2 1,55 g/ml to 1,85 g/ml.

NOTE 1 This attribute is only required when the strength range (presentation) attribute is valued with the denominator as a non-unitary amount.

EXAMPLE 3 Strength range (presentation) = 25 mg/5 ml; strength range (concentration) = 5 mg/ml.

NOTE 2 For solid dose forms, strength range (concentration) is generally the same as strength (presentation) and therefore is not required to be expressed separately; the strength (presentation) only is required. The representation of this information is described in this subclause.

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. The representation of this information is further described in 7.6.2.10.3 for manufactured item or 7.8.2.1.2 for 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.

7.7.2.4.3 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 aerosolization). In these instances, the measurement point can be described using text, as applicable.

7.7.2.4.4 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 code elements.

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

7.7.2.5 Reference strength

Strength can be further described by a reference strength.

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

EXAMPLE Lithium carbonate 300 mg refers to a reference strength of 12,2 mmol lithium.

7.7.2.5.1 Reference strength 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 resulting terminology. A term and a term identifier shall be used.

7.7.2.5.2 Reference strength 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.

7.7.2.5.3 Reference strength range

The reference strength range shall be specified. A numerator value and numerator unit as well as a denominator value and denominator unit shall be specified as described in 7.7.2.4.2.

7.7.2.5.4 Reference strength measurement point

The reference strength measurement point, if applicable, can be described as outlined in 7.7.2.4.3.

7.7.2.5.5 Reference strength country

Where a reference strength country is applicable as outlined in 7.7.2.4.4, it can be specified based on the ISO 3166-1 alpha-2 code elements.

7.8 Pharmaceutical Product and Device

7.8.1 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.

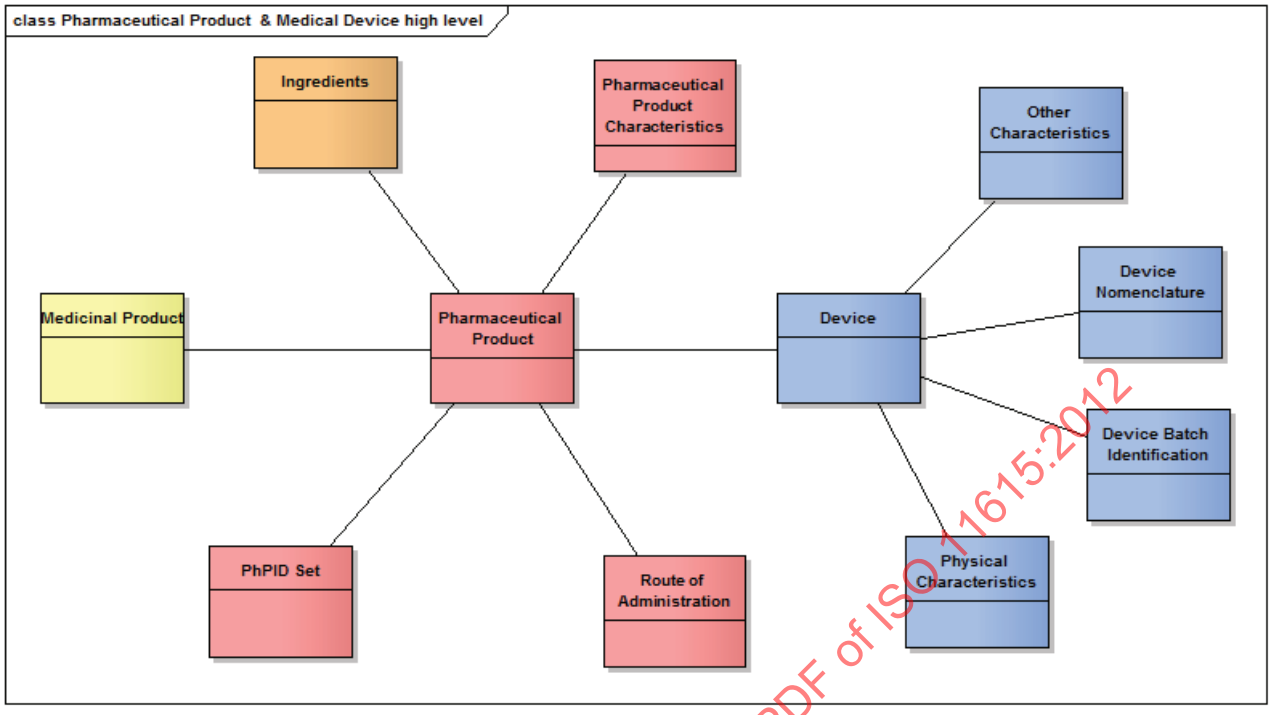

Figure 17 — Pharmaceutical Product and Device section high-level diagram

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. Ingredients are described in greater detail in 7.7.

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

7.8.2 Detailed description of Pharmaceutical Product and Device information

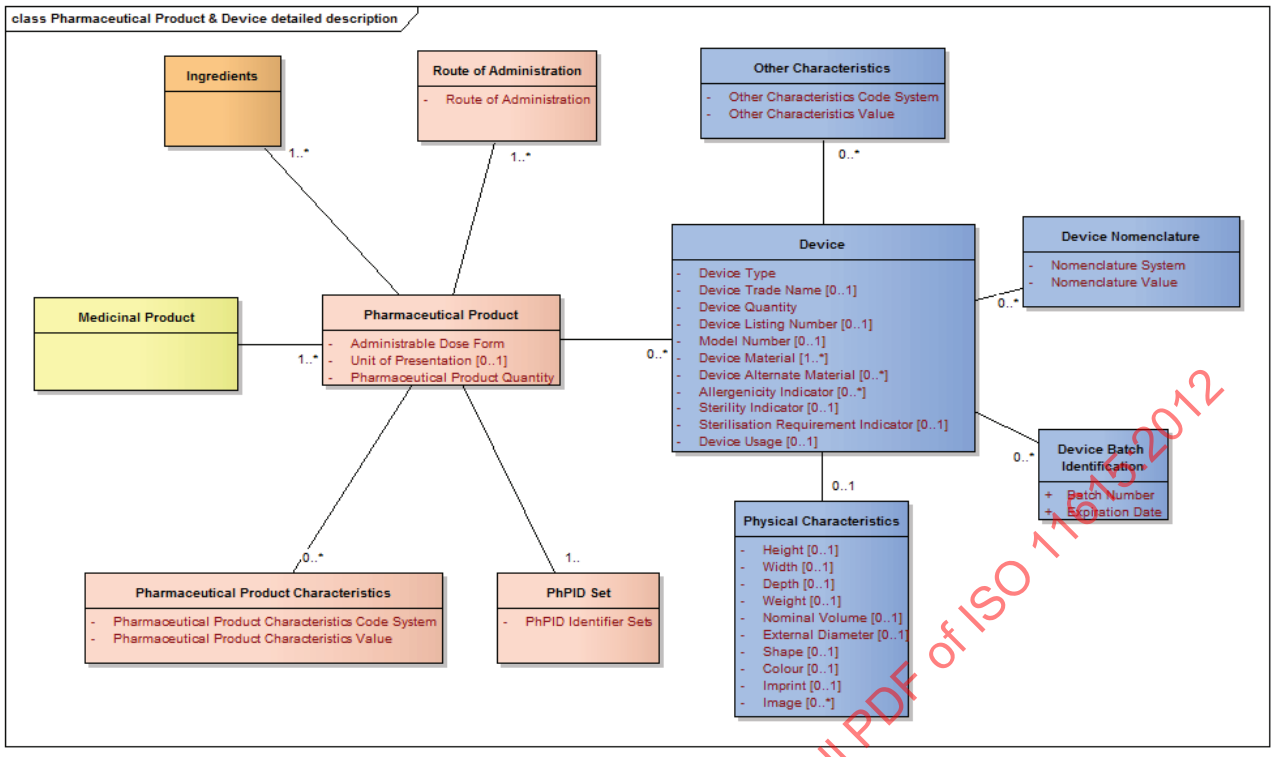

Figure 18 — Pharmaceutical Product and Device section detailed description diagram

7.8.2.1 Pharmaceutical Product

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.

7.8.2.1.1 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 the resulting terminology. The term and the term identifier shall be specified.

EXAMPLES Tablet, capsule, oral solution, solution for injection.

NOTE 1 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.

NOTE 2 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”.

7.8.2.1.2 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 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 the resulting terminology.

EXAMPLE 1 To describe strength: a tablet, spray or puff “contains 100 mcg per actuation” (unit of presentation = actuation).

EXAMPLE 2 To describe quantity: a bottle or vial “contains 100 ml per bottle” (unit of presentation = bottle).

7.8.2.1.3 Pharmaceutical product quantity

The quantity (or count number) of the pharmaceutical product shall be described. It shall be specified as a value and a unit, and the units shall be specified as a symbol and a symbol identifier as defined in ISO 11240 and the resulting controlled vocabulary.

For solid dose forms and other items that are measured by counting integer quantities, the unit for quantity shall be “1 unit” and the unit of presentation shall be the item that is counted.

7.8.2.2 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 identifiers as defined in ISO 11239 and its resulting terminology.

EXAMPLES Oral, subcutaneous, ophthalmic.

7.8.2.3 Pharmaceutical product characteristics

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

7.8.2.3.1 Pharmaceutical product characteristics code system

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

7.8.2.3.2 Pharmaceutical product characteristics 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.

EXAMPLES Characteristic code system: onset of action types

Characteristic value: immediate acting

Characteristic code system: regulatory classification

Characteristic value: advanced therapy

Characteristic code system: regulatory classification

Characteristic value: biologic

7.8.2.4 Device (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. The detail of these three classes is as described in 7.6.2.7, 7.6.2.8 and 7.6.2.12 respectively. 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 (see 7.8.2.5).

7.8.2.5 PhPID Set

This class shall carry the relevant identifiers as defined by ISO 11616. 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.

7.9 Clinical Particulars

7.9.1 General

This section 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.

NOTE A 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.

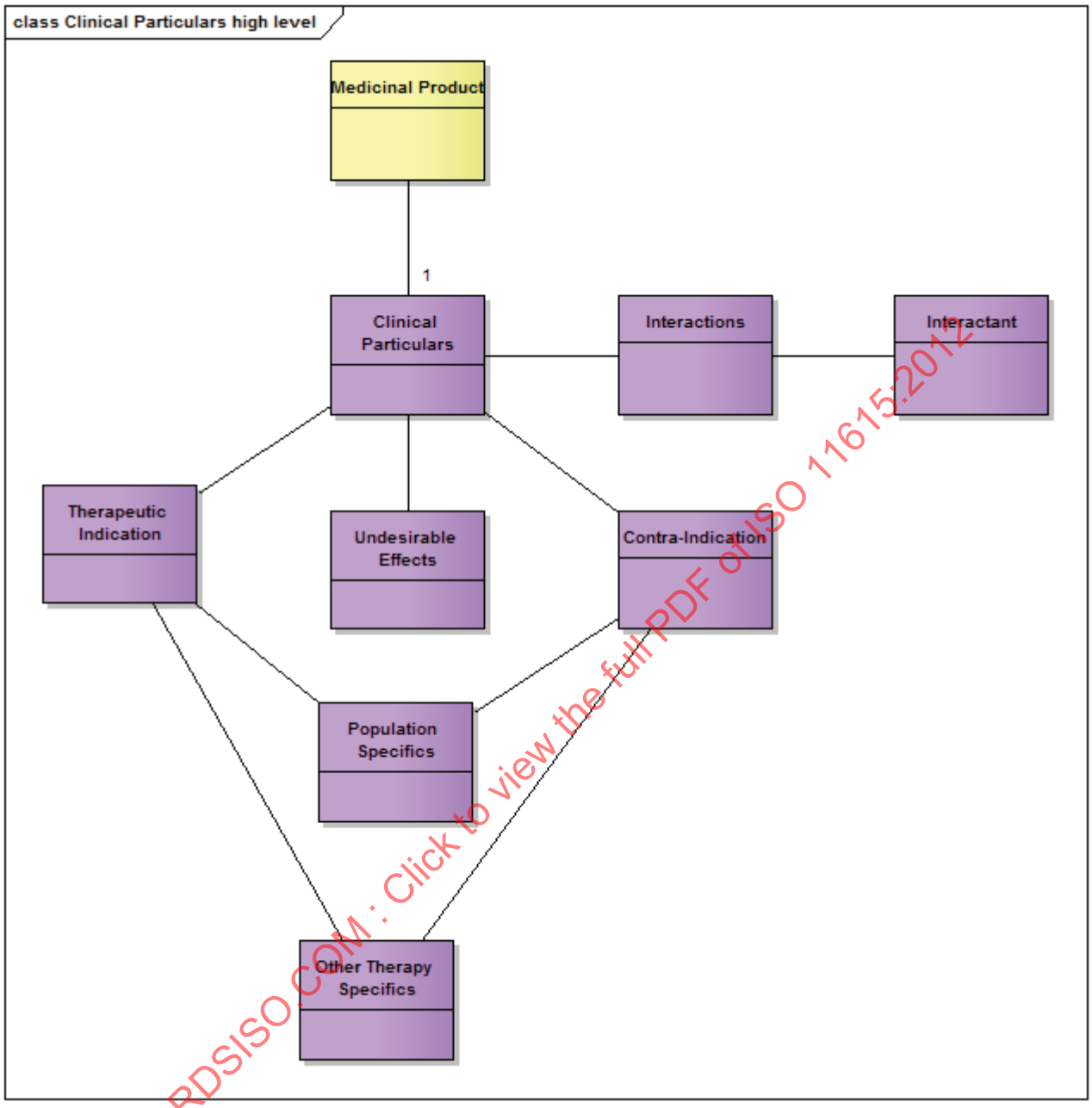

Figure 19 — Clinical Particulars section high-level diagram

A Medicinal Product is associated with a set of clinical particulars. These consist of information about the Medicinal Product's indication(s), its contra-indication(s), its undesirable effect(s) and its interactions.

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

Interaction information has the interactant specified in a separate class.

NOTE The Clinical Particulars class itself is a conceptual "parent" class, drawn into the high-level drawings for ease of visualization; it does not hold information in and of itself, and therefore it is not realized in the detailed description attribute model (see 7.9.2).

7.9.2 Detailed description for Clinical Particulars information

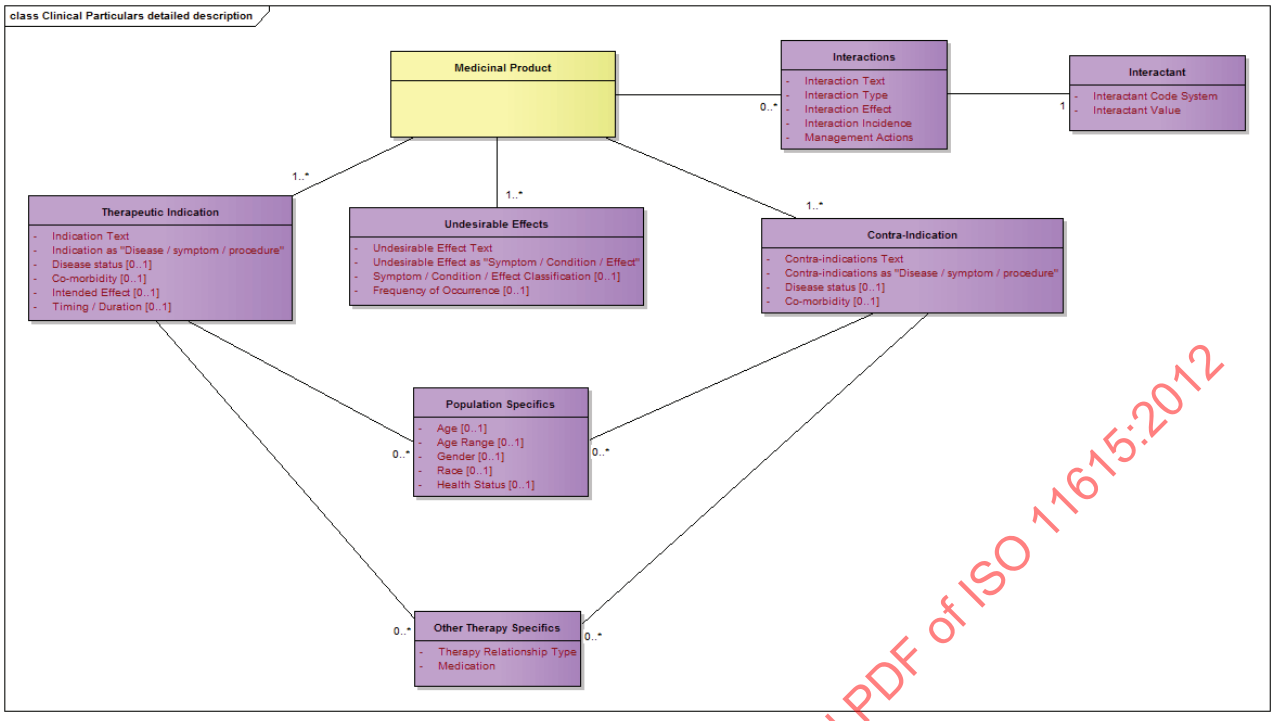

Figure 20 — Clinical Particulars section detailed description diagram

7.9.2.1 Therapeutic Indication

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

NOTE A jurisdiction 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.

7.9.2.1.1 Indication text

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

EXAMPLE Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.

7.9.2.1.2 Indication as "disease/symptom/procedure"

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

EXAMPLE 1 Treatment of primary hypertension.

EXAMPLE 2 Relief of motion sickness.

EXAMPLE 3 Prior to emergency surgery.

7.9.2.1.3 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.

EXAMPLE 1 Treatment of chronic active liver disease.

EXAMPLE 2 Management of refractory hypercalcaemia.

EXAMPLE 3 Treatment of metastatic breast cancer.

7.9.2.1.4 Co-morbidity

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

EXAMPLE 1 Treatment of exocrine pancreatic insufficiency due to cystic fibrosis.

EXAMPLE 2 Treatment of pneumocystitis pneumonia in AIDS.

7.9.2.1.5 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.

EXAMPLE 1 Prophylaxis of acid aspiration.

EXAMPLE 2 Diagnosis of hypopituitarism.

EXAMPLE 3 Palliative therapy for trigeminal neuralgia.

EXAMPLE 4 Reduction of symptoms in hayfever.

EXAMPLE 5 Maintenance treatment in end-stage renal failure.

EXAMPLE 6 Passive immunization against rabies infection.

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.

7.9.2.1.6 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.

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

7.9.2.2 Contra-Indication

This class shall be used to describe the authorized contra-indication(s) for the Medicinal Product as described in the regulated product information.

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

7.9.2.2.1 Contra-indication text

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

EXAMPLE Contra-indicated in the presence of severe/significant renal impairment.

7.9.2.2.2 Contra-indication as “disease/symptom/procedure”

The underlying disease, symptom or procedure of the contra-indication shall be specified as it is referenced in the regulated product information using an appropriate controlled reference terminology. The controlled term and the controlled term identifier shall be specified.

EXAMPLE 1 Contra-indicated in ulcerative disorders of the GI tract.

EXAMPLE 2 Contra-indicated in recent or active hepatitis.

7.9.2.2.3 Disease status

The status of the disease or symptom of the contra-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.

EXAMPLE 1 Contra-indicated in recent or active hepatitis.

EXAMPLE 2 Contra-indicated in refractory heart failure.

7.9.2.2.4 Co-morbidity

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

EXAMPLE 1 Contra-indicated in myocardial insufficiency due to cor pulmonale.

EXAMPLE 2 Contra-indicated in pulmonary oedema due to mitral stenosis.

7.9.2.3 Undesirable Effects

This class shall be used to describe the undesirable effects of the Medicinal Product as described in the regulated product information.

NOTE 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.

7.9.2.3.1 Undesirable effect text

The text of the undesirable effect shall be given.

EXAMPLE Hepatic toxicity including rare cases of fatalities.

7.9.2.3.2 Undesirable effect as “symptom/condition/effect”

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

EXAMPLE 1 Hepatic toxicity.

EXAMPLE 2 Erythema multiforme.

EXAMPLE 3 Headache.

EXAMPLE 4 Hypercalcaemia.

7.9.2.3.3 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 reference terminology.

EXAMPLE Gastrointestinal disorders (for undesirable effect = gastric ulceration).

EXAMPLE 2 Skin and subcutaneous tissue disorder (for undesirable effect = urticaria).

EXAMPLE 3 Nervous system disorders (for undesirable effect = migraine headache).

7.9.2.3.4 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.

EXAMPLES Rarely, very rarely, less than 1 %.

7.9.2.4 Population specifics

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

7.9.2.4.1 Age

The age group of the specific population for an indication or a contra-indication as authorized for the Medicinal Product 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.

EXAMPLE 1 Contra-indicated in elderly patients with diabetes mellitus.

EXAMPLE 2 Contra-indicated in adolescents.

7.9.2.4.2 Age range

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

EXAMPLE 1 For treatment of coughs in children older than 12 months and younger than 4 years.

EXAMPLE 2 Adults over 35 years with primary hyperlipidaemia.

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

7.9.2.4.3 Gender

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

EXAMPLE For the treatment of men with prostate cancer.

7.9.2.4.4 Race

The race of the specific population for an indication or a contra-indication 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.

EXAMPLE Contra-indicated in Afro-Caribbean patients.

7.9.2.4.5 Health status specifics

Various aspects of the health status of the specific population for an indication or contra-indication 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.

EXAMPLE 1 Nutritional status: malnourishment, vitamin deficiency, over-weight, under-weight.

EXAMPLE 2 Natural events: menopause, pregnancy, lactation.

EXAMPLE 3 Clinical chemistry/haematology: low CD4 count, hyperkalaemia.

EXAMPLE 4 General status: debilitation, immunodeficiency.

7.9.2.5 Other therapy specifics

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

7.9.2.5.1 Therapy relationship type

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

EXAMPLE 1 To be used as co-therapy with beta-blockers in the treatment of...

EXAMPLE 2 Contra-indicated when past therapy with...

EXAMPLE 3 Indicated for second line treatment with steroids for...

EXAMPLE 4 Indicated prior to treatment with DMARDs.

7.9.2.5.2 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 contra-indication in accordance with the regulated product information shall be specified using an appropriate controlled reference terminology. The controlled term and the controlled term identifier shall be specified.

EXAMPLE 1 Prevention of atherothrombotic events in combination with acetyl salicylic acid.

EXAMPLE 2 Treatment of type 2 diabetes mellitus combination with sulfonylureas.

EXAMPLE 3 Prior to treatment with DMARDs.

EXAMPLE 4 Contra-indicated if previous exposure to alkylating agents.

7.9.2.6 Interactions (with other Medicinal Products and other forms of interaction)

This class shall be used to describe the interactions of the Medicinal Product and other forms of interaction as described in the regulated product information.

7.9.2.6.1 Interactions text

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

EXAMPLE The effect of phenytoin on warfarin is variable and prothrombin times should be determined when these agents are combined. Serum level determinations are especially helpful when possible drug interactions are suspected.

7.9.2.6.2 Interactions type

The type of interaction in line with the regulated product information shall be described using an appropriate controlled reference vocabulary.

EXAMPLES Drug-drug interaction, drug-food interaction, drug-laboratory test interaction.

7.9.2.6.3 Interaction effect

The effect of the interaction in line with the regulated product information shall be described using an appropriate controlled reference vocabulary.

EXAMPLES Serum level of secondary medication reduced, gastric absorption of primary medication impaired.

7.9.2.6.4 Interaction incidence

The incidence of the interaction in accordance with the regulated product information shall be described using an appropriate controlled reference vocabulary.

EXAMPLES No interaction, theoretical interaction, observed interaction.

7.9.2.6.5 Management actions

The actions to provide management of the interaction in accordance with the regulated product information shall be described using an appropriate controlled reference vocabulary.

EXAMPLES Caution in concomitant use, dose reduction of secondary interactant, concomitant use not recommended.

7.9.2.7 Interactant

This class shall 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.

7.9.2.7.1 Interactant code system

The code system being used to describe the secondary interactant shall be specified using an appropriate identification system.

EXAMPLE 1 Interactant code system: WHO Anatomical Therapeutic Chemical (ATC) Classification System.

EXAMPLE 2 Interactant code system: SubsID (ISO 11238).

EXAMPLE 3 Interactant code system: MedDRA.

7.9.2.7.2 Interactant value

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

EXAMPLES Interactant code system: WHO Anatomical Therapeutic Chemical (ATC) Classification System

Interactant value: J02AB imidazole derivatives

Interactant code system: SubsID (ISO 11238)

Interactant value: 123-ABC-XYZ phenytoin (base)

Interactant code system: SubsID (ISO 11238)

Interactant value: 333-XYZ-KLM grapefruit juice

Interactant code system: MedDRA

Interactant value: 10005455 – blood cortisol

8 Identifying characteristics for Investigational Medicinal Products

8.1 General

This section describes Investigational Medicinal Products (IMPs) that do not have a marketing authorization and which are subject to an investigation in one or more clinical trials. The section also applies to authorized 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 authorized form, or when used for an unauthorized 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.

8.2 Primary identifiers

8.2.1 General considerations

To satisfy the requirements as described in 4.1, the following four identifiers shall be specified:

a) IMPID — Investigational Medicinal Product Identifier;

b) IPCID — Investigational Medicinal Product Package Identifier;

c) IBAID_1 — Investigational Medicinal Product Batch Identifier, allocated to a specific batch of an Investigational Medicinal Product, which appears on the outer packaging of the Investigational Medicinal Product;

d) IBAID_2 — Investigational Medicinal Product Batch Identifier, allocated to a specific batch of an Investigational Medicinal Product, which appears on the immediate packaging, where this is not the outer packaging.

In addition, there is an association with Pharmaceutical Product Identifiers (PhPIDs) as defined in ISO 11616. While the elements related to the PhPID are identical for authorized Medicinal Products and Investigational Medicinal Products, the regulatory information and additional characteristics may differ, which are outlined in this section.

Further details as regards the use of these identifiers can be provided in implementation guidance.

8.3 Investigational Medicinal Product Identifier (IMPID)

8.3.1 General considerations

For each Investigational Medicinal Product, a unique IMPID shall be assigned. The IMPID shall be allocated in addition to any existing identifier as ascribed by a Medicines Regulatory Agency in a jurisdiction or a sponsor of a clinical trial. This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of Investigational Medicinal Products worldwide.

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

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

b) Sponsor (Organization Identifier) code segment;

c) Sponsor product code and/or regulator product code (depending on regional requirements) segment.

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

8.3.2 IMPID Code segments

The IMPID code segments shall be generated as described below:

8.3.2.1 Country Code segment

This code segment shall reflect the jurisdiction(s) where the clinical trial application is submitted to a Medicines Regulatory Agency. The ISO 3166-1 alpha-2 code shall be used. If there are multiple countries authorizing the clinical trial, then multiple country codes are entered into the country code segment.

8.3.2.2 Sponsor (Organization Identifier) Code segment

This code segment shall reflect the unique identifier of the sponsor (organization) of the Investigational Medicinal Product. An international coding system for unique sponsor (organizations) identifiers can be applied, if available.

8.3.2.3 Sponsor Product Code and/or Regulator Product Code (depending on regional requirements) segment

This code segment shall reflect a unique Investigational Medicinal Product identifier assigned to the Investigational Medicinal Product. It utilizes the following attributes to define a single Investigational Medicinal Product, to which a code is assigned:

a) substances(active)/specified substances (e.g. active, adjuvant);

b) device(s) (where an investigational 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 Investigational Medicinal Product);

c) therapeutic indication(s) studied in the clinical trial.

A separate unique IMPID shall be assigned whenever any of the above items of information for an Investigational Medicinal Product are different in any way that is relevant to the Medicines Regulatory Agency's process.

This process may result in changes to the IMPID for an Investigational Medicinal Product when existing regulatory identifiers would not change. This International Standard does not require such existing regulatory identifiers to be changed in step with the IMPID. Each jurisdiction can continue with its existing working practices for existing identifiers.

8.4 Investigational Medicinal Product Package Identifier (IPCID)

8.4.1 General provisions

For each packaged Investigational Medicinal Product, a unique IPCID can be assigned.

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

a) IMPID for the Investigational Medicinal Product;

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

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

The IPCID code segment shall use the defining attribute sets as described below:

8.4.2 Package Description Code segment

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

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

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

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

A separate unique IPCID shall be assigned whenever any of the aforementioned attribute sets of a packaged Investigational Medicinal Product are different in any way that is relevant to the medicines regulatory process.

This process may result in changes to an IPCID when existing regulatory identifiers would not change. This International Standard does not require such existing regulatory identifiers to be changed in step with the IPCID. Each jurisdiction may continue with its existing working practices for existing identifiers.

8.5 Investigational Medicinal Product Batch Identifier (IBAID_1)

For each Investigational Medicinal Product, an IBAID_1 can be assigned. The IBAID_1 shall use the batch number allocated by the manufacturer or sponsor and the expiration date together with the IPCID. The IBAID_1 shall use the batch number as it appears on the outer packaging of a specific batch of the Investigational Medicinal Product.

The IBAID_1 shall use a common attribute set related to an Investigational Medicinal Product, which when all of them have a value, define a specific IBAID_1 concept:

a) IPCID;

b) batch number (outer packaging);

c) expiration date (optional attribute) (month/year) using the ISO 8601 date format.

8.6 Investigational Medicinal Product Batch Identifier (IBAID_2)

For each Investigational Medicinal Product, an IBAID_2 can be assigned. The IBAID_2 shall use the batch number allocated by the manufacturer or the sponsor and the expiration date together with the PCID. The IBAID_2 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 Investigational Medicinal Product.

The IBAID_2 shall use a common attribute set related to a packaged Investigational Medicinal Product, which when all of them have a value, define a specific IBAID_2 concept:

a) IPCID;

b) batch number (immediate packaging, when not the outer packaging);

c) expiration date (optional attribute) (month/year) using the ISO 8601 date format.

9 Information for an Investigational Medicinal Product

NOTE In the following subclauses, information is given only where it differs from that given for the authorized Medicinal Product.

9.1 Conceptual overview of the information for an Investigational Medicinal Product

In addition to the primary identifiers described in 8.5 and 8.6, the main concepts modelled in Figure 19 and described in the text below shall apply in order to identify and characterize an Investigational Medicinal Product which itself is identified by the IMPID.

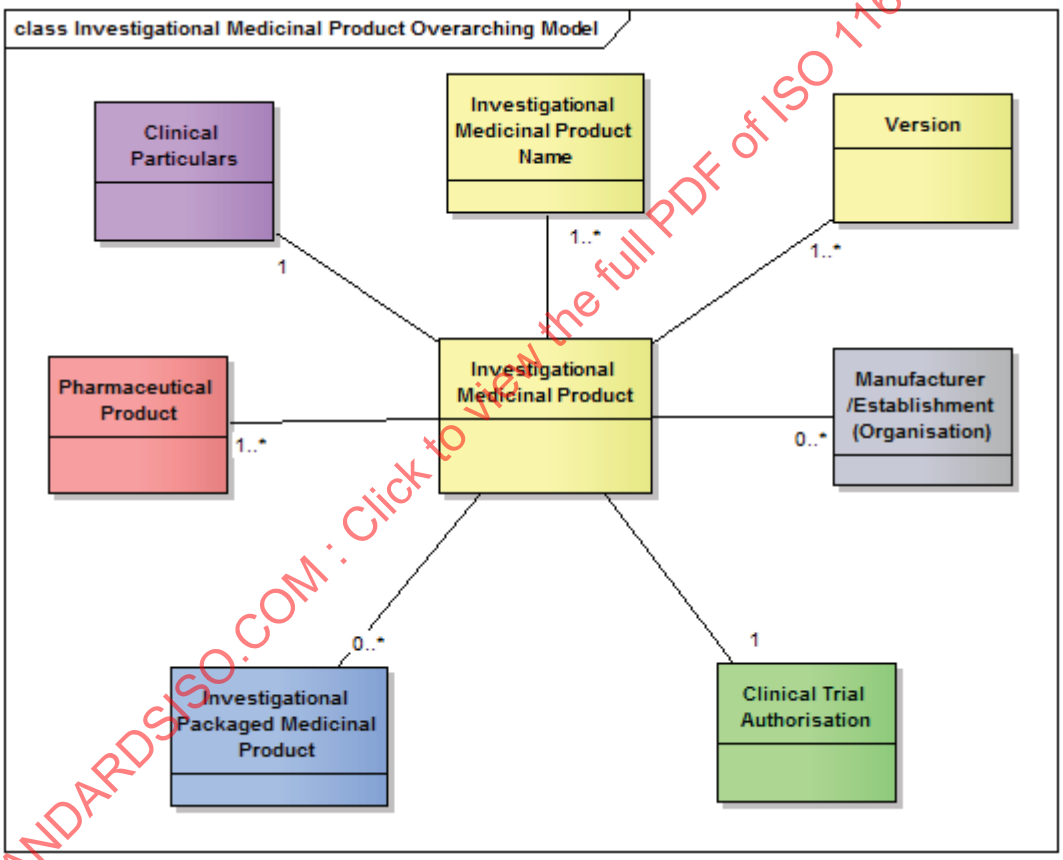

Figure 21 — Investigational Medicinal Product overarching model

9.1.1 Investigational Medicinal Product

This section specifies the IMPID together with the information that uniquely identifies and characterizes an Investigational Medicinal Product as authorized for investigation in a clinical trial by a Medicines Regulatory Agency in a jurisdiction.

9.1.2 Investigational Medicinal Product name

This section specifies the name of the Investigational Medicinal Product as given by a sponsor, together with an analysis of the name into various parts. There are some small differences between this section and the equivalent section for the authorized Medicinal Product; these are described in more detail below.

9.1.3 Version

This section specifies the versioning of the core identifiers related to an Investigational Medicinal Product, as well as the characteristics associated with the Investigational Medicinal Product and the documentation that supports the versioning.

This section is as it is for the authorized Medicinal Product.

9.1.4 Clinical Trial Authorization

This section specifies the information about the clinical trial authorization as issued by a Medicines Regulatory Agency, which grants permission to a sponsor to place an Investigational Medicinal Product into trial in a specific jurisdiction.

9.1.5 Manufacturer/Establishment

This section specifies characteristics about the manufacturing and other associated operations and their authorizations as issued by a Medicines Regulatory Agency, which grants permission to a manufacturer/establishment to undertake manufacturing and other associated operations related to an Investigational Medicinal Product in a specific jurisdiction.

This section is as it is for the authorized Medicinal Product, with the requirement for the information optional rather than mandatory.

9.1.6 Investigational Packaged Medicinal Product

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

This section is as it is for the authorized Medicinal Product, with the requirement for the information optional rather than mandatory.

9.1.7 Pharmaceutical Product

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

9.1.8 Clinical Particulars

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

This section is as it is for the authorized Medicinal Product.

NOTE A 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.

9.2 Investigational Medicinal Product

This section specifies the IMPID together with the information that uniquely identifies and characterizes an Investigational Medicinal Product as approved for investigation in a clinical trial by a Medicines Regulatory Agency in a jurisdiction.

The general pattern of information is as for an authorized Medicinal Product, with some additional attributes.

9.2.1 Detailed description of Investigational Medicinal Product information

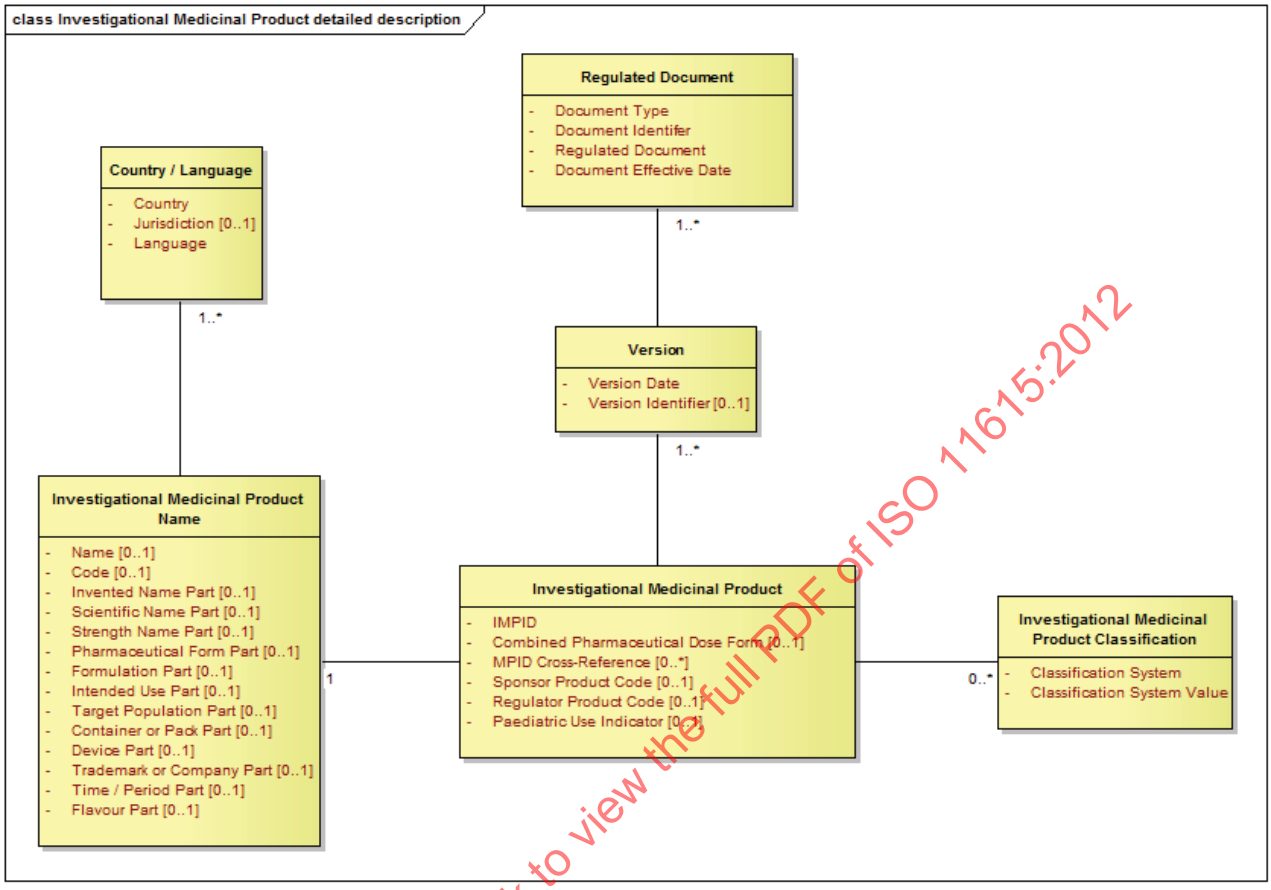

Figure 22 — Investigational Medicinal Product section detailed description diagram

9.2.1.1 Investigational Medicinal Product

This represents the Investigational Medicinal Product as authorized for use in a clinical trial by a Medicines Regulatory Agency in a specific jurisdiction and has the following attributes.

9.2.1.1.1 IMPID

The identifier for the Investigational Medicinal Product shall be always specified, as text.

9.2.1.1.2 Combined pharmaceutical dose form

The combined pharmaceutical dose form shall be specified, where applicable, as described in 7.2.2.1.2.

9.2.1.1.3 MPID cross reference

Where an authorized Medicinal Product is subject to investigation in a clinical trial but is used or assembled (formulated or packaged) in a way different from the authorized form, or when used for an unauthorized indication, it shall be specified as an Investigational Medicinal Product based on the characteristics described in this section.

A cross reference to the MPID of the authorized Medicinal Product shall be included for reference purposes.

There may be occasions where more than one MPID is cross-referenced, if an IMPID is representing a new therapeutic regimen.

9.2.1.1.4 Sponsor product code

The product code (identifier) for the Investigational Medicinal Product as designated by the sponsor can be specified, in text. Either this code or the regulator product code (below) shall be specified.

9.2.1.1.5 Regulator product code

The product code (identifier) for the Investigational Medicinal Product as designated by the Medicines Regulatory Agency can be specified, in text. Either this code or the Sponsor Product Code (above) shall be specified.

9.2.1.1.6 Paediatric use indicator

If the Investigational Medicinal Product refers to a specific paediatric formulation, this can be specified using a controlled vocabulary. A term and a term identifier shall be used.

EXAMPLE Specific paediatric formulation.

9.2.1.2 Version

Versioning shall be applied as described in 7.2.2.2.

9.2.1.3 Regulated document

“Regulated document” can refer to, for example, the investigator’s brochure, the clinical trial protocol and any other regulated product information (as applicable for authorized Medicinal Products), which shall be specified as described in 7.2.2.3.

9.2.1.4 Investigational Medicinal Product classification

The Investigational Medicinal Product can be classified according to various classification systems, which may be jurisdictional or international. One or more of these various classifications of the product can be specified as described in 7.2.2.4.

9.2.1.5 Investigational Medicinal Product name

9.2.1.5.1 Name

The full and complete Investigational Medicinal Product name as assigned by the sponsor can be specified as text. Unlike the authorized Medicinal Product name, this information is not mandatory for Investigational Medicinal Products, but either this attribute or the product code attribute below shall be valued.

9.2.1.5.2 Code

The Investigational Medicinal Product may, in its initial development, be described by an informal “code” rather than by name; this shall be specified here, where applicable.

EXAMPLE A&B693.

For all the other name part attributes, the information is as described previously in 7.2.2.5.

9.2.1.6 Country/language

The country and language shall be specified as described in 7.2.2.6.

9.3 Clinical Trial Authorization

A clinical trial authorization is issued by the appropriate Medicines Regulatory Agency. In compliance with the laws and regulations applicable in a jurisdiction, an authorization is required before an Investigational Medicinal Product can be studied in a clinical trial.

9.3.1 Detailed description of Clinical Trial Authorization information

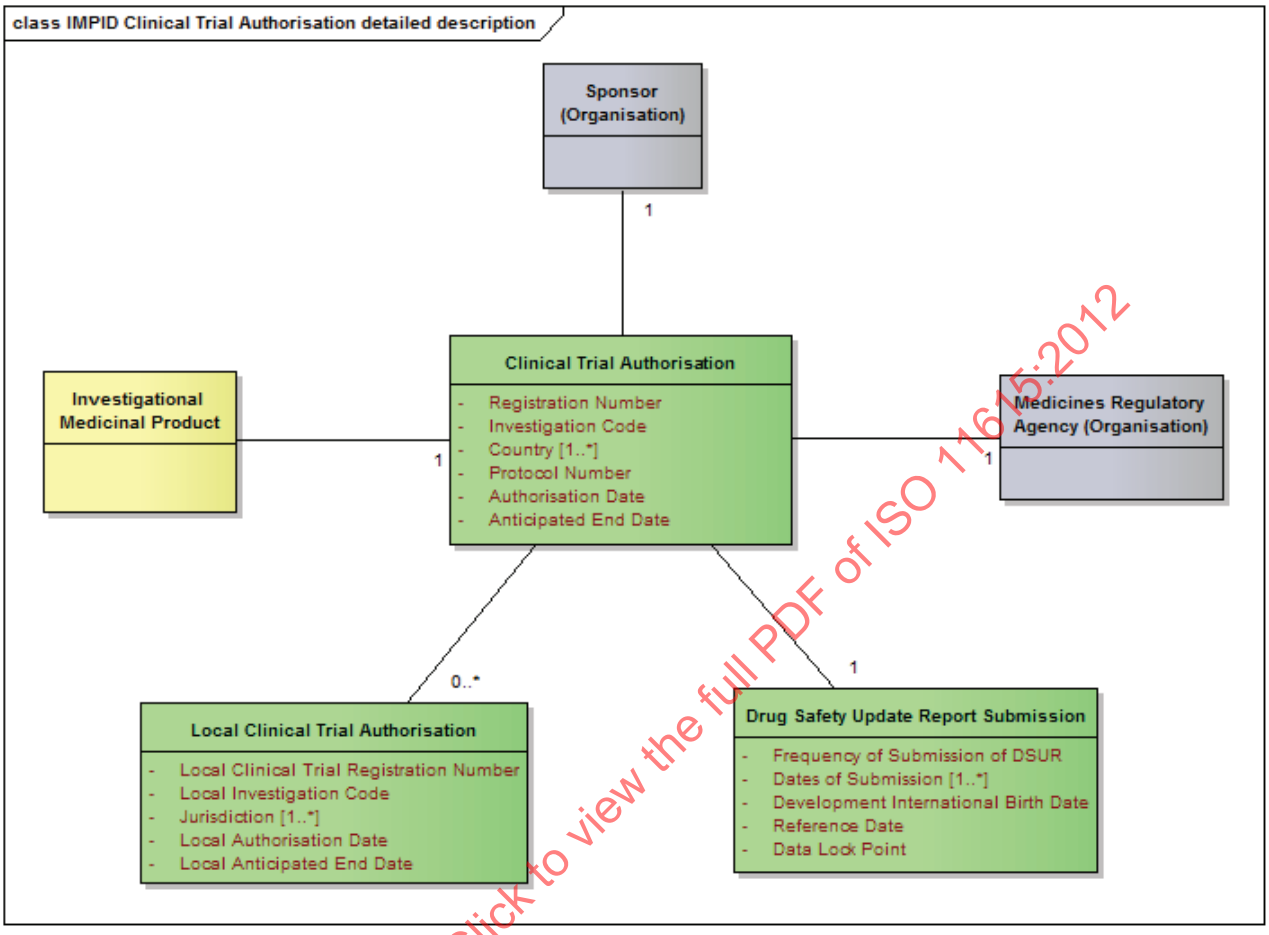

Figure 23 — Clinical Trial Authorization section detailed description diagram

9.3.1.1 Clinical Trial Authorization

An Investigational Medicinal Product shall have a clinical trial authorization specified, using the following information.

9.3.1.1.1 Registration number

The registration number (identifier) for a clinical trial in a jurisdiction shall be specified, in text.

9.3.1.1.2 Investigation code

The code for a particular investigation (trial) as assigned in a jurisdiction for a clinical trial shall be specified, in text.

9.3.1.1.3 Country

The jurisdiction(s) in which the clinical trial authorization was granted shall be described using ISO 3166-1 alpha-2 or alpha-3 codes.

9.3.1.1.4 Protocol number

The number assigned to the clinical trial protocol shall be specified, in text.

9.3.1.1.5 Authorization date

The date when the clinical trial authorization was granted by a Medicines Regulatory Agency in a jurisdiction shall be provided. A complete point in time date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.1.1.6 Anticipated end date

The date when the clinical trial is anticipated to be completed in accordance with the authorized clinical trial protocol in a jurisdiction shall be provided. A complete point in time date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.1.2 Local clinical trial authorization

Local information in relation to a clinical trial authorization (e.g. in a country within a jurisdiction) as granted by a Medicines Regulatory Authority shall be specified, where applicable.

9.3.1.2.1 Local clinical trial registration number

The registration number (identifier) for a clinical trial as assigned by the Regulatory Medicines Authority locally shall be specified in text.

9.3.1.2.2 Local investigation code

The “code” for an Investigational Medicinal Product as assigned locally for a clinical trial of a set of clinical trials shall be specified in text.

9.3.1.2.3 Jurisdiction

The jurisdiction(s) in which the clinical trial authorization was granted shall be described using ISO 3166-1 alpha-2 or alpha-3 codes.

EXAMPLE For the country of Canada, the jurisdiction of Quebec province may be specified.

9.3.1.2.4 Local authorization date

The date when the clinical trial authorization was granted locally by a Regulatory Medicines Authority shall be provided. A complete point in time date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.1.2.5 Local anticipated end date

The date when the clinical trial is anticipated to be completed in accordance with the authorized clinical trial protocol shall be provided. A complete point in time date consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.1.3 Drug safety update report submission

Drug safety update reports (DSUR) provide safety information from all ongoing clinical trials and other studies that the sponsor is conducting or has completed during a specific review period.

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

9.3.1.3.1 Frequency of submission of DSUR

The frequency of the submission of a DSUR can be defined by legislation or as part of a clinical trial authorization in a jurisdiction. The frequency shall be described using a numerical value for the repeating interval 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.

EXAMPLE DSUR submission frequency defined as annually.

9.3.1.3.2 Dates of submission

The dates of submission of DSURs in line with the defined frequency of submission of DSURs shall be presented. Complete point in time dates consisting of day, month and year shall be specified using the ISO 8601 date format.

9.3.1.3.3 Development International Birth Date

The Development International Birth Date (DIBD) is used to determine the start of the (annual) period for the DSUR. This date is the sponsor's first authorization to conduct a clinical trial in any country worldwide. The start of the period for the DSUR submission is the month and date of the DIBD. A complete point in time date consisting of day, month and year or a partial point in time date consisting of month and year shall be specified using the ISO 8601 date format.

9.3.1.3.4 Reference date

Where Investigational Medicinal Products that are subject to different clinical trial authorizations contain the same active substance or the same combination of active substances, the frequency and dates of submission of the DSURs may be amended and harmonized by a Medicines Regulatory Agency or Agencies in a jurisdiction, for example to enable a single assessment to be made in the context of DSUR work-sharing procedures and to set a reference date from which the dates of submission are calculated. A complete date consisting of day, month and year, or a partial date consisting of month and year, shall be specified using the ISO 8601 date format.

9.3.1.3.5 Data lock point

The data lock point is the date designated as the cut-off for data to be included in a DSUR. A complete point in time date consisting of day, month and year or a partial point in time date consisting of month and year shall be specified using the ISO 8601 date format.

9.3.1.4 Sponsor

Details in relation to the sponsor to which a clinical trial authorization in a jurisdiction was granted shall be specified using an Organization class as described in 7.4 above.

9.3.1.5 Medicines Regulatory Agency

Details in relation to the Medicines Regulatory Agency that granted the clinical trials authorization for an Investigational Medicinal Product shall be specified using an Organization class as described in 7.4 above.

9.4 Manufacturer/Establishment

Information as described previously for authorized Medicinal Products in 7.5 applies. Note that this information is optional for an Investigational Medicinal Product and the information shall be specified in accordance with the regulatory requirements in a specific jurisdiction.

9.5 Investigational Packaged Medicinal Product

Information as described previously for authorized Medicinal Products in 7.6 applies. Note that this information is optional for an Investigational Medicinal Product.

9.6 Pharmaceutical Product

This section describes the Investigational Medicinal Product in terms of its qualitative and quantitative composition and in the pharmaceutical dose form studied in line with the clinical trial protocol. These characteristics of the Investigational Medicinal Product are referred to as pharmaceutical product.

For certain medicines, a device can form an integral part of the Investigational 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.

9.6.1 Detailed description of Pharmaceutical Product Information (Investigational Medicinal Product)

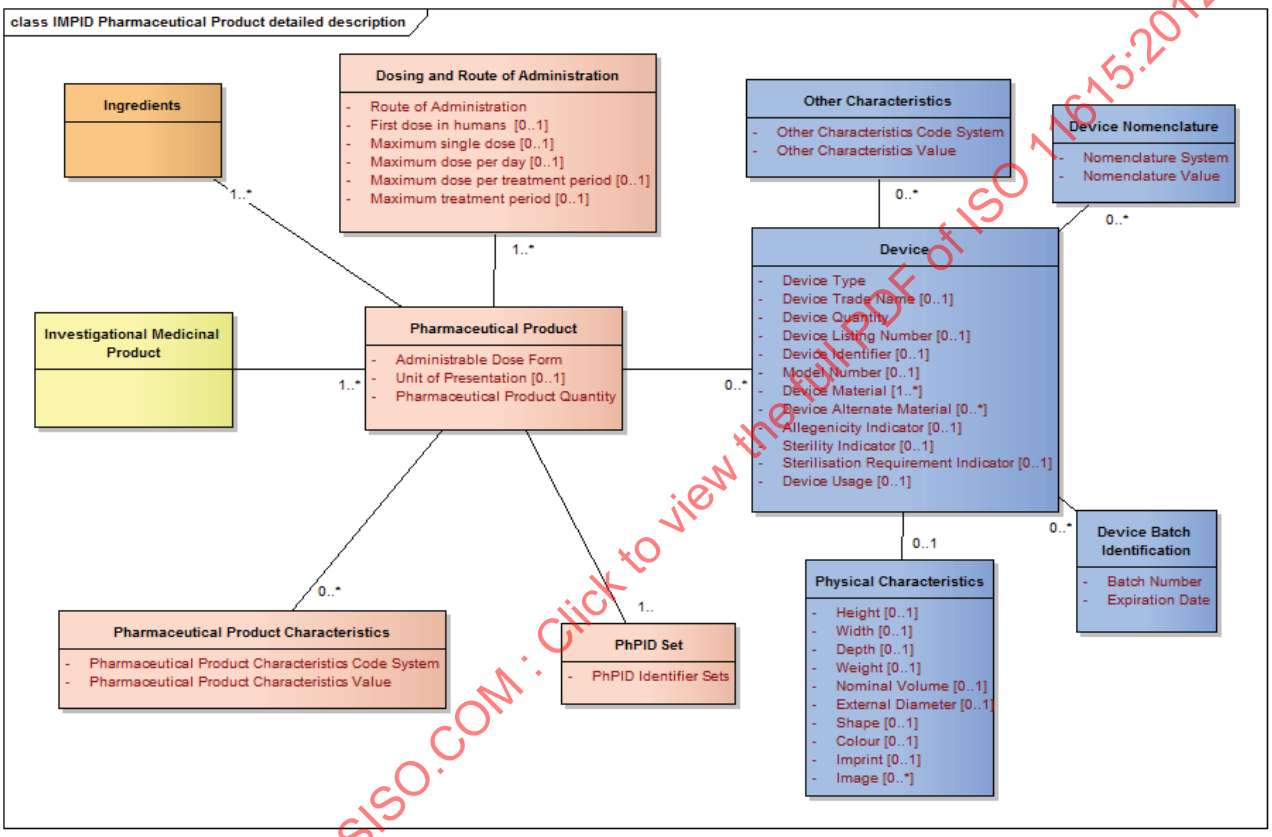

Figure 24 — Pharmaceutical Product (Investigational Medicinal Product) section detailed description diagram

This information is as previously described in 7.8, with the exceptions given below.

9.6.1.1 Dosing and route of administration

9.6.1.1.1 General

This section describes information about the dosing of the Investigational Medicinal Product in relation to the clinical trial in which the product is subject to investigation. All information about dose quantities and treatment periods are in the context of the route of administration specified in the first attribute. If the trial uses more than one route of administration for the administration of the Investigational Medicinal Product, multiple instances of this class shall be used.

9.6.1.1.2 Route of administration

The route of administration shall be specified using terms and term identifiers as defined in ISO 11239 and its resulting terminology.

EXAMPLES Oral, subcutaneous, ophthalmic.

9.6.1.1.3 First dose in humans

The first dose (dose quantity) administered in humans 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 symbol identifier shall be used.

9.6.1.1.4 Maximum single dose

The maximum single dose (maximum single dose quantity) that can be administered as per the protocol referenced in the clinical trial authorization 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.

9.6.1.1.5 Maximum dose per day

The maximum dose per day (maximum dose quantity to be administered in any one 24-hour period) that can be administered as per the protocol referenced in the clinical trial authorization 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.

9.6.1.1.6 Maximum dose per treatment period

The maximum dose per treatment period (maximum total dose quantity to be administered in the treatment period specified in 9.6.1.1.7) that can be administered as per the protocol referenced in the clinical trial authorization 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.

9.6.1.1.7 Maximum treatment period

The maximum treatment period during which the Investigational Medicinal Product can be administered as per the protocol referenced in the clinical trial authorization can be specified using a numerical value and its unit of time measurement. The unit of time measurement shall be specified in accordance with ISO 11240 and the resulting terminology. The symbol and the symbol identifier shall be used.

9.7 Ingredient

Information as described in 7.7 for authorized Medicinal Products applies.

9.8 Clinical particulars

Information as described in 7.9 for authorized Medicinal Products applies. Note that contra-indication and undesirable effects information is optional for an Investigational Medicinal Product, but that therapeutic indication information is still required.

Annex A
(informative)

Full model — Authorized Medicinal Products conceptual level

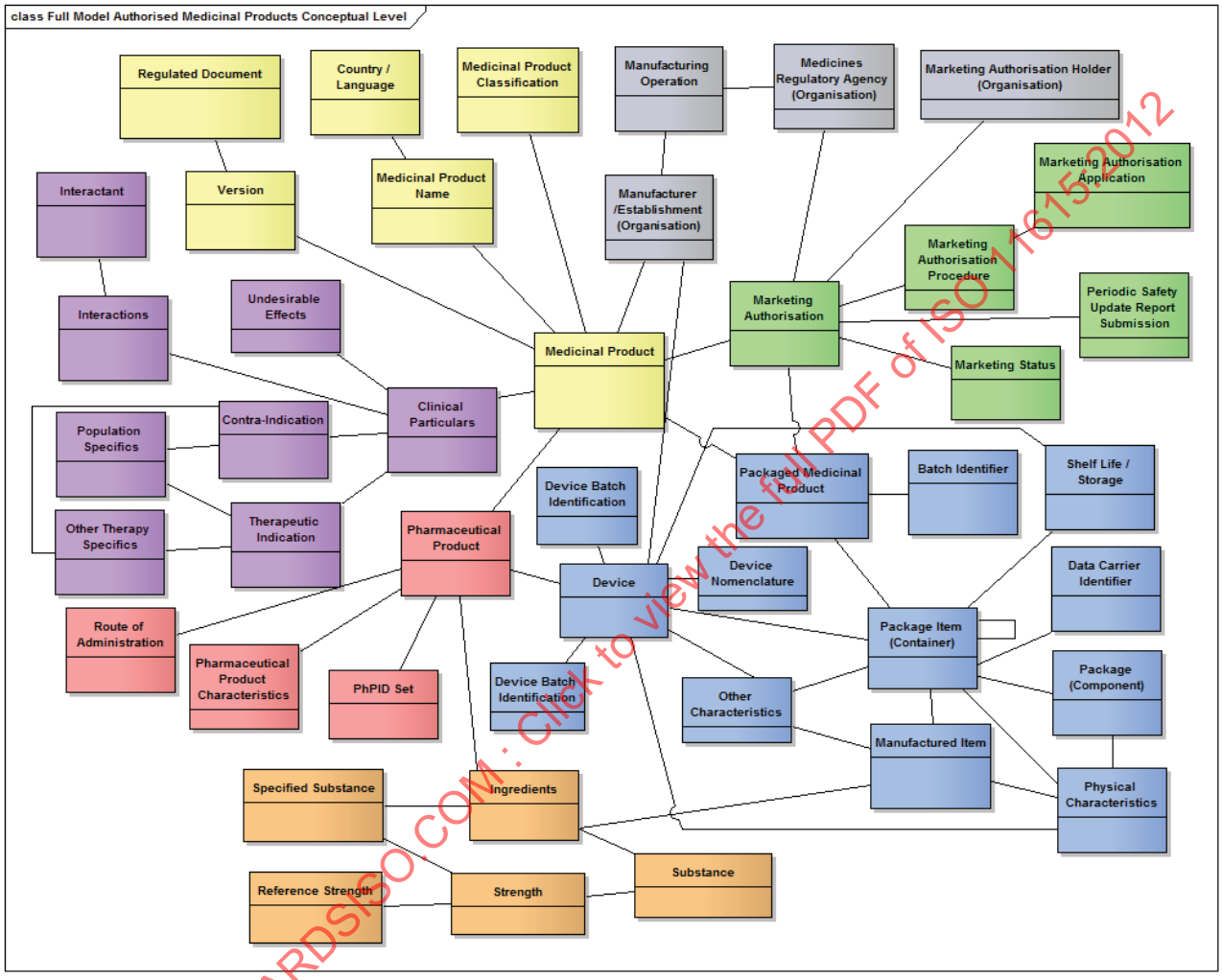

Figure A.1 — Authorized Medicinal Products full conceptual level diagram

Annex B
(informative)

Full model — Authorized Medicinal Products detailed diagram

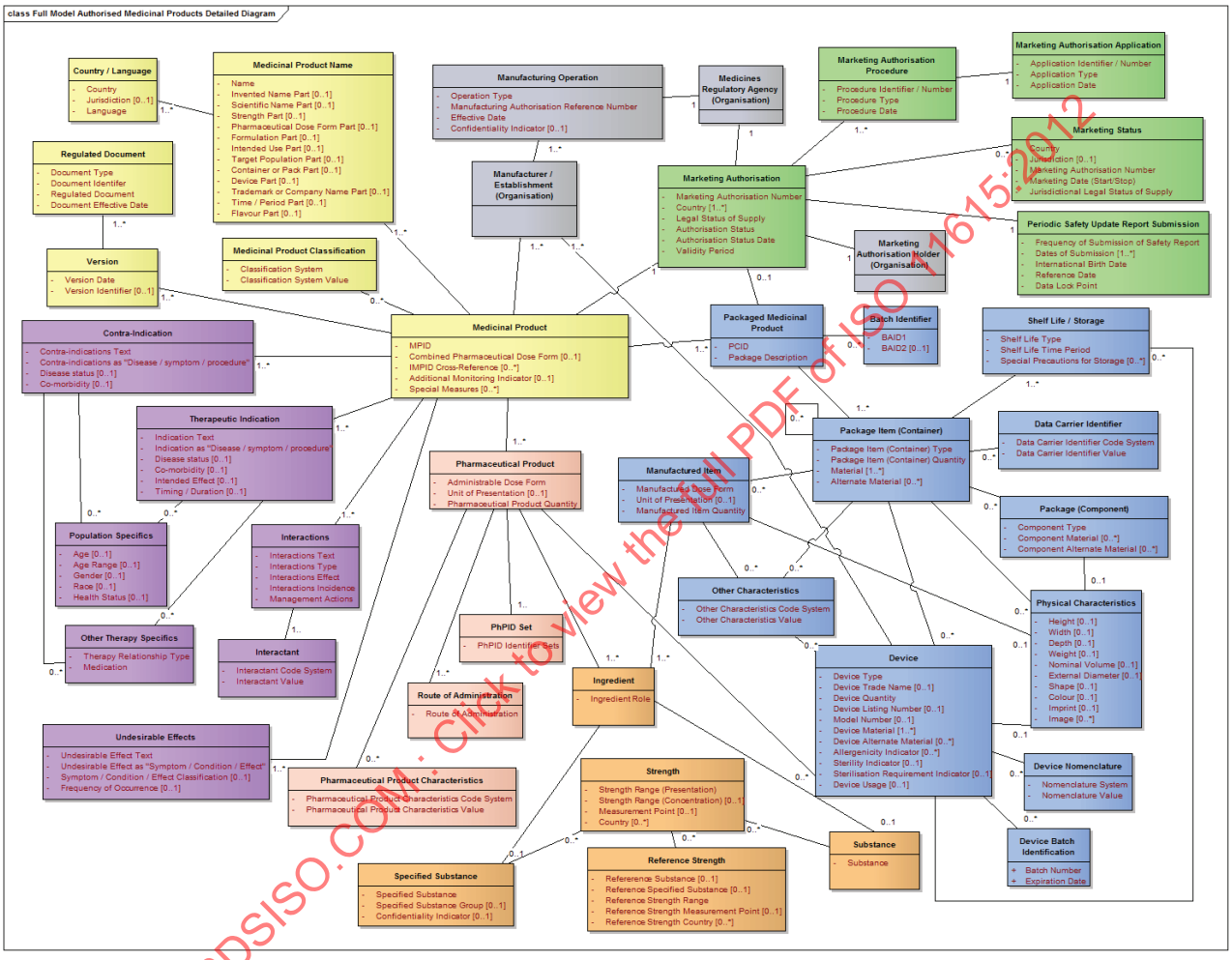

Figure B.1 — Authorized Medicinal Products full detailed diagram

Annex C
(informative)

Full model — Investigational Medicinal Products conceptual level

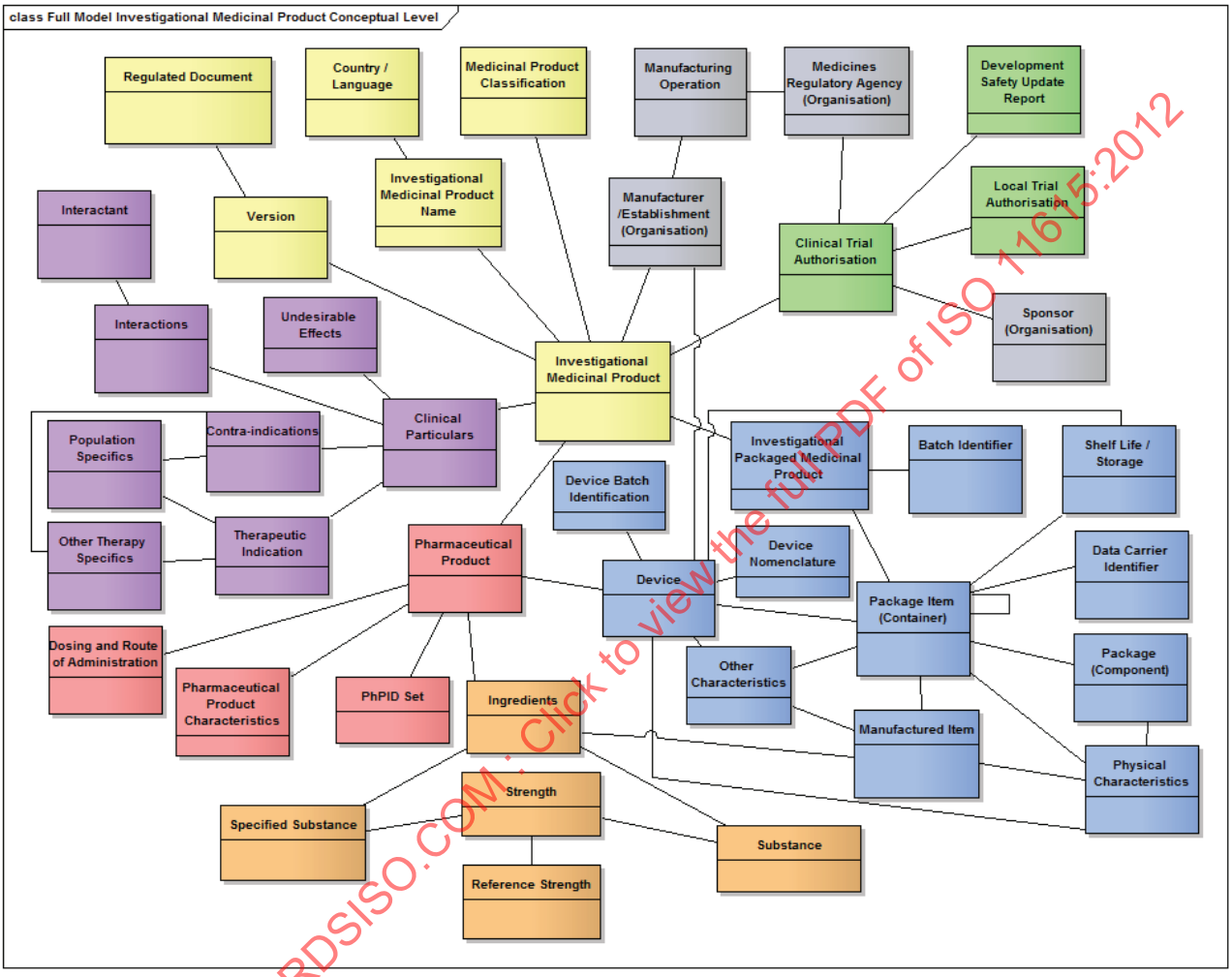

Figure C.1 — Investigational Medicinal Products full conceptual level diagram

Annex D
(informative)

Full Model — Investigational Medicinal Products detailed diagram

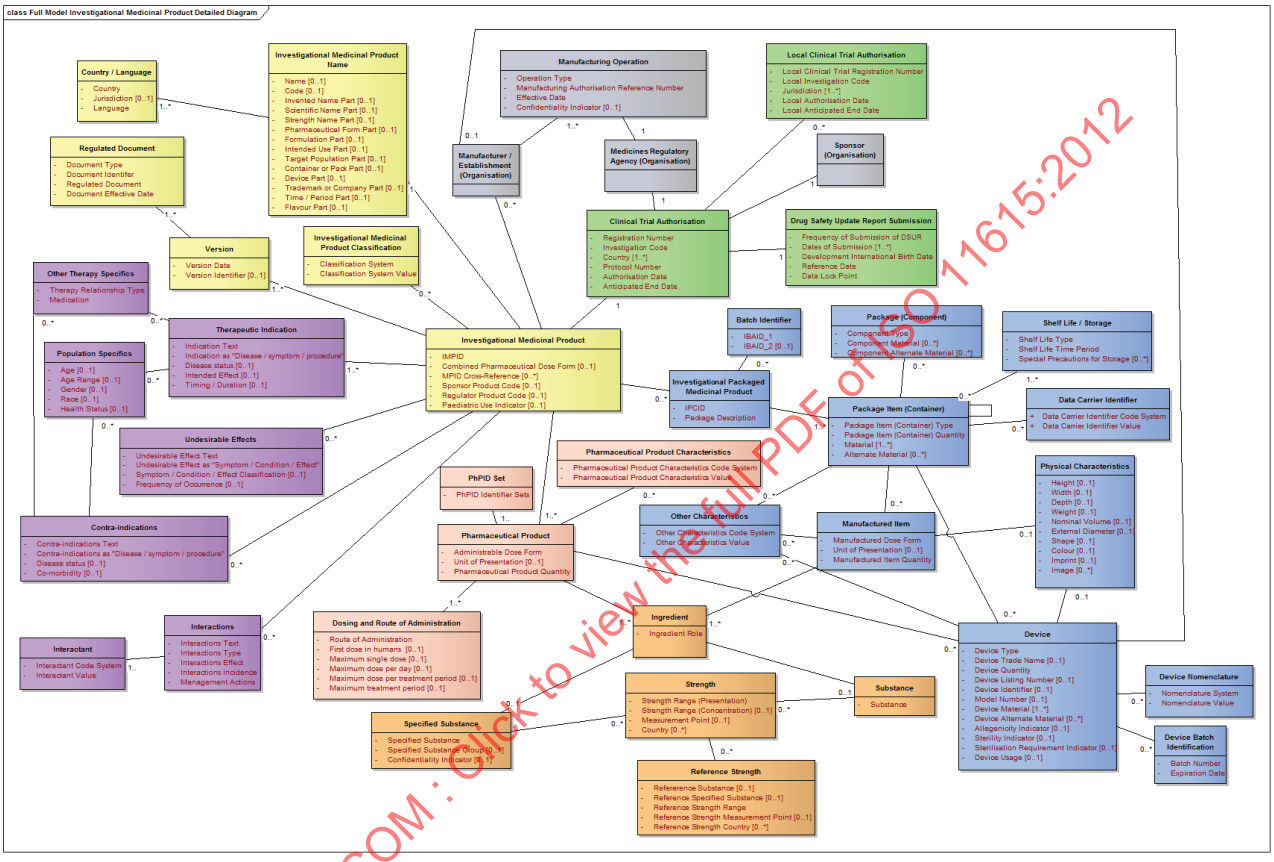

Figure D.1 — Investigational Medicinal Products full detailed diagram

Annex E
(informative)

Worked example in tabular form

Table E.1 — Example, INFLUENZAVAC[7)] in accordance with the approved product labelling

NOTE The example provided below is not a representation of the full information required by the standard since some data elements presented require both a term identifier and the term, and in this example only a human readable term is given, as controlled vocabulary identifiers are not currently available.

Medicinal Product	
MPID	EU-45678-999999
Additional monitoring	Medicinal product subject to additional monitoring (black symbol)
Combined dosage form	Suspension and emulsion for emulsion for injection
Special measures	N/A
Version	
Version date	2011-06-03
Version identifier	1.0
Regulated document	
Document type	SmPC
Document identifier	1.1
Regulated document	(link to SmPC document in PDF format)
Document effective date	2011-06-03
Medicinal Product Name	
Name	INFLUENZAVAC suspension and emulsion for emulsion for injection, pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvated)
Invented name	INFLUENZAVAC
Scientific name	Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvated)
Pharmaceutical form	Suspension and emulsion for emulsion for injection
Country/Language	
Country	EU
Language	English
Product Classification	
Classification system	WHO Anatomical Therapeutic Chemical (ATC) Classification System
Classification value	J07BB02
Marketing Authorization	
Marketing number	EU/H/08452001
Country	EU
Legal status of supply	Medicinal product subject to medical prescription
Authorization status	Active
Authorization status date	2011-01-01
Validity period	2011-01-01. to 2015-12-31
Marketing Authorization Holder	

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

Table E.1 *(continued)*

Marketing Authorization Holder identifier	45678
Marketing Authorization Holder name	COMPANY A
Marketing Authorization Holder address	Street, Number 5, Paris, FR
Confidentiality indicator	N/A
Contact Person	
Name	MIGUEL FRANCE
Telecom	+33-1-000-000; miguel.france@companyA.com
Role	Qualified Person Responsible for Pharmacovigilance
Medicines Regulatory Agency	
Medicines Regulatory Agency ID	77777
Medicines Regulatory Agency name	REGULATOR A
Medicines Regulatory Agency address	Rue de la loi, 1040 Brussels, Belgium
Contact Person	
Name	MICHELLE XYZ
Telecom	+32-1-XXX-XXX; michelle.xyz@regulatorA.gov
Role	Administrator
Confidentiality indicator	N/A
Marketing Authorization Procedure	
Procedure identifier	123 XYZ
Procedure type	Centralised procedure
Procedure date	2010-01-05
Marketing Authorization Application	
Application identifier/number	EMA-00001
Application type	Initial application
Application date	2009-12-11
Associated document identifier	Decision document 12345
Marketing Status	
Country	BE
Marketing start date	2011-01-20
Jurisdictional marketing authorization number	123-456-789
Marketing Status	
Country	FR
Marketing start date	2011-03-01
Jurisdictional marketing authorization number	009-009-999
Marketing Status	
Country	UK
Marketing start date	2011-01-01
Jurisdictional marketing authorization number	666-066-666
Manufacturer/Establishment	
Manufacturer identifier	11111
Manufacturer name	COMPANY K
Manufacturer address	Street, Number 11, London, UK
Confidentiality indicator	N/A

Table E.1 *(continued)*

Contact Person	
Name	JOHN ABC
Telecom	+44-207-XXX-XXXX; john.ABCf@companyK.com
Role	Responsible Person for Batch Release
Manufacturing Operation	
Operation type	Batch release
Manufacturing authorization reference number	5454TZ
Effective date	2009-04-15
Confidentiality indicator	N/A
Medicines Regulatory Agency (manufacturing)	
Medicines Regulatory Agency ID	88888
Medicines Regulatory Agency name	REGULATOR B
Medicines Regulatory Agency address	ABC Strada 67, Rome, IT
Contact Person	
Name	ROBERTO LMN
Telecom	+39-1-999-999; Roberto.lmn@ regulatorB.gov.it
Role	Administrator
Packaged Medicinal Product	
PCID	EU-45678-999999-001
Package description	INFLUENZAVAC suspension and emulsion for emulsion for injection, pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvated), pack of one vial (type I glass) of 2, ml suspension with a stopper (butyl rubber) and one vial (type I glass) of 2,5 ml emulsion with a stopper (butyl rubber)
Package Item (Container)	
Package item container type	Box
Package item container quantity	1
Package item material	Recycled cardboard (identifier from ISO 11238)
Alternate material	N/A
Data carrier identifier	(01)07665431234887(17)101231(10)ABC
Package Component	
Component type	N/A
Component material	N/A
Component material alternate	N/A
Physical Characteristics	
Height	8,0 cm
Width	8,0 cm
Depth	4,3 cm
Image	Link to box.jpg
Batch Identifier	
BAID_1	EU-45678-999999-001-999879-060514
Package Item (Container)	
Package item container type	Vial
Package item container quantity	1
Batch Identifier	
BAID_2	EU-35353-111111-001-123456-060514

Table E.1 *(continued)*

Data carrier identifier	(01)07665431234566(17)101231(10)XYZ
Package item material	Type I glass (identifier from ISO 11238)
Alternate material	N/A
Physical Characteristics	
Height	6,5 cm
External diameter	2,5 cm
Nominal volume	7,00 ml
Colour	Clear
Package Component	
Component type	Stopper
Component material	Butyl rubber (identifier from ISO 11238)
Component material alternate	Propyl rubber (identifier from ISO 11238)
Physical Characteristics	
Height	0,5 cm
External diameter	0,80 cm
Colour	Grey
Manufactured Item	
Manufactured dose form	Suspension for emulsion
Unit of presentation	Vial
Manufactured item quantity	0,5 ml
Ingredient	
Ingredient role	Active
Substance(s)	
Specified substance group 2	A/Nevada/9/2009 (H1N1)v-like strain (Z-999Z), Smith and Co
Confidentiality indicator – specified substance	NA
Strength (presentation)	3,75 micrograms/0,5 ml
Strength (concentration)	7,5 micrograms/1 ml
Ingredient(s)	
Ingredient role	Excipient
Specified substance group 3	Polysorbat 80, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient(s)	
Ingredient role	Excipient
Specified substance group 3	Octoxynol 10, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient(s)	
Ingredient role	Excipient
Substance	Thiomersal
Confidentiality indicator	N/A
Ingredient(s)	
Ingredient role	Excipient
Specified substance group 3	Disodium phosphate, anhydrous, (Na2HPO4) European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient(s)	

Table E.1 *(continued)*

Ingredient role	Excipient
Specified substance group 3	Potassium chloride, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient(s)	
Ingredient role	Excipient
Specified substance group 3	Magnesium chloride, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient(s)	
Ingredient role	Excipient
Specified substance group 3	Water for injections, European Pharmacopoeia
Confidentiality indicator	N/A
Package Item (Container)	
Package item container type	Vial
Package item container quantity	1
Batch Identifier	
BAID_2	EU-35353-111111-001-123456-060514
Data carrier identifier	(09)067999441234588(25)108787(10)XYZ
Package item material	Type I glass (identifier from ISO 11238)
Alternate material	N/A
Data carrier identifier	(01)07665777734566(17)101231(10)UVW
Physical Characteristics	
Height	2,5 cm
External diameter	1,5 cm
Nominal volume	3,00 ml
Colour	Clear
Package Component	
Component type	Stopper
Component material	Butyl rubber (identifier from ISO 11238)
Component material alternate	Propyl rubber (identifier from ISO 11238)
Physical Characteristics	
Height	0,5 cm
External diameter	0,80 cm
Colour	Blue
Manufactured Item	
Manufactured dose form	Emulsion
Unit of presentation	Vial
Manufactured item quantity	0,5 ml
Ingredient	
Ingredient role	Adjuvant
Specified substance group 1	AS03
Confidentiality indicator	N/A
Ingredient	
Ingredient role	Excipient
Specified substance group 3	Sodium chloride, European Pharmacopoeia
Confidentiality indicator	N/A

Table E.1 *(continued)*

Ingredient	
Ingredient role	Excipient
Specified substance group 3	Disodium phosphate, anhydrous, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient	
Ingredient role	Excipient
Specified substance group 3	Potassium chloride, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient	
Ingredient role	Excipient
Specified substance group 3	Water for injections, European Pharmacopoeia
Confidentiality indicator	N/A
Device	
Device type	Administration device
Device trade name	N/A
Device quantity	1
Device listing number	N/A
Model number	N/A
Batch number	N/A
Expiration date	N/A
Device material	Stainless steel (identifier from ISO 11238)
Device material alternate	N/A
Allergenicity indicator	N/A
Sterility indicator	Sterile
Sterilization requirement indicator	N/A
Device usage	Single use
Device Nomenclature	
Nomenclature system	UDI
Nomenclature value	123-Syr
Device Batch Identifier	
Batch number	123-ABD
Expiry date	2016-12-18
Physical Characteristics	
Height	3 cm
Weight	N/A
Depth	N/A
Weight	N/A
Nominal volume	N/A
External diameter	21 G
Shape	N/A
Colour	N/A
Imprint	N/A
Image	N/A
Other Characteristics	
Other characteristics code	N/A

Table E.1 *(continued)*

Other characteristics code	N/A
Shelf Life/Storage	
Shelf life type	In original pack
Shelf life time period	2 years
Special precautions for storage	Do not store below 2 °C and above 25 °C
Pharmaceutical Product	
Administrable dose form	Emulsion for injection
Unit of presentation	Vial
Manufactured item quantity	0,5 ml
Pharmaceutical Product Characteristics	
Pharmaceutical product characteristics code system	Regulatory classification system
Pharmaceutical product characteristics value	Biologic, vaccine
Manufactured Item	
Manufactured dose form	Suspension for emulsion
Unit of presentation	Vial
Manufactured item quantity	0,5 ml
Ingredient	
Ingredient role	Active
Specified substance group 2	A/Nevada/9/2009 (H1N1)v-like strain (Z-999Z), manufacturer B
Confidentiality indicator – specified substance	Yes
Strength (concentration)	3,75 micrograms/0,5 ml
Ingredient(s)	
Ingredient role	Excipient
Specified substance group 3	Polysorbate 80, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient(s)	
Ingredient role	Excipient
Specified substance group 3	Octoxynol 10, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient(s)	
Ingredient role	Excipient
Substance	Thiomersal
Confidentiality indicator	N/A
Ingredient(s)	
Ingredient role	Excipient
Specified substance group 3	Disodium phosphate, anhydrous, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient(s)	
Ingredient role	Excipient
Specified substance group 3	Potassium chloride, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient(s)	

Table E.1 *(continued)*

Ingredient role	Excipient
Specified substance group 3	Magnesium chloride, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient(s)	
Ingredient role	Excipient
Specified substance group 3	Water for injections, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient	
Ingredient role	Adjuvant
Specified substance group 1	AS03
Confidentiality indicator	N/A
Ingredient	
Ingredient role	Excipient
Specified substance group 3	Sodium chloride, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient	
Ingredient Role	Excipient
Specified substance Group 3	Disodium phosphate, anhydrous, European Pharmacopoeia
Confidentiality Indicator	N/A
Ingredient	
Ingredient role	Excipient
Specified substance group 3	Potassium chloride, European Pharmacopoeia
Confidentiality indicator	N/A
Ingredient	
Ingredient role	Excipient
Specified substance group 3	Water for injections, European Pharmacopoeia
Confidentiality indicator	N/A
PhPID Set	
PhPID_SUB_L1	7876567666 - A/Nevada/9/2009 (H1N1)v-like strain (Z-999Z)
PhPID_SUB_L2	7876567888 - A/Nevada/9/2009 (H1N1)v-like strain (Z-999Z) – 3,75 micrograms/0,5 ml
PhPID_SUB_L3	3232321121 - A/Nevada/9/2009 (H1N1)v-like strain (Z-999Z) – emulsion for injection
PhPID_SUB_L4	7957493029 - A/Nevada/9/2009 (H1N1)v-like strain (Z-999Z) - 3,75 micrograms/0,5 ml - emulsion for injection
PhPID_SPSUB_L1	8432123456 - A/Nevada/9/2009 (H1N1)v-like strain (Z-999Z), manufacturer B – AS03
PhPID_SPSUB_L2	7876567888 - A/Nevada/9/2009 (H1N1)v-like strain (Z-999Z), manufacturer B – AS03 - 3,75 micrograms/0,5 ml
PhPID_SPSUB_L3	5454321678 - A/Nevada/9/2009 (H1N1)v-like strain (Z-999Z), manufacturer B – AS03 – emulsion for injection
PhPID_SPSUB_L4	3431684358 - A/Nevada/9/2009 (H1N1)v-like strain (Z-999Z), manufacturer B – AS03 3,75 micrograms/0,5 ml emulsion for injection
Administrable Dose Form	
Administrable dose form	Emulsion for injection
Administrable dose form	Administrable dose form
Route of Administration	

Table E.1 *(continued)*

Route of administration	Intramuscular injection
Therapeutic Indication	
Indication text	Prophylaxis of influenza in an officially declared pandemic situation
Indication as disease/symptom/ procedure	Influenza
Disease status	Pandemic
Intended effect	Prophylaxis
Timing/duration	N/A
Population specifics	N/A
Other therapy specifics	N/A
Undesirable Effects	
Undesirable effect as symptom/ condition/effect	Lymphadenopathy
Frequency of occurrence	Very common (≥1/10)
Symptom/condition/effect classification	Blood and lymphatic system disorders
Undesirable Effects	
Undesirable Effect as Symptom/ Condition/Effect	Insomnia
Frequency of occurrence	Uncommon (≥1/1 000 to < 1/100)
Symptom/condition/effect classification	Psychiatric disorders
Undesirable Effects	
Undesirable effect as symptom/ condition/effect	Ecchymosis at the site injection
Frequency of occurrence	Common (≥1/100 to ≥ 1/10)
Symptom/condition/effect classification	Skin and subcutaneous tissue disorders
Undesirable Effects	
Undesirable effect as symptom/ condition/effect	Pain
Frequency of occurrence	60,0 %
Age range	3-5 years
Contra-indications	
Contra-indication as symptom/ condition/effect	Anaphylactic (i.e. life-threatening) reaction to any of the constituents or trace residues (egg and chicken protein, ovalbumin, formaldehyde, gentamicin sulfate and sodium deoxycholate) of this vaccine
Disease status	History of anaphylactic reactions
Co-morbidity	N/A
Population specifics	N/A
Other therapy specifics	N/A

Annex F
(informative)

Class and attribute listing

Table F.1 — Medicinal Product

Attribute	Datatype description	ISO 21090 datatype	Description/comments
MPID	Text	< II >	
IMPID Cross Reference	Text	< II >	
Combined pharmaceutical dose form	ID and Term from ISO 11239	< CD >	
Additional monitoring indicator	ID and Term from a CV	< CD >	
Special measures	ID and Term from a CV	< CD >	
NOTE 1 ID = Identifier. NOTE 2 CV = Controlled Vocabulary.			

Table F.2 — Version

Attribute	Datatype	ISO 21090 datatype	Description/comments
Version date	Point in time	< TS >	
Version identifier	Text	< II >	

Table F.3 — Regulated Document

Attribute	Datatype	ISO 21090 datatype	Description/comments
Document Type	ID and Term from a CV	< CD >	
Document Identifier	Text	< II >	
Regulated Document	Document format	< ED >	
Document Effective Date	Point in time	< TS >	
NOTE 1 ID = Identifier. NOTE 2 CV = Controlled Vocabulary.			