



BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of EN ISO 11615:2017+A1:2022. It is identical to ISO 11615:2017, incorporating amendment 1:2022. It supersedes BS EN ISO 11615:2012, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by **A1** **A1**.

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

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

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2022
Published by BSI Standards Limited 2022

ISBN 978 0 539 14101 6

ICS 35.240.80

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 January 2018.

Amendments/corrigenda issued since publication

Date	Text affected
30 September 2022	Implementation of ISO amendment 1:2022 with CEN endorsement A1:2022

English Version

**Health informatics - Identification of medicinal products -
Data elements and structures for the unique identification
and exchange of regulated medicinal product information
(ISO 11615:2017)**

Informatique de santé - Identification des médicaments
- Éléments de données et structures pour
l'identification unique et l'échange d'informations sur
les médicaments contrôlés (ISO 11615:2017)

Medizinische Informatik - Identifikation von
Arzneimitteln - Datenelemente und -strukturen zur
Identifikation von Arzneimitteln für den Austausch von
behördlich genehmigten Arzneimittelinformationen
(ISO 11615:2017)

This European Standard was approved by CEN on 17 November 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 11615:2017) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2018, and conflicting national standards shall be withdrawn at the latest by June 2018.

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

This document supersedes EN ISO 11615:2012.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11615:2017 has been approved by CEN as EN ISO 11615:2017 without any modification.

European foreword to Amendment 1

This document (EN ISO 11615:2017/A1:2022) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

This Amendment to the European Standard EN ISO 11615:2017 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2023, and conflicting national standards shall be withdrawn at the latest by March 2023.

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

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice to Amendment 1

The text of ISO 11615:2017/Amd 1:2022 has been approved by CEN as EN ISO 11615:2017/A1:2022 without any modification.

Contents

Page

Foreword	vi
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms, definitions and abbreviated terms	2
4 Message exchange format	13
5 Conformance terminology and context as it relates to the ISO IDMP standards and corresponding IDMP technical specifications	14
6 Concepts required for the unique identification of Medicinal Products	14
6.1 General considerations	14
6.2 Authorised Medicinal Products	14
6.3 Investigational Medicinal Products	15
6.4 Concepts required for the unique identification of a Medicinal Product and the association with PhPID(s)	15
6.5 Concepts required for the unique identification of Medicinal Products and the association with the marketing authorisation number	15
6.6 Concepts required for the unique identification of Medicinal Products and the association with data carrier identifiers	16
7 Description of the information modelling principles and practices	17
7.1 General considerations	17
7.2 Conceptual overview diagrams	17
7.3 High-level diagrams	18
7.4 Detailed description diagrams	18
7.4.1 General	18
7.4.2 Relationships between classes	19
7.4.3 Attributes of classes	20
7.4.4 Generalised classes and patterns	20
7.4.5 Translation and language	20
8 Identifying characteristics for authorised Medicinal Products	20
8.1 Primary identifiers — General considerations	20
8.2 Medicinal Product Identifier (MPID)	21
8.2.1 General considerations	21
8.2.2 MPID code segments	21
8.3 Packaged Medicinal Product Identifier (PCID)	22
8.3.1 General considerations	22
8.3.2 Package description (PCID) code segment	23
8.4 Medicinal Product Batch Identifier (BAID1)	23
8.5 Medicinal Product Batch Identifier (BAID2)	23
9 Information for an authorised Medicinal Product	24
9.1 Authorised Medicinal Product — Information overview	24
9.1.1 General	24
9.1.2 Medicinal Product	24
9.1.3 Medicinal Product name	24
9.1.4 Header	25
9.1.5 Manufacturer/Establishment (organisation)	25
9.1.6 Marketing authorisation	25
9.1.7 Packaged Medicinal Product	25
9.1.8 Pharmaceutical product	25
9.1.9 Ingredient	25
9.1.10 Clinical particulars	25
9.2 Medicinal Product	25

9.2.1	General	25
9.2.2	Detailed description of Medicinal Product information	26
9.3	Marketing authorisation	32
9.3.1	General	32
9.3.2	Detailed description of marketing authorisation information	33
9.4	Organisation	38
9.4.1	General	38
9.4.2	Detailed description of organisation information	38
9.5	Manufacturer/Establishment (organisation)	41
9.5.1	General	41
9.5.2	Detailed description of manufacturer/establishment (organisation) information	41
9.6	Packaged Medicinal Product, including manufactured item and device	42
9.6.1	General	42
9.6.2	Detailed description of Packaged Medicinal Product information	43
9.7	Ingredient, substance and strength	52
9.7.1	General	52
9.7.2	Detailed description of ingredients, substance and strength information	52
9.8	Pharmaceutical product and device	55
9.8.1	General	55
9.8.2	Detailed description of pharmaceutical product and device information	55
9.9	Clinical particulars	57
9.9.1	General	57
9.9.2	Detailed description for clinical particulars information	58
10	Identifying characteristics for Investigational Medicinal Products	62
10.1	General	62
10.2	Primary identifiers	62
10.2.1	General considerations	62
10.3	Investigational Medicinal Product Identifier (IMPID)	63
10.3.1	General considerations	63
10.3.2	IMPID code segments	63
10.4	Investigational Medicinal Product Package Identifier (IPCID)	64
10.4.1	General provisions	64
10.4.2	Package description code segment	64
10.5	Investigational Medicinal Product Batch Identifier (BAID1)	65
10.6	Investigational Medicinal Product Batch Identifier (BAID2)	65
11	Information for an Investigational Medicinal Product	65
11.1	General	65
11.2	Conceptual overview of the information for an Investigational Medicinal Product	65
11.2.1	General	65
11.2.2	Investigational Medicinal Product	66
11.2.3	Investigational Medicinal Product name	66
11.2.4	Header	66
11.2.5	Manufacturer/Establishment (organisation)	66
11.2.6	Clinical trial authorisation	67
11.2.7	Investigational Packaged Medicinal Product	67
11.2.8	Pharmaceutical product	67
11.2.9	Ingredient	67
11.2.10	Clinical particulars	67
11.3	Investigational Medicinal Product	67
11.3.1	General	67
11.3.2	Detailed description of Investigational Medicinal Product information	67
11.4	Clinical trial authorisation	70
11.4.1	General	70
11.4.2	Detailed description of clinical trial authorisation information	70
11.5	Manufacturer/Establishment (organisation)	72
11.6	Investigational Packaged Medicinal Product	72

11.7	Pharmaceutical product.....	72
11.7.1	General.....	72
11.7.2	Pharmaceutical product.....	73
11.7.3	Dosing and route of administration.....	73
11.8	Ingredient.....	73
11.9	Clinical particulars.....	74
11.10	PhPID sets.....	74
11.11	Device nomenclature.....	74
11.12	Device batch identifier.....	74
11.13	Physical characteristics.....	74
11.14	Other characteristics.....	74
Annex A (normative) Full model — Authorised Medicinal Products detailed diagram.....		75
Annex B (normative) Full model — Investigational Medicinal Products detailed diagram.....		76
Annex C (informative) Class name and attribute translations and synonyms for the identification of medicinal products (IDMP) .....		77
Bibliography.....		78

Foreword

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

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

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

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

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

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

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

Introduction

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

These sets of standards and technical specifications comprise:

- ISO 11615
- ISO/TS 20443;
- ISO 11616;
- ISO/TS 20451;
- ISO 11238;
- ISO/TS 19844;
- ISO 11239;
- ISO/TS 20440;
- ISO 11240.

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

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

- regulatory medicines authority to regulatory medicines authority;
- pharmaceutical company to regulatory medicines authority;
- sponsor of a clinical trial to regulatory medicines authority;
- regulatory medicines authority to other stakeholders (as applicable);
- regulatory medicines authority to worldwide-maintained data sources.

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

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

There are many terms in use to describe basic concepts in the regulatory, pharmaceutical and healthcare standards development domain for different purposes and in different contexts. The terms and definitions given in this document are to be applied for the concepts which are required to uniquely identify, characterise and exchange regulated Medicinal Products and associated information.

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

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

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

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

A1 Reference to the use of other normative IDMP and messaging standards for Medicinal Product information is included in this document to support successful information exchange. **A1**

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

1 Scope

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

Taken together, the standards listed in the Introduction define, characterise and uniquely identify regulated Medicinal Products for human use during their entire life cycle, i.e. from development to authorisation, post-marketing and renewal or withdrawal from the market, where applicable.

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

2 Normative references

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

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

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

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

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

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

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

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

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

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

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

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

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

HL7 Version 3 Standard, Structured Product Labelling

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

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

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

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

3.1.1

adjuvant

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

3.1.2

administrable dose form

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

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

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

3.1.3

administration device

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

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

[SOURCE: ENV 12610:1997]

3.1.4

allergen

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

3.1.5

authorisation date

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

3.1.6**authorisation procedure**

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

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

3.1.7**authorisation status**

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

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

3.1.8**batch**

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

3.1.9**batch number**

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

3.1.10**characteristic**

abstraction of a property of an object

3.1.11**clinical trial**

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

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

3.1.12**clinical trial authorisation**

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

3.1.13**class**

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

3.1.14**combined pharmaceutical dose form**

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

3.1.15**common name**

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

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

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

3.1.16

container

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

3.1.17

contraindication

situations where the *Medicinal Product* ([3.1.50](#)) shall not be given for safety reasons

3.1.18

controlled vocabulary

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

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

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

3.1.19

datatype

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

[SOURCE: ISO 11404:2007, 3.12]

3.1.20

device listing number

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

3.1.21

device model number

identifier ([3.1.26](#)) assigned by a medical device *manufacturer* ([3.1.38](#)) to a particular design or version of a *medical device* ([3.1.49](#))

3.1.22

distributor

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

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

3.1.23

dose

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

3.1.24

dose form

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

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

3.1.25**Global Trade Item Number****GTIN**

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

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

3.1.26**identifier**

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

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

[SOURCE: ENV 12610:1997]

3.1.27**immediate container**

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

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

[SOURCE: ENV 12610:1997]

3.1.28**ingredient**

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

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

3.1.29**intermediate packaging**

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

3.1.30**invented name**

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

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

3.1.31**Investigational Medicinal Product**

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

3.1.32

Investigational Medicinal Product Identifier

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

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

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

3.1.33

Investigational Medicinal Product Package Identifier

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

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

3.1.34

jurisdiction

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

3.1.35

legal status of supply

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

3.1.36

manufactured dose form

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

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

3.1.37

manufactured item

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

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

3.1.38

manufacturer

organisation that holds the authorisation for the manufacturing process

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

3.1.39**manufacturing authorisation**

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

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

3.1.40**marketing authorisation**

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

3.1.41**marketing authorisation holder**

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

3.1.42**marketing authorisation number**

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

3.1.43**marketing authorisation procedure**

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

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

3.1.44**marketing start date**

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

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

3.1.45**marketing stop date**

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

3.1.46**marketing status**

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

3.1.47**material**

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

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

3.1.48**measurement point**

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

3.1.49

medical device

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

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

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

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

3.1.50

Medicinal Product

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

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

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

[SOURCE: ENV 13607 and ENV 12610]

3.1.51

Medicinal Product Batch Identifier 1

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

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

3.1.52

Medicinal Product Batch Identifier 2

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

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

3.1.53**Medicinal Product Identifier**

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

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

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

3.1.54**Medicinal Product name**

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

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

3.1.55**Medicinal Product Package Identifier**

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

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

3.1.56**medicines regulatory agency**

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

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

3.1.57**outer packaging**

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

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

3.1.58**package item**

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

3.1.59**Packaged Medicinal Product**

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

3.1.60

pharmaceutical product

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

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

3.1.61

pharmaceutical product identifier

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

3.1.62

pharmacovigilance

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

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

- collecting and managing data on the safety of medicines;
- looking at the data to detect “signals” (any new or changing safety issue);
- evaluating the data and making decisions with regard to safety issues;
- acting to protect public health (including regulatory action);
- communicating with stakeholders;
- auditing of both the outcomes of action taken and the key processes involved.

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

- patients as the users of medicines;
- doctors, pharmacists, nurses and all other healthcare professionals working with medicines and regulatory authorities responsible for monitoring the safety of medicines;
- pharmaceutical companies, and companies importing or distributing medicines.

3.1.63

physical characteristic

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

3.1.64

primary identifier

each one of the unique IDMP *identifiers* (3.1.26)

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

3.1.65

procedure number

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

3.1.66

procedure type

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

3.1.67

product classification

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

3.1.68**product labelling**

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

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

3.1.69**protocol number**

identification or tracking number assigned to the clinical trial protocol

3.1.70**qualitative composition**

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

- the *substance* (3.1.80) and *specified substance* (3.1.77) description;
- the excipients, whatever their nature or the quantity used, including colouring matter, preservatives, *adjuvants* (3.1.1), stabilisers, thickeners, emulsifiers, flavouring and aromatic substances, etc.

3.1.71**quantitative composition**

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

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

3.1.72**reference strength**

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

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

3.1.73**region**

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

3.1.74**registration number**

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

3.1.75**regulated document**

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

3.1.76

route of administration

path by which the *pharmaceutical product* ([3.1.60](#)) is taken into or makes contact with the body

3.1.77

specified substance

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

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

3.1.78

sponsor

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

3.1.79

strength range

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

3.1.80

substance

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

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

3.1.81

target population

type of patients or consumers for which the indication of a *Medicinal Product* ([3.1.50](#)) is authorised or is under investigation

3.1.82

therapeutic indication

defines the target disease or condition for which the *Medicinal Product* ([3.1.50](#)) is authorised or under investigation

3.1.83

trademark

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

3.1.84

unit of presentation

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

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

3.1.85**vocabulary**

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

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

3.2 Abbreviated terms

BAID1	Medicinal Product Batch Identifier (outer packaging)
BAID2	Medicinal Product Batch Identifier (immediate packaging)
BRIDG	The Biomedical Research Integrated Domain Group Model
CV	Controlled Vocabulary
GTIN	Global Trade Item Number
IBAIID1	Investigational Medicinal Product Batch Identifier (outer packaging)
IBAIID2	Investigational Medicinal Product Batch Identifier (immediate packaging)
IBD	International Birth Date
ID	Identifier
IDMP	Identification of Medicinal Products
IMP	Investigational Medicinal Product
IMPID	Investigational Medicinal Product Identifier
INN	International non-proprietary name
IMDRF	International Medical Devices Regulators' Forum
IPCID	Investigational Medicinal Product Package Identifier
MPID	Medicinal Product Identifier
OID	Object Identifier
OMG	Object Management Group
PCID	Medicinal Product Package Identifier
PhPID	Pharmaceutical Product Identifier
SPC/SmPC	Summary of Product Characteristics
UML	Unified Modeling Language (Object Management Group, Inc.)
UDI	Unique Device Identification Code (IMDRF)
WHO	World Health Organization

4 Message exchange format

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

files exist and range from basic software tools to comprehensive information management systems. SPL instances (code snippets) are provided in the ISO/TS 20443 to illustrate the representation of an IDMP concept within the HL7 SPL message exchange format. Technical conformance criteria for SPL messages will not be addressed in this document nor in the ISO/TS 20443 and shall be left to regional guidance/implementation per their respective requirements. A reference to the most up to date HL7 CPM and SPL reference as a resource for IDMP implementation is accessible on the HL7 website: <http://www.hl7.org>.

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

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

6 Concepts required for the unique identification of Medicinal Products

6.1 General considerations

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

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

Such identification shall apply the principles described below.

6.2 Authorised Medicinal Products

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

- a) the assignment of a unique Medicinal Product Identifier (MPID) to reliably recognise, monitor and trace the use of Medicinal Products;
- b) the assignment of a unique Medicinal Product Package Identifier (PCID) to reliably recognise and trace Medicinal Products as packaged for sale or supply;
- c) the assignment of a unique Medicinal Product Batch Identifier (BAID1) to reliably recognise and trace a manufacturer’s batch number, which appears on the outer packaging of the Medicinal Product, in compliance with the requirements of the marketing authorisation;
- d) the assignment of a unique Medicinal Product Batch Identifier (BAID2) to reliably recognise and trace a batch number on the immediate packaging of the Medicinal Product, where this is not the outer packaging, in compliance with the requirements of the marketing authorisation.

6.3 Investigational Medicinal Products

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

- a) the assignment of a unique Investigational Medicinal Product Identifier (IMPID) to reliably recognise, monitor and trace the use of Investigational Medicinal Products which are studied in clinical trials;
- b) the assignment of a unique Investigational Medicinal Product Package Identifier (IPCID), where applicable, to reliably recognise and trace the Investigational Medicinal Product as packaged for supply during clinical trials;
- c) the assignment of a unique Investigational Medicinal Product Batch Identifier (BAID1), where applicable, to reliably recognise and trace a batch number which appears on the outer packaging of the Investigational Medicinal Product in compliance with the requirements of the clinical trial authorisation;
- d) the assignment of a unique Investigational Medicinal Product Batch Identifier (BAID2), where applicable, to reliably recognise and trace a batch number which appears on the immediate packaging of the Investigational Medicinal Product, where this is not the outer packaging, in compliance with the requirements of the clinical trial authorisation.

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

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

- a) a Medicinal Product may relate to one or more pharmaceutical products as part of a treatment regimen (e.g. a kit containing vaginal tablets 500 mg and a vaginal cream 10 %);
- b) the characterisation of the pharmaceutical product(s) using the active substance(s) or specified substance(s), the (reference) strength thereof, the pharmaceutical (administrable) dose form(s) and any medical device being an integral part of the Medicinal Product (e.g. a scaffolding for cell-based Medicinal Product);
- c) the description of the pharmaceutical product(s) in the pharmaceutical dose form approved for administration, where applicable, after reconstitution and as authorised in accordance with the regulated product information;
- d) the association of the regulated (investigational) Medicinal Product and the pharmaceutical product(s) using the PhPID(s).

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

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

- a) To a Medicinal Product — without specific discrimination between different pack sizes (e.g. Drug B - ursodeoxycholic acid¹⁾ - 250 mg film-coated tablets 50 tablets - authorisation number 15.2YZ; Drug B - 250 mg film-coated tablets 100 tablets - authorisation number also 15.2YZ).
- b) To a Medicinal Product and one or more packages — allowing for discrimination at product and package level (e.g. Drug C - amoxicillin capsule, Pharmacopoeia, for oral administration, containing

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

250 mg - authorisation number (product level) OXYZ1-20Z0; authorisation number (package level) OXYZ1-20Z0-01 for bottles of 100 and OXYZ1-20Z0-05 for bottles of 500. Drug C - amoxicillin capsules, Pharmacopoeia, for oral administration, containing 500 mg - authorisation number (product level) OXYZ1-20K0; authorisation number (package level) OXYZ1-20K0-01 for bottles of 100 and OXYZ1-20K0-05 for bottles of 500).

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

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

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

- The MPID shall always be associated with the applicable marketing authorisation number of the Medicinal Product (e.g. the MPID “Country-055-0957” shall be associated with the authorisation number *Country 15.2YZ* for Drug B -250 mg film-coated tablets, which comes in two pack sizes of 50 and 100 tablets).
- The PCID shall always be associated with the applicable marketing authorisation number for a specific package or presentation (e.g. PCID *Country-0787-2550-05* shall be associated with *OXYZ1-20Z0-05* for amoxicillin capsules, Pharmacopoeia, for oral administration, containing 250 mg).

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

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

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

- product name, product brand and product description;
- formulation (active ingredients);
- strength;
- dosage (or usage);
- net quantity (weight, volume, or other dimension impacting trade);
- packaging configuration;
- form, fit or function;
- for groupings, the number of elementary items contained and their subdivision in subpackaging units, the nature of the grouping (carton, blister, blister-cell).

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

NOTE Reference is made to ISO/TS 16791.

7 Description of the information modelling principles and practices

7.1 General considerations

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

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

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



Figure 1 — Legend for colour coding of model classes

7.2 Conceptual overview diagrams

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

The Medicinal Product and Investigational Medicinal Product overarching models (see [Figure 5](#) and [Figure 15](#)) show a single representative class from each particular information section, related to the core concept (either the Medicinal Product or the Investigational Medicinal Product).

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

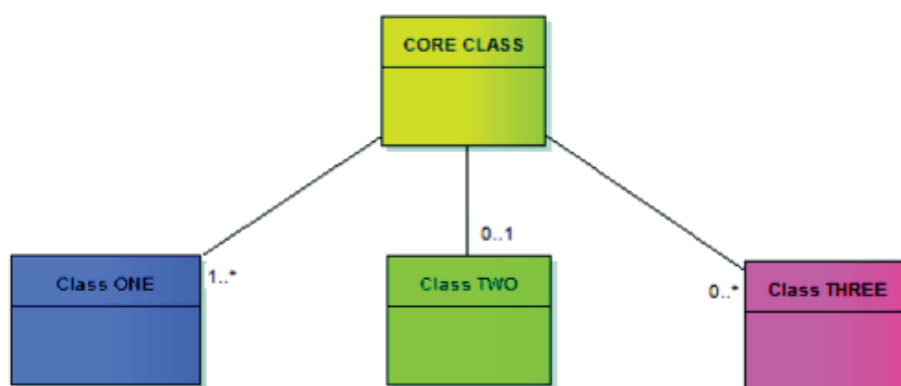


Figure 2 — Example conceptual overview diagram

7.3 High-level diagrams

The high-level diagrams (see [Figure 3](#)) provided at the start of each subclause of information show all the classes required to describe the information for that section and the conceptual relationships between those classes, with the starting point always as the (investigational) Medicinal Product.

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

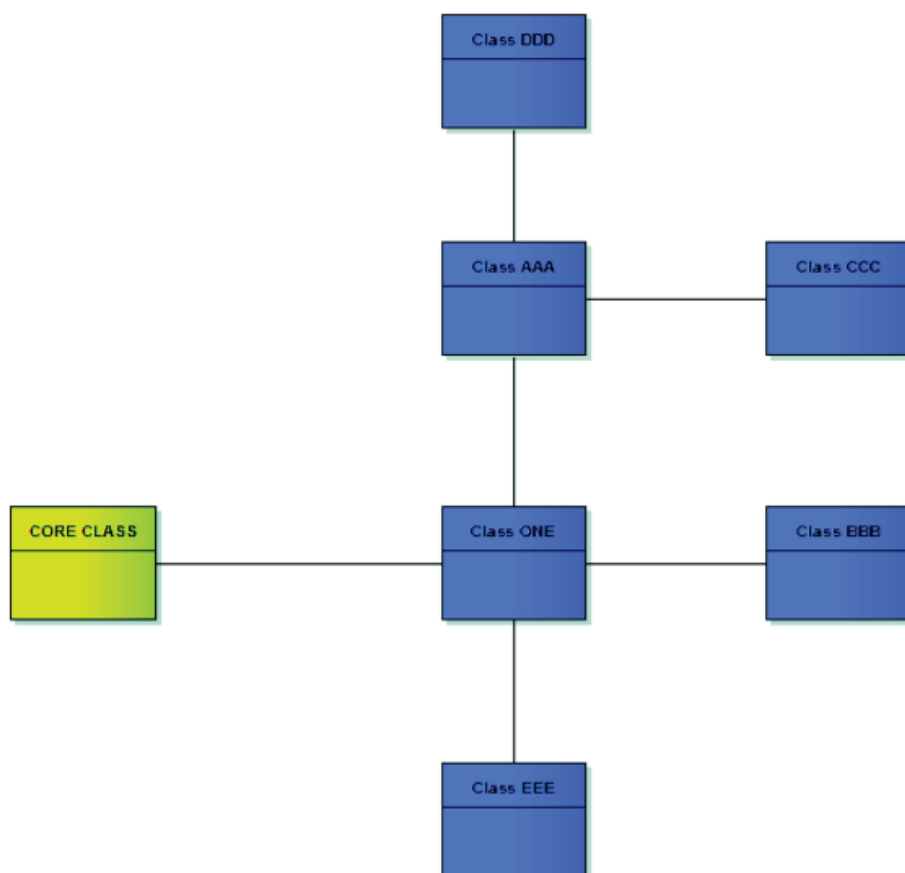


Figure 3 — Example high-level diagram

7.4 Detailed description diagrams

7.4.1 General

The detailed description diagrams (see [Figure 4](#)) for each subclause show all the classes and all the attributes required to describe the information for that section and the detail of the conceptual relationships between those classes.