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

Informatique de santé — Identification des produits médicaux — Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées concernant les informations du produit médical

ICS 35.240.80
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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 document 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, and by Technical Committee CEN/TC 251, Health informatics and in collaboration and with the co-operation of the Clinical Data Interchange Standards Consortium (CDISC), Health Level Seven (HL7) and the International Health Terminology Standards Development Organisation (IHTSDO).
0 Introduction

0.1 General introduction

This standard was developed in response to a worldwide demand for internationally harmonised specifications for medicinal products. It is one of a group of five standards which together provide the basis for the unique identification of medicinal products. The group of standards comprises:

- ISO/DIS 11615 Health Informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information
- ISO/DIS 11616 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information
- ISO/DIS 11238 Health Informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances
- ISO/DIS 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/DIS 11240 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement

The 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 medicinal products and pharmacovigilance it is necessary to reliably exchange medicinal product information in a robust and reliable manner. The IDMP standards therefore support the following interactions:

- Regulator to regulator e.g. European Medicines Agency to the US Food and Drug Administration (FDA) or vice versa
- Pharmaceutical company to regulator e.g. Pharma Company A to Health Canada
- Sponsor of clinical trial to regulator e.g. University X to Austrian Medicines Agency
- Regulator to other stakeholders e.g. UK Medicines Health Regulatory Agency (MHRA) to National Health System (NHS)
- Interaction of regulator with worldwide-maintained data sources e.g. Pharmaceutical and Medical Device Agency (PMDA) and the assignment of a new substance identifier.

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 to support 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
described in this standard apply 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 standard are intended to facilitate the interpretation and application of legal and regulatory requirements but they are used without prejudice to any legally binding document. In case of doubt or potential conflict, the terms and definitions contained in legally binding documents prevail.

0.2 Context of data elements, structures and their relationships

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

- to specify data elements, structures and relationships between the data elements required to uniquely and with certainty identifies medicinal products for human use;
- to specify definitions of terms for all data elements required to uniquely and with certainty identifies medicinal products for human use.

In addition, to support successful related information exchange, a reference to the use of other normative IDMP and messaging standards for medicinal product information is included in this standard.
Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated medicinal product information

1 Scope

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 authorization, post-marketing and renewal or withdrawal from the market, where applicable.

More specifically, the standard establishes definitions and concepts and describes data elements and their structural relationships, which are required for the detailed description and unique identification of medicinal products.

Furthermore, to support the successful information exchange in relation to the unique identification and characterisation of medicinal products, the use of other normative IDMP messaging standards is also included, which together shall be applied in the context of this 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/DIS 11616, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

ISO/DIS 11238, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances

ISO/DIS 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/DIS 11240, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement

ISO/DIS 27953, Health Informatics — Pharmacovigilance — Individual Case Safety Report


ISO 2382-4:1999, Information technology - Vocabulary - Part 4: Organization of data

ISO 3166-1:2006, Codes for the representation of names of countries and their subdivisions - Part 1: Country codes
3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

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

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

EXAMPLES

- Mineral salts, e.g., aluminium hydroxide and aluminium or calcium phosphate gels.
- Oil emulsions and surfactant based formulations, e.g., MF59 (microfluidised detergent stabilised oil-in-water emulsion), QS21 (purified saponin), AS02 [SBAS2] (oil-in-water emulsion + MPL + QS-21), Montanide ISA-51 and ISA-720 (stabilised water-in-oil emulsion).
- Particulate adjuvants, e.g., virosomes (unilamellar liposomal vehicles incorporating influenza haemagglutinin), AS04 ([SBAS4] Al salt with MPL), ISCOMS (structured complex of saponins and lipids), polylactide co-glycolide (PLG).
- Microbial derivatives (natural and synthetic), e.g., monophosphoryl lipid A (MPL), Detox (MPL + M. Phlei cell wall skeleton), AGP [RC-529] (synthetic acylated monosaccharide), DC_Chol (lipoidal immunostimulators able to self organise into liposomes), OM-174 (lipid A derivative), CpG motifs (synthetic oligonucleotides containing immunostimulatory CpG motifs), modified LT and CT (genetically modified bacterial toxins to provide non-toxic adjuvant effects).

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1 To be published
• Endogenous human immunomodulators, e.g., hGM-CSF or hIL-12 (cytokines that may be administered either as protein or plasmid encoded), Immudaptin (C3d tandem array). Inert vehicles, such as gold particles.

NOTE Other novel types of adjuvants not listed above can be under development.

3.1.2 administrable dose form
pharmaceutical dose form as administered to the patient, after any necessary transformation of the packaged, manufactured pharmaceutical dose form has been carried out

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

3.1.3 administration device
device intended for correct administration of the medicinal product

[ENV 12610:1997]

3.1.4 allergens
materials of concern
nonparasitic antigen capable of stimulating a type-I hypersensitivity reaction in atopic individuals

EXAMPLE Materials of concern relate to ingredients in a medical device that may trigger an allergic or hypersensitive reaction (e.g. Latex).

3.1.5 alternates
allowable specified options in

EXAMPLES Packaging material where one or another specific material is allowed to be used for the manufacturing of the package. Different types of rubber for a stopper.

3.1.6 authorization date
date of authorization granted by a medicines regulatory authority for a specific activity in the pharmaceutical domain

EXAMPLE the authorization to put a medicinal product on the market or to conduct a clinical trial.

3.1.7 authorization procedure
marketing authorization procedure
formal procedure applied by a medicines regulatory authority to grant a marketing authorization, to amend an existing one, to extend its duration or to revoke it

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

EXAMPLE Revocation of a marketing authorization due to serious safety concerns of the medicine.

3.1.8 batch
specific manufacturing release of a product or item by the manufacturer
3.1.9 batch number
lot number
application identifier assigned to a specific manufactured item resulting from a manufacturing process at a specific point of time

NOTE The terms batch number and lot number are synonymous.

3.1.10 characteristic
abstraction of a property of an object

3.1.11 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 an investigational medicinal product(s) with the object of ascertaining its safety and/or efficacy

NOTE The terms clinical trial and clinical study are synonymous.

3.1.12 clinical trial authorization
authorization granted by a medicines regulatory authority to run a clinical trial in a jurisdiction

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

3.1.14 clinical trial registration number
registration number (identifier for tracking purposes) for a clinical trial as assigned by the regulatory medicines authority in a jurisdiction

3.1.15 code value
result of applying a coding scheme to an element within a coded set

[ISO 2382-4]

3.1.16 coding scheme
collection of rules that maps the elements of one set on to the elements of a second set


NOTE The coding scheme applied in this standard refers to the following ISO standards:

- ISO/DIS 11616 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information
- ISO/DIS 11238 Health Informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances
- ISO/DIS 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/DIS 11240 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement

3.1.17
common name
international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name

[adapted from World Health Organization. 46th Consultation on International Nonproprietary Names (INNs) for Pharmaceutical Substances. http://www.who.int/medicines]

3.1.18
concept
unit of knowledge constructed through combining characteristics

3.1.19
concept system
set of concepts structured according to the relations among them

3.1.20
controlled vocabulary term identifier
TermID
concept identifier intended to be used as the preferred unique identifier for that concept in that code system and which is published by the author of a code system

[adapted from HL7 Core Principles]

NOTE The TermID remains constant over time, independent of the particular version of the knowledge resource.

3.1.21
country
nation with its own government, occupying a particular territory

[Oxford English Dictionary]

3.1.22
common terminology services
CTS
standardized interface for the usage and management of terminologies

[adapted from HL7 Version 3 Standard: Common Terminology Services, HL7 Draft Standard for Trial Use, DSTU Release 2]

3.1.23
controlled vocabulary
finite set of values that represent the only allowed values for a data item

[adapted from CDISC Clinical Research Glossary V8.0, 2009]

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

3.1.24
date of actual marketing of a medicinal product
authorization date of actual commencement of marketing of the medicinal product by the marketing authorization holder

NOTE The date of actual marketing of a medicinal product is always after a marketing authorization has been granted by a medicines regulatory authority.
3.1.25
date of marketing cessation of a medicinal product
date on which the medicinal product ceases to be placed on the market, either temporarily or permanently

3.1.26
designation
symbolic representation of a concept

[ISO 1087-1]

3.1.27
device model number
device reference number
information which identifies a specific device

3.1.28
distribution authorization
permission granted by a medicines regulatory authority to distribute or market a medicinal product

3.1.29
distributor
organisation in possession of a license covering the procuring, holding, supplying or exporting of medicinal products, apart from supplying medicinal products to the public

NOTE Is applicable to “wholesale distribution of medicinal products”.

3.1.30
dose
specified quantity of a medicine, to be taken at one time or at stated intervals

3.1.31
dose 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 and pharmaceutical dose form are synonymous.

NOTE 2 Pharmaceutical dose form can refer to the administered dose form or the packaged (manufactured) dose form, depending on the medicinal product that it is describing.

3.1.32
dosing
amount of a medicine to be administered at one time

3.1.33
excipient
constituents of a pharmaceutical form that are not active based on its pharmacological properties

NOTE 1 According to their function, these constituents can be classified as technological, applicatory, stabilising or biopharmaceutical excipients.

NOTE 2 Excipients include e.g. colouring matters, antioxidants, preservatives, adjuvants, stabilisers, thickeners, emulsifiers, solubilisers, permeation enhancers, flavouring and aromatic substances as well the constituents of the outer covering of the medicinal products, e.g. gelatine capsules.

3.1.34
first authorisation date
first authorization date when the first marketing authorization was granted for the medicinal product by a regulatory medicines agency in a jurisdiction
3.1.35
Global Trade Identification Number  
GTIN™
GS1 unique identifier of items that are traded (e.g. Pharmaceuticals, Medical Devices) in the supply chain

NOTE 1 A Global Trade Item Number (GTIN) is used to identify any item upon which there is a need to retrieve pre-defined information and that may be priced or ordered or invoiced at any point in any supply chain. GTINs may be 8, 12, 13 or 14-digits in length.

NOTE 2 A Global Trade Item Number (GTIN) is used to identify any item upon which there is a need to retrieve pre-defined information and that may be priced or ordered or invoiced at any point in any supply chain. GTINs may be 8, 12, 13 or 14-digits in length.

3.1.36
healthcare professional
person who is authorized by a nationally recognised body as qualified to perform certain health duties

[based on ISO/TS 17090-1:2002]

3.1.37
investigational medicinal product batch identifier  
IBAID_1
unique identifier allocated to a specific batch of an investigational medicinal product supplementary to any existing identifier as ascribed by a medicines regulatory authority in a jurisdiction and a batch number as assigned by a manufacturer

NOTE This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of medicinal products worldwide.

3.1.38
investigational medicinal product package batch identifier  
IBAID_2
unique identifier allocated to a specific batch of an investigational medicinal product package supplementary to any existing identifier as ascribed by a medicines regulatory authority in a jurisdiction and a batch number as assigned by a manufacturer

NOTE This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of medicinal products worldwide.

3.1.39
identifier
ID
description that is sufficient to differentiate objects in a given environment

[ISO 12610]

NOTE Applied to this domain: list of identifying characteristics that together unambiguously identify a medicinal product, a pharmaceutical product, a substance, a specified substance,, a route of administration, a dose form and any other element, which requires to be uniquely identified.

3.1.40
indication
intended use of the medicinal product as authorized by the medicines regulatory authority in a jurisdiction

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

3.1.41
ingredient
material used in the preparation of a medicinal/pharmaceutical product
NOTE 1  An ingredient is a substance that may contain additional distinguishing characteristics to further define subtypes of a substance (Specified Substance). This additional information could include such characterising elements as the grade, source, physical form and manufacturer. An ingredient will only map to one substance, but a substance may map to many ingredients. For example, the ingredients ‘purified water’, ‘water for injection’, ‘steam’, and ‘distilled water’ would each map to the substance ‘water’, but the substance ‘water’ would map to ‘purified water’, ‘water for injection’, ‘steam’, and ‘distilled water’.

NOTE 2  The ingredient that alone or in combination with one or more ingredients is part of a medicinal product. The ingredient is also a component of a pharmaceutical product [ISO 12610]. Ingredient equals to the detailed description of a substance.

NOTE 3  In some countries, e.g. Germany, an active ingredient that is intended to influence the performance of other active ingredients is called an auxiliary ingredient and identified as such.

3.1.42
international non-proprietary name
INN
official non-proprietary or generic name given to a pharmaceutical substance, as designated by the World Health Organization

3.1.43
intended use part
descriptor provided as part of the medicinal product name that describes in general terms the authorized indication of the product
EXAMPLE  heartburn relief

3.1.44
intermediate packaging
container between the outer packaging and the immediate container

3.1.45
invented name
name for an innovative medicinal product as authorized by a medicines regulatory authority in a jurisdiction
NOTE  Synonym to trade name of a medicinal product.

3.1.46
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, or when used for an unauthorized indication, or when used to gain further information about the authorized form

3.1.47
investigational medicinal product identifier
IMPID
unique identifier allocated to an investigational medicinal product supplementary to any existing identifier as ascribed by a medicines regulatory authority 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.

3.1.48
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 authority 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.
3.1.49
items in package
number of product units the package contains if fully packed

3.1.50
jurisdiction
geospatial area or subject-matter to which the pharmaceutical legislative authority applies

3.1.51
legal representative of the sponsor
person/organisation/entity that represents the sponsor in the jurisdiction where the clinical trial is conducted

NOTE Applies in cases where a sponsor is not located in the jurisdiction where the clinical trial is conducted to represent the sponsor in this jurisdiction as regards all aspects in relation to the conduct of the trial.

3.1.52
legal status of supply
jurisdiction rule whether or not a medicinal product is subject to a medical prescription before it may be supplied to a patient or consumer

3.1.53
manufactured dose form
pharmaceutical dose form of a medicinal product as manufactured and where applicable before reconstitution

EXAMPLE Powder and solvent for solution for injection.

3.1.54
manufactured item
description of the qualitative and quantitative composition of the 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) must 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.

3.1.55
manufacturing
manufacture
process of production from the acquisition of all materials through all processing stages and including final packaging

NOTE Applied to this domain:
— Manufacturing and manufacture are synonymous.
— Manufacturing details at detailed substance description level, which refer to the details related to the manufacturer responsible for the final batch release.
— Manufacturing at medicinal product level: which refers to the details related to the manufacturer responsible for the final batch release of the medicinal product.
— No further details are captured for ease of maintenance.

3.1.56
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.

3.1.57 manufacturing authorization date
date when the manufacturing authorization was granted

3.1.58 manufacturing authorization holder
tentity/organisation that holds the authorization for the manufacturing process

3.1.59 marketing authorization
authorization issued from a medicines regulatory authority that a medicinal product may be placed on the market

NOTE Exceptions may apply in special circumstances.

3.1.60 marketing authorization date
date when the marketing authorization was granted by a medicines regulatory authority in a jurisdiction

3.1.61 marketing authorization expiry date
date of expiry of the marketing authorization as granted by a medicines regulatory authority in a jurisdiction

3.1.62 marketing authorization holder
tentity/organisation that holds the authorization for marketing a medicinal product in a jurisdiction

3.1.63 marketing authorization number
code or identifier assigned by a medicines regulatory authority to a medicinal product

3.1.64 marketing authorization procedure
authorization procedure
formal procedure applied by a medicines regulatory authority to grant a marketing authorization, to amend an existing one, to extend its duration or to withdraw it

NOTE Marketing authorization procedure and authorization procedure are synonymous.

3.1.65 marketing start date
date when the authorized medicinal product is marketed in a jurisdiction

3.1.66 marketing stop date
date when the marketing of the authorized medicinal product is stopped in a jurisdiction

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

NOTE Applies to a medicinal product package.

3.1.68 measurement point
physical location on an administration device where the quantity of the medication being delivered is measured
3.1.69  
**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

[European Commission Medical Devices Directive 2007/47]

3.1.70  
**medicinal product**

any substance or combination of substances, which 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

[ENV 13607, ENV 12610]

NOTE 1  A medicinal product may consist of one or several 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.

3.1.71  
**medicinal product identifier**

**MPI**

unique identifier allocated to a medicinal product supplementary to any existing authorization number as ascribed by a medicines regulatory authority 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.

3.1.72  
**medicinal product name**

name as authorized by a medicines regulatory authority

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

3.1.73  
**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 authority 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.

3.1.74  
**medicinal product strength**

content of the substance(s)/specified substance(s) expressed quantitatively per dosage unit, unit of presentation, per unit of volume or weight according to the dose form
3.1.75 **medicines regulatory authority**

authorizing medicines regulator authority
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 authorization

NOTE 1 Medicines Regulatory Authority and Authorizing Medicines Regulatory Authority are synonymous.

NOTE 2 In certain jurisdictions the role of the institutional body that 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* [e.g. 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].

3.1.76 **organisation**

legal entity

3.1.77 **organisation identifier**

unique identification of an organisation

3.1.78 **outer packaging**

external container in which a medicinal product is supplied

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.

EXAMPLE Box, carton.

3.1.79 **pack size**

number of items supplied in a packaged medicinal product

EXAMPLE 5 ampoules, 20 tablets

3.1.80 **packaged item**

individual, distinct item(s) contained in a packaged medicinal product for sale or distribution

3.1.81 **packaged medicinal product**

medicine in a container being part of a package, representing the entirety that has been packaged for sale or supply

NOTE 1 The representation of the packaged medicinal product may be in its real or actual form as something made, or described in a more conceptual generic or virtual way.

NOTE 1the packaged medicinal product always represents a medicine contained in a package.

3.1.82 **pharmaceutical product**

qualitative and quantitative composition of the pharmaceutical product as administered to the patient in line with the regulated product information

NOTE 1 A medicinal product may contain one or more pharmaceutical products to be administered.
NOTE 2 In many instances the administered pharmaceutical product is equal to the packaged manufactured item. However, there are instances where the packaged manufactured item must undergo a transformation before being administered to the patient, and the two (i.e. manufactured item and pharmaceutical product) are not equal.

3.1.83 pharmacovigilance

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

NOTE Pharmacovigilance is a key public health function and 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
- Audit, both of the outcomes of action taken and of 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.

3.1.84 pharmaceutical product identifier

PHPID

unique identifier for a pharmaceutical product

3.1.85 physical characteristics

relates to the description of the height, weight, width, depth, volume, colour and shape of an item

3.1.86 primary identifiers

set of unique IDMP identifiers allocated supplementary to any existing authorization number as ascribed by a medicines regulatory authority 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

3.1.87 procedure number

tracking or identification number assigned by a regulatory medicines authority in relation to a specific medicines regulatory process

EXAMPLE Initial marketing authorization procedure

3.1.88 procedure type

regulatory stage of a medicinal product (e.g. initial authorization, variation, renewal, line extension, withdrawal)

3.1.89 product

short form for medicinal product or investigational medicinal product

3.1.90 product classification

categorisation or grouping of medicinal products based on specific properties

EXAMPLE Pharmacological classification, classification by therapeutic effect.
3.1.91 qualitative composition
composition with all the constituents of the investigational/authorized medicinal product, if applicable after reconstitution and the function 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, stabilisers, thickeners, emulsifiers, flavouring and aromatic substances, etc.

3.1.92 quantitative composition
quantitative strength
amounts of substance and specified substance constituents of the investigational/authorized medicinal product expressed in a ratio scale

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

NOTE 2 Substances/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.

3.1.93 reference strength
substance(s) and/or specified substance(s) used as a reference to form the basis of strength of an investigational or authorized medicinal product

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 quantity of the ‘Pharmaceutical Product’.

3.1.94 regulated document
document issued by a medicines regulatory authority in the context of an authorized medicinal product or an investigational medicinal product

3.1.95 regulatory authorization procedure
type of legal process applied to authorize or maintain a medicinal product marketing authorization

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

EXAMPLES Oral, intravenous, oromucosal, ocular.

3.1.97 specified substance
concept to further specify substances or describe intermediate products

NOTE Information needed to further specify a substance. This could include grade, units of measure, physical form, constituents, manufacturer, and critical manufacturing processes (i.e. extraction, synthetic, recombinant processes). Intermediate products are also described as specified substances.

3.1.98 sponsor
individual, company, institution or organisation, which takes responsibility for the initiation, management and/or financing of a clinical trial
3.1.99  
**sponsor status**
specifies the clinical trial sponsor as ‘commercial’ or ‘non-commercial’

3.1.100  
**status**
refers to the actual state of the marketing authorization

EXAMPLES  
Active, Suspended, Expired, Revoked

3.1.101  
**substance**
any matter that has discrete existence, whose origin may be biological, mineral or chemical

NOTE 1  
Substances may be either single substances or mixture substances.

NOTE 2  
Single substances are always 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.

NOTE 3  
Pharmacopeial terminology and defining characteristics are used when available and appropriate. Defining elements are dependent on the type of substance.

NOTE 4  
Discrete existence refers to the ability of a substance to exist independently of any other substance. Substances may either be well-defined entities containing definite chemical structures, synthetic (i.e. isomeric mixtures) or naturally-occurring (i.e. conjugated estrogens) 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.

3.1.102  
**summary of product characteristics**
summary of product labelling
medicinal product information as authorized by a medicines regulatory authority in a jurisdiction

NOTE 1  
The Summary of Product Characteristics and Product Labeling content may not be changed except with the approval of the originating medicines regulatory authority. 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 Labeling are synonymous.

3.1.103  
**target population**
type of patients or consumers for which the indication of a medicinal product is authorized

3.1.104  
**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

3.1.105  
**unique device identification code**
UDI
unique identifier assigned to a medicinal product

[GHTF (Global Harmonisation Task Force)]

3.1.106  
**unit of presentation**
qualitative term describing the unit in which the strength(s) of the manufactured item or pharmaceutical product is presented and described
NOTE 1 Often used specifically at the point of delivery to the patient in cases where a quantitative unit of measurement is not applicable.

NOTE 2 A unit of presentation may have the same ‘display name’ as in another controlled vocabulary, such as a pharmaceutical dose form, but the two concepts are not equivalent, and each has a unique controlled vocabulary term identifier.

EXAMPLE Tablet, spray, puff. “Contains 100 mcg per spray” (unit of presentation = spray).

3.1.107 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

3.2 Abbreviations

3.2.1 GHTF Global Harmonisation Task Force; http://www.ghtf.org/

3.2.2 GTIN™ Global Trade Identification Number [GS1; http://www.gs1.org/]

3.2.3 IBAID_1 investigational medicinal product batch identifier

3.2.4 IBAID_2 investigational medicinal product package batch identifier

3.2.5 ID identifier

3.2.6 IDMP identification of medicinal product

3.2.7 INN international non-proprietary name

3.2.8 IMPID investigational medicinal product identifier

3.2.9 IPCID investigational medicinal product package identifier

3.2.10 MPID medicinal product identifier
3.2.11
OID
object identifier

3.2.12
PCID
medicinal product package identifier

3.2.13
PHPID
pharmaceutical product identifier

3.2.14
SPC / SmPC
summary of product characteristics

3.2.15
UML

3.2.16
UDI
unique device identification code [GHTF]

3.2.17
WHO
World Health Organization [http://www.who.int]

4 Requirements

4.1 Concepts required for the unique identification of medicinal products

4.1.1 General considerations

The standard defines the concepts required for the unique identification of medicinal products at 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 authorizations numbers, package identifiers, batch numbers, bar codes and the like. The additional identifiers defined in this standard provide an indexing mechanism that shall be supplementary to these existing systems. It shall NOT be a replacement for them.

Such identification shall apply the principles in 4.1.22 and 4.1.33.

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:

The assignment of a unique medicinal product identifier (MPID) to reliably recognise, monitor and trace the use of medicinal products;

The assignment of a unique medicinal product package identifier (PCID) to reliably recognise and trace medicinal products as packaged for sale or supply;

The assignment of a unique medicinal product batch identifier (BAID_1) to reliably recognise and trace a manufactured batch or lot in compliance with the requirements of the marketing authorization;
The assignment of a unique medicinal product package batch identifier (BAID_2) to reliably recognise and trace a manufactured batch or lot in compliance with the requirements of the marketing authorization;

The definition of the main characteristics that are associated with the MPID, PCID, BAID_1 and BAID_2, which represent:

- Name of the medicinal product
- Legal status
- Terms of the marketing authorization
- Marketing authorization (license) holder
- Manufacturer(s)
- Authorizing medicines regulator authority
- Qualitative and quantitative composition
- Strength, pharmaceutical form, route of administration
- Medical device, where it is a part of a medicinal product
- Authorized indication(s)
- Product classification
- Package description (e.g. container, administration devices and pack sizes)

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 recognise, 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) to reliably recognise and trace the product as packaged for supply during clinical trials;

c) The assignment of a unique investigational medicinal product batch identifier (IBAID_1) to reliably recognise and trace a manufactured batch or lot in compliance with the requirements of the clinical trial authorization;

d) The assignment of a unique investigational medicinal product package batch identifier (IBAID_2) to reliably recognise and trace a manufactured batch or lot in compliance with the requirements of the clinical trial authorization;

e) The definition of the main characteristics that are associated with the IMPID, IPCID and IBAID_1 and IBAID_2, which represent:

- Name(s) or code associated with the investigational medicinal product
- Terms of the clinical trial authorization
- Sponsor of the clinical trial
4.2 Concepts required for the unique identification of a medicinal product and the association with Pharmaceutical Product Identifier(s) (PHPID)

The standard shall define 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/DIS 11616. Such 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 regime (e.g. kit containing vaginal tablets 500 mg and a vaginal cream 10%);

b) The characterisation of the pharmaceutical product(s) using the active substance(s)/specified substance(s), the (reference) strength thereof, the pharmaceutical (administrable) dose form(s) and the medical device (e.g. a scaffolding for cell based medicinal products) being part of the medicinal product;

c) The description of the pharmaceutical product(s) ready for administration to a patient, where applicable after reconstitution and as authorized in accordance with the summary of product characteristics or product labelling;

d) The association of the regulated (investigational) medicinal product and the pharmaceutical product(s) using the PhPID(s).

4.3 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 authority of a jurisdiction may refer to the following main principles:

- At ‘medicinal product level’, without specific discrimination between different pack sizes (e.g. Drug B - ursodeoxycholic acid - 250 mg-film-coated tablets 50 tablets – authorization authorization number 15.2YZ; Drug B - 250mg -film-coated tablets 100 tablets – authorization number 15.2YZ);

- At ‘medicinal product and package level’, allowing for a discrimination at product and package level (e.g. Drug C - Amoxicillin Capsules, Pharmacopoeia, for oral administration, contain 250 mg or 500 mg amoxicillin. Authorization number for 250 mg capsules (product level) 0XYZ1-20Z0; authorization number (package level) 0XYZ1-20Z0-01 for bottles of 100 and 0XYZ1-20Z0-05 for bottles of 500; authorization number for 500 mg capsules (product level) 0XYZ1-20K0; authorization number (package level) 0XYZ1-20K0-01 for bottles of 100 and 0XYZ1-20K0-05 for bottles of 500);

- At ‘medicinal product presentation level’, 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) - 10ml (1.4 mg/ml) - 1 vial Country/V/00/1YX/001; DRUG A - 100 IU/ml - Suspension for injection - Subcutaneous use - Vial (glass) - 10 ml (3.5 mg/ml) - 1 vial Country/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 standard defines the concepts required to associate the MPID and PCID with the relevant marketing authorization number(s) as assigned by a medicines regulatory authority in a jurisdiction. Such association shall use the following two principles:

a) 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 - 250mg-film-coated tablets, pack sizes 50 and 100 tablets).

b) 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).

4.4 Concepts required for the unique identification of medicinal products and the association with the Global Trade Item Number™ (GTIN™)

GTINs in healthcare uniquely identify items that are traded (e.g. Pharmaceuticals, Medical Devices) in the supply chain. A Global Trade Item Number (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. Their data structures require up to 14-digit fields. The GS1 Healthcare User Group advocates the use of global standardisation 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 GTIN trade item are:

- 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, pallet, box-pallet, flat-pallet…) 

A modification to any of the basic elements that characterise a trade item will usually lead to a change in the GTIN. In addition to the product identification (GTIN), batch number and expiration date are normally required in bar code form.

This standard defines the concepts required to associate the PCID and the BAID_2 with the relevant GTIN. Such association shall use the following two principles:

a) The PCID shall always be associated with the applicable GTIN of the medicinal product.
b) Where the batch number and expiration date are included in the GTIN bar code form, it shall be associated with the BAID_2.

5 Identifying Characteristics for Authorized Medicinal Products

5.1 Conceptual Overview

5.1.1 General considerations

The main concepts modelled in Figure 1 and described in 5.1.2 to 5.1.10 shall apply to identify an authorized medicinal product:

5.1.2 Marketing Authorization

The marketing authorization as issued by a medicines regulatory authority, which grants permission to a pharmaceutical company to place a medicinal product on the market in a specific jurisdiction.

5.1.3 Medicinal Product Name

The name of the medicinal product as authorized by a medicines regulatory authority in a jurisdiction together with an analysis of the name into various parts.

5.1.4 MPID

The criteria for the unique identification of an authorized medicinal product.
Figure 1 – Core Concepts (other classes have been omitted for clarity)

5.1.5 Product Batch Identifier

Identifier for actual production batches where the distinction is not at pack level but at product level.

5.1.6 PCID

The criteria for the unique identification of a packaged authorized medicinal product.

5.1.7 Packaged Medicinal Products

The description of the packaging of the medicine and associated device(s), where applicable both as supplied by the manufacturer for sale and distribution (manufactured item) and as reconstituted for administration (pharmaceutical product) to the patient.

This is a complex of five classes:
- PCID Attribute Set
- Package Item
- Package Item Part
- Manufactured Item
- Pharmaceutical Product
5.1.8 Package Batch Identifier

Identifier for each actual batch produced and packaged.

5.1.9 Ingredients

The set of substances and specified substances of which both the manufactured (manufactured product) and administrable medicine (pharmaceutical product) is composed.

5.1.10 PhPID

The link to the ISO 11616 standard.

5.2 Primary Identifiers

5.2.1 General considerations

To satisfy the requirements as described in section 3.1.39, the following four identifiers shall be specified:

- **MPID** – Medicinal Product Identifier
- **PCID** – Medicinal Product Package Identifier
- **BAID_1** – Medicinal Product Batch Identifier
- **BAID_2** – Medicinal Product Package Batch Identifier

These shall be associated with the Pharmaceutical Product Identifier (PhPID) as defined in ISO/DIS 11616. The relationship between these different identifiers is shown in Figure 2 and is further defined in 5.2.2 to 5.2.3.

![Figure 2 – Relationship of Core Identifiers (other attributes have been omitted for clarity)](image)

5.2.2 Medicinal Product Identifier (MPID) Attribute Set

5.2.2.1 General provisions

For each authorized medicinal product, a medicinal product identifier (MPID) shall be assigned. The MPID shall be allocated supplementary to any existing authorization number as ascribed by a medicines regulatory
authority 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.

![Figure 3 – Defining Attributes for MPID (other attributes have been omitted for clarity)](image)

The MPID shall use a common attribute set related to a medicinal product, which when all of them have a value, define a specific MPID concept:

- Country Code Segment
- Marketing Authorization Holder (Organisation) Code Segment
- Medicinal Product Code Segment

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

The MPID code segments shall be generated as described in 5.2.2.2 to 5.2.2.4.

### 5.2.2.2 Country Code Segment

This code segment shall reflect the country code of that jurisdiction, where the medicinal product is authorized [ISO 3166-1-alpha-2 code elements].

### 5.2.2.3 Marketing Authorization Holder (Organisation) Code Segment

This code segment shall reflect the unique identifier of the marketing authorization holder (organisation) of the medicinal product. An international coding system for unique marketing authorization holders (organisations) identifiers shall be applied.

### 5.2.2.4 Medicinal Product Code Segment

This code segment shall reflect a code assigned to the medicinal product. It shall use the following defining attribute set:

- Marketing Authorization in relation to the jurisdiction and the legal status of supply (e.g. prescription only or OTC)
- Medicinal Product Name
- Pharmaceutical Product in relation to the pharmaceutical dose form, the ingredients as characterised by the substances/specified substances and their strength
- Medical device, where it is a part of a medicinal product
- Indication(s) as authorized for the medicinal product

A separate unique MPID shall be assigned whenever any of the pre-defined attribute sets of a medicinal product are different in any way that is relevant to the medicines regulatory process.

This process may result in changes to the MPID when existing regulatory identifiers – marketing authorization number for example – would not change. The standard shall NOT require such existing regulatory identifiers to be changed in step with the MPID. Each jurisdiction may continue with its existing working practices for existing identifiers.

5.2.3 Medicinal Product Package Identifier (PCID) Attribute Set:

5.2.3.1 General provisions

For each authorized medicinal product, a 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 authority in a jurisdiction.

Figure 4 – Defining Attributes for PCID (other attributes have been omitted for clarity)

The PCID shall use a common attribute set related to a package of a medicinal product, which when all of them have a value, define a specific PCID concept:

- MPID Attribute Set
- Package Description Code segment

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

The PCID code segments shall use the defining attribute sets as described in 5.2.3.2.
5.2.3.2 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 and the Type, the Packaged Form and Items per Package
- Packaged Item Part: Type, Material, Alternates
- Manufactured Item: Pack Size, Manufactured Dose Form, Unit of Presentation
- Ingredients of the Manufactured Item: Type, Substances and Strength

A separate unique PCID shall be assigned whenever any of the pre-defined attribute sets of a medicinal product are different in any way that is relevant to the medicines regulatory process.

This process may result in changes to PCID when existing regulatory identifiers – marketing authorization number for example – would not change. The standard shall 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.

Formalising the rules for when a new PCID shall be generated allows the generation to be automated applying the appropriate notification of changes.

5.3 Medicinal Product Batch Identifier (BAID_1) Attribute Set

5.3.1 General considerations

For each authorized medicinal product, a batch identifier (BAID_1) shall be assigned. The BAID_1 shall use the batch number allocated by the manufacturer or the marketing authorization holder and the expiration date.

![Figure 5 – Defining Attributes for BAID_1 (other attributes have been omitted for clarity)](image)

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

- ‘MPID Attribute Set’
5.3.2 Batch Code Segment

This code segment shall represent the batch number assigned by the manufacturer or the marketing authorization holder. It shall use the following defining attribute set:

- Batch number
- Expiration date

5.4 Medicinal Product Batch Identifier (BAID_2) Attribute Set

For each authorized medicinal product, a batch identifier (BAID_2) shall be assigned. The BAID_2 shall use the batch number and expiration date allocated by the manufacturer or the marketing authorization holder.

Figure 6 – Defining Attributes for BAID_2 (other attributes have been omitted for clarity)

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:

- 'PCID Attribute Set'
- Batch Code Segment

Any change of the values related to these code segments shall result in the assignment of a new BAID_2.

A separate unique BAID_1 and BAID_2 shall be assigned whenever any of the pre-defined attribute sets of a medicinal product are different in any way that is relevant to the medicines regulatory process. This process may result in changes to BAID_1 and BAID_2 when existing regulatory identifiers – marketing authorization number for example – would not change. The standard shall NOT require such existing regulatory identifiers to be changed in step with the BAID_1 and BAID_2. Each jurisdiction may continue with its existing working practices for existing identifiers.

Formalising the rules for when a new BAID_1 and BAID_2 shall be generated allows the generation to be automated applying the appropriate notification of changes.
Note The batch number and expiration date specified for BAID_1 and BAID_2 shall be identical.

5.5  Version

5.5.1 General considerations

The characteristics of authorized medicinal products as defined in this standard shall be versioned. This refers to the fact that at the given effective date, some characteristics of the medicinal product have changed. These characteristics are not different to a sufficient extent to warrant the assignment of a new Primary Identifier Attribute Set as specified in section 5.2.

![MPID Attribute Set](image)

**Figure 7 – Version and immediately related classes**

5.5.2 Effective Date

The date of the authorization or the latest update of the regulated medicinal product information (e.g. elements related to the Summary of Product Characteristics, Product Labelling), which serves as the reference for the unique identification of medicinal products and their characteristics, shall be specified. The date shall be specified using a TS.Date data type.

5.5.3 Regulated Document

The reference to the regulatory decision document related to the granting of the authorization or the latest update of the regulated medicinal product information shall be specified. The reference document ID shall be specified using an II data type.

5.6 Medicinal Product Name

5.6.1 General considerations

The convention of naming medicinal products may differ within regulatory 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 may refer to e.g. a single invented name or a scientific name (when available, the International Non-Proprietary Name of the active substance(s)) accompanied by a trademark or other characteristics.

Such characteristics may e.g. refer to strength, pharmaceutical form, intended usage and administration devices.

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. Where applicable, these name parts shall be described for all official languages in a jurisdiction.

The ‘Name’ and its elements and ‘Language’ are actually all part of the EN data type as provided by ISO 21090. They are defined in full here for clarity. Implementations shall use the EN data type.

There may be multiple instances of this class to cover multiple languages in a jurisdiction and the multiple countries for which the Medicinal Product has a name.
5.6.2 Name

The full and complete medicinal product name as approved by the medicines regulatory authority in a jurisdiction shall be specified.

EXAMPLE LITHIUM CARBONATE capsule XYZ Pharmaceutical Corp

5.6.3 Language

The ISO 639-2 Language Code of the medicinal product name as applicable in the jurisdiction shall be specified. The Language shall be defined using a CD data type.

5.6.4 Country (jurisdiction)

The country or jurisdiction where the medicinal product name is applicable shall be described using ISO 3166-1 alpha-2 codes. It shall be defined using a CD data type.

5.6.5 Invented Name Part

The invented name (i.e. trade name) of the medicinal product without e.g. the trademark or any other descriptors reflected in the product name shall be specified.

EXAMPLE For the medicinal product name ‘Drug XYZ® Accuhaler 200 mg for adults’ the invented (trade) name element is ‘Drug XYZ’.

5.6.6 Scientific Name Part

The scientific or common (i.e. generic) name of the medicinal product without any other descriptors shall be specified.

EXAMPLE For the medicinal product name ‘Irbesartan/Hydrochlorothiazide Pharma KK’ the common (generic) name element is ‘Irbesartan/Hydrochlorothiazide’.

5.6.7 Strength Name Part

The strength, if reflected in the medicinal product name, shall be specified. This strength name part may differ from the concept of ‘Strength’ as described in section 5.13.5. The use of decimal points shall be accommodated, if required.
EXAMPLE For the medicinal product name ‘Drug K Forte (Paracetamol 500mg, dihydrocodeine tartrate 30mg)’, the strength name part is ‘Forte’.

5.6.8 Pharmaceutical Dose Form Part

The pharmaceutical dose form, if reflected in the medicinal product name, shall be specified. This pharmaceutical dose form name part may differ from the concept of ‘Administrable Dose Form’ and ‘Manufactured Dose Form’ as described in section X.

EXAMPLE For the medicinal product name ‘Novo-DrugX EASY-TO-SWALLOW CAPLETS’, the pharmaceutical dose form name element is ‘EASY-TO-SWALLOW CAPLETS’.

5.6.9 Intended Use Part

The intended use, if reflected in the medicinal product name, shall be specified.

EXAMPLE For the medicinal product name ‘Drug-BI Caplets - Heartburn Relief’, the intended use part is ‘Heartburn Relief’.

5.6.10 Target Population Part

The target population, if reflected in the medicinal product name, shall be specified.

EXAMPLE For the medicinal product name ‘Broncho-Drug 3.5 mg-capsules for children’, the intended use part is ‘children’.

5.6.11 Container Part

The container, if reflected in the medicinal product name, shall be specified.

EXAMPLE For the medicinal product name ‘LXA – 10 mg/ ml - Solution for injection – Subcutaneous use - Vial (glass) - 4 ml - 1 Vial’, the container part is ‘vial (glass)’.

5.6.12 Device Part

The device, if reflected in the medicinal product name, shall be specified.

EXAMPLE For the medicinal product name ‘LXA ‘Drug XYZ® Accuhaler 200 mg for adults’, the device part is ‘Accuhaler’.

5.6.13 Trademark or Company Part

The trademark, if present in the medicinal product name, shall be provided.

EXAMPLE For the medicinal product name ‘Clopidrogel Pharma®’, the trademark element is ‘Pharma®’.

5.6.14 Time/Period Name Element

The time/period, if present in the medicinal product name, shall be provided.

5.7 Marketing Authorization

5.7.1 General considerations

Depending on regional laws and regulations a formal marketing authorization is required in countries/jurisdictions for certain categories of medicinal products (e.g. certain OTC drugs or ‘grandfather’ drugs). For these medicinal products, the same principles apply as for authorized medicinal products. Where no formal marketing authorization holder is established for certain types of products, the distributor should be specified.

Figure 9 – Overview of Marketing Authorization Class Set and immediately related classes

The marketing authorization is issued by the appropriate regulatory medicines authority in a jurisdiction. In line with the laws and regulations applicable in a jurisdiction, an authorization is required before a medicinal product is placed on the market. For some categories of medicinal products (e.g. ‘grandfather’ drugs) exemptions may be applicable. For these type of medicines, the same principles 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.
5.7.2 Marketing Authorization Number

The number as assigned to a medicinal product by the regulatory medicines authority of a jurisdiction shall be specified. For medicinal products, which allow distribution without a marketing authorization by legislation in a jurisdiction, 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.

5.7.3 Holder

Details in relation to the marketing authorization holder to which the marketing authorization in a jurisdiction was granted shall be specified using an ‘Organisation’ class as described in section 5.10.

For medicinal products, which allow 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.

5.7.4 Country

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

5.7.5 Legal Status of Supply

The legal status of supply of the medicinal product as classified by the regulatory medicines authority shall be specified (e.g. subject to medical prescription or not). The status shall use the CD data type and an appropriate controlled vocabulary. The controlled term and the controlled term identifier shall be specified.

EXAMPLE

- A medicinal product subject to medical prescription,
- A medicinal product not subject to medical prescription.
5.7.6 Regulator

Details in relation to the regulatory medicines authority that granted the marketing authorization in a jurisdiction shall be specified using an Organisation class as described in section 5.10.

5.7.7 Authorization Date

The date of the ‘Status’ of the medicinal product authorization in relation to the authorization decision issued by the regulatory medicines authority of the respective jurisdiction shall be specified, where applicable. A complete date consisting of day, month and year shall be provided using the ISO date format [ISO 8601].

5.7.8 Status

The status of the marketing authorization shall be specified using a CD data type.

EXAMPLE Active, Suspended, Expired, Revoked

5.7.9 GTIN

The code as supplied by GS1 shall be provided and held in a CD data type.

5.7.10 Authorized Combined Pharmaceutical Dose Form

Where the Pharmaceutical Dose Form is a compound expression made from two constituent dose forms the authorized name for the combination shall be held in this attribute. It shall be held in a CD data type.

5.7.11 Product Classification

A means of identifying any external classification system to which the product belongs.

5.8 Marketing Authorization Procedure

5.8.1 General considerations

The regulatory procedure applied to grant the marketing authorization of the medicinal product shall be specified.

![Diagram of Marketing Authorization Procedure](image)

**Figure 11 – Overview of Marketing Authorization Procedure and immediately related classes**

5.8.2 Procedure Type

The procedure type shall be specified in relation to the marketing authorization authorization. A controlled vocabulary for regulatory procedure types shall be applied. The controlled term and the controlled term identifier shall be specified.

EXAMPLE Initial authorization, variation, renewal, line extension.
### 5.8.3 Procedure Reference Code

The regulatory authorization procedure as applicable in a jurisdiction shall be specified. A controlled vocabulary for regulatory authorization procedures shall be applied. The controlled term and the controlled term identifier shall be specified.

**EXAMPLE** Central authorization procedure in the EU, a product marketed under an approved Biologic License Application (BLA) in the US.

### 5.8.4 Procedure ID

The unique identifier for the specific instance of procedure shall be provided and defined using an II data type.

### 5.8.5 Document ID

The reference number of the regulatory document formally granting an authorization /update of an existing medicinal product authorization by the regulatory medicines agency in a jurisdiction shall be specified.

### 5.8.6 Date

The date when the procedure described as ‘Procedure Type’, took effect. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

### 5.9 Local Marketing Authorization

#### 5.9.1 General consideration

Local marketing authorization is intended to provide for additional local information in a jurisdiction.

![Figure 12 – Overview of Local Marketing Authorization Information and immediately related classes](image)

#### 5.9.2 Local Authorization Number

The marketing authorization assigned locally within a jurisdiction shall be specified.

**EXAMPLE** In a country a local marketing authorization number is assigned in addition to the authorization number designated at EU level for centrally authorized medicinal products.

#### 5.9.3 Local Legal Status of Supply

For medicinal products, which are available on medical prescription only, the regulatory medicines authorities may assign additional sub-categories locally, which shall be specified as applicable. A controlled vocabulary for different categories of legal status of supply shall be applied. The controlled term and the controlled term identifier shall be specified.
EXAMPLES

Medicinal products on medical prescription for renewable or non-renewable delivery (e.g. likely to present a danger, need a medical supervision)

Medicinal products subject to special medical prescription (e.g. containing a narcotic or psychotropic substance, possible addiction or illegal misuse)

Medicinal products on "restricted" medical prescription, reserved for use in certain specialised areas (e.g. treatment only possible in hospital).

5.9.4 Marketing Start Date

The date when the medicinal product is “placed on the market” by the marketing authorization holder — or where applicable the manufacturer/distributor- shall be provided. The date of “placed on the market” refers to the date of release of the medicinal product into the distribution chain. A complete date consisting of day, month and year shall be specified using the ISO 8601 date format.

5.9.5 Marketing Stop Date

The date when a medicinal product is no longer placed on the market by the marketing authorization holder— or where applicable the manufacturer/distributor- shall be provided. A complete date consisting of day, month and year should be specified shall be specified using the ISO 8601 date format.

5.9.6 Local Marketing Authorization Country

The country/jurisdiction in which the local marketing authorization has been granted. It should be specified using the ISO 3166-1 alpha-2 codes (including EU).

5.9.7 Local GTIN

The code as supplied by GS1 shall be held in a CD data type.

5.10 Organisation

5.10.1 General considerations

This refers to a general class that describes details about an organisation.

Figure 13 – Overview of Organisation and immediately related classes
5.10.2 Organisation Identifier

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

5.10.3 Organisation Name

The name of the organisation shall be provided.

5.10.4 Organisation Address

The address of the organisation using AD ISO Data Type shall be provided.

5.11 Manufacturing Authorization

5.11.1 General considerations

Details of the ‘Manufacturing Authorization’ granted by a regulatory medicines authority shall be provided.

5.11.2 Manufacturing Authorization Holder

Details in relation to the organisation that holds the manufacturing authorizations shall be provided. This shall be specified using an ‘Organisation’ class as described in section 5.10.

5.11.3 Manufacturing Authorization Date

The date when the manufacturing authorization was issued by the regulatory authority shall be specified using the ISO 8601 date format.

5.11.4 Manufacturing Authorization Authority

Details in relation to the organisation that granted the manufacturing authorizations shall be provided. This shall be specified using an ‘Organisation’ class as described in section 5.10.

5.12 Packaged Medicinal Product

5.12.1 General considerations

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). The relationship of the main classes and the attributes of these classes are shown in Figures 15 and 16.

The relationship between these classes is illustrated by the example for a kit containing several items to be found in Annex A.
Packaged Medicinal Product

- **Classes::Marketing Authorisation**
  - 0..1

- **Classes::MPID Attribute Set**
  - 1.

- **Classes::PCID Attribute Set**
  - 0..1

- **Classes::Outer Packaging**
  - notes
    - This is the package as seen and handled by end users.

- **Classes::Package Item**
  - notes
    - These are the distinct kinds of items that make up the package. There will only be more than one instance of this class if the Package Medicinal Product is a kit or includes an administration device.

- **Classes::Package Item Part**
  - notes
    - This is the inner packaging and/or parts of an administration device. Most importantly it identifies the material directly in contact with the medicine.

- **Classes::Manufactured Item**
  - notes
    - This is the medicine as supplied by the manufacturer.

- **Classes::Pharmaceutical Product**
  - notes
    - This is the medicine as reconstituted ready to be given to the patient.

- **Classes::Medical Device**
  - notes
    - This is a device that is part of a pharmaceutical product.

- **Classes::Ingredient**
  - 0..1

**Figure 15 – Packaged Medicinal Product Main Classes (some related classes have been omitted for clarity)**
Figure 16 – Packaged Medicinal Product Main Attributes (some attributes and related classes have been omitted for clarity)

5.12.2 PCID Attribute Set

5.12.2.1 General provisions

The ‘PCID Attribute Set’ class acts as a collector for more descriptive classes. In particular, there is one ‘Packaged Item’ class for each separate item packaged and a ‘Physical Characteristics’ class to describe the dimension, colour, shape, weight, volume and dimension as applicable and to carry the image of the item as required. It also links to the ‘Outer Packaging’ class.

Where a medicinal product has multiple layers of packaging or contains a number of items, the ‘Packaged Medicinal Product’ configuration shall refer to the outermost of these layers. The class ‘Packaged Item’ shall describe the other layers.
5.12.2.2 PCID (Medicinal Product Package Identifier)

The assigned ‘Medicinal Product Package Identifier’ as described in section 5.2.3.

5.12.2.3 Marketing Authorization

The relevant information related to the ‘Marketing Authorization’ as described in section 5.7.

5.12.3 Physical Characteristics

The physical attributes of the packaged item such as height, weight, width, depth, volume, colour and shape shall be provided. One or more images of the packaged item shall be also included as applicable.

The values for ‘Height’, ‘Weight’, ‘Width’, ‘Depth’ and ‘Volume’ shall be described using the value set as specified in ISO/DIS 11240. The symbol and the symbol identifier shall be used. They are to be specified using a PQ data type.

The ‘Colour’ and ‘Shape’ shall be described using a controlled vocabulary. The term and the term identifier shall be used. They are to be specified using CD data types.

One or more ‘Images’ and/or ‘Imprints’ of the packaged item shall be included as applicable. The format of the image shall follow ISO 12639:2004 and shall be held in an ED data type.

5.12.4 Other Characteristics

Zero or more other observations shall be made about the characteristics of the ‘Packaged Medicinal Product’, where applicable. They are represented by naming the characteristic in the ‘Code’ attribute using a CD data type, and then if required providing a ‘Value’ for the characteristic named using an ANY data type. This facility is useful for capturing unusual details not explicitly catered for in the other attributes. For example, the International Society Blood Transfusion (ISBT) code for blood products could be captured as follows:
5.12.5 Outer Packaging

5.12.5.1 General provisions

The outward facing package of the medicinal product as manufactured for sale or supply shall be described.

5.12.5.2 Material

A value drawn from a value set specified in ISO/DIS 11238 shall be provided. It shall be specified using a CD data type.

5.12.5.3 Alternates

This is a pointer to further sets of ‘Materials’ (defined as in section 5.12.5.2) that represent alternative parts of the packaging.

5.12.6 Package Item

5.12.6.1 General provisions

‘Package Item’ contains either a single item or multiple items. Those items may be of the same kind or of different kinds.

There shall be one ‘Packaged Item’ for each distinct kind of item in a ‘Packaged Medicinal Product’. Where there are several identical 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 ‘Packaged Item’ contains a further package, ‘Packaged Item’ shall be nested to provide the correct representation.

5.12.6.2 Type

The value for the ‘Packaged Item Type’ shall be described using a CD data type and using a defined value set.

EXAMPLE

- Container: for example, bottle amber PET with polypropylene child resistant closure fitted with expanded polythene liner.
- Pharmaceutical Item: for example, a pessary.
- (Administration) Device: for example, an applicator for a cream or a spoon with a 5 ml and 2.5 ml measure.

5.12.6.3 Package Type

‘Package Type’ describes the physical type of the container of the medicine. This is a term and a term identifier specified in ISO/DIS 11239 and its resulting controlled vocabulary. It is to be specified using a CD data type.

EXAMPLE Pre-Filled Pen, Blister, Tube.

5.12.6.4 Items in Package

The number (quantity) of identical items per package shall be described using an INT data type.

EXAMPLE The item per package may refer to:

- ‘One’ container holding a syrup,
- ‘Two’ identical tubes of cream,
- ‘One’ container being a bottle amber PET with polypropylene child resistant closure fitted with expanded polythene liner,
- ‘One’ administration device being a spoon with a 5 ml and 2.5 ml measure.

5.12.6.5 Physical Characteristics

The physical attributes of the ‘Package Item’ such as height, weight, width, depth, volume, colour and shape shall be provided as described in section 5.12.3. One or more images of the ‘Packaged Item’ shall be included as applicable as described in section 5.12.3.

The following figure shows where in the classes the values and units of sizing are held.
5.12.7 Package Item Part

5.12.7.1 General provisions

The ‘Package Item Part’ class shall describe the inner packaging, which is in direct contact with the medicine contained in the package. ‘Package Item’ shall include administration devices such as pre-filled injection pens. For devices where a unique device identifier is available, this shall be specified. Administration devices such as spoons or applicators should also be specified here.

Figure 21 – Package Item Part and immediately related packaging classes

Note that ‘Package Item’ classes may contain as a child a ‘Package Item Part’ class, which may themselves contain further child ‘Package Item Part’ classes. In this way, the packaging may be described in a hierarchical way. This is useful for an administration device such as a ‘Pre-Filled Pen’, which has a number of distinct parts with a number of sub-parts.

If necessary this class may also be used to describe such items as ‘Graduated Spoon’.
5.12.7.2 Component Part

This is a term and a term identifier as defined in ISO/DIS 11239 and its resulting controlled vocabulary. It is to be specified using a CD data type.

EXAMPLE Pre-Filled Pen, Stopper.

5.12.7.3 Material

This is a term and a term identifier as defined in ISO/DIS 11238 and the resulting controlled vocabulary. It is to be specified using a CD data type.

5.12.7.4 Alternates

This is a pointer to further sets of ‘Materials’ (defined in section 5.12.5.2) that represent alternative components of the packaging.

5.12.7.5 UDI

If the component has a Unique Device Identifier it should be recorded here.

5.12.8 Medical Device

5.12.8.1 General provisions

The ‘Medical Device’ part shall be described using the following attributes:

Figure 22 – Medical Device and immediately related packaging classes

5.12.8.2 UDI (Unique Device Identification) Code

A unique device identifier shall be specified using the UDI code. UDI code and term shall be using the Unique Device Identification System as established by the Global Harmonisation Task Force (GHTF).

5.12.8.3 Device Name (generic name)

The generic device name shall be specified.
5.12.8.4 Trade Name

The trade name of the medical device shall be specified, where applicable.

5.12.9 Manufacturer

5.12.9.1 General provisions

The manufacturer details shall be specified. This shall be done using an ‘Organisation’ class as described in section 5.10.

5.12.9.2 Device Model Number (or reference number)

The device model or reference number shall be specified, where applicable.

5.12.9.3 Nomenclature

A global nomenclature code shall be specified of internationally recognised coded descriptors in the format of preferred terms with definitions used to generically identify medical devices and related health care products (e.g.: Global Medical Device Nomenclature (GMDN) as defined in ISO 15225).

5.12.9.4 Physical Characteristics

The physical attributes of the ‘Medical Device’ such as height, weight, width, depth, volume, colour and shape shall be provided. One or more images of the ‘Medical Device’ shall be included as applicable.

These attributes are described in detail in section 5.12.3.

5.12.10 Other Characteristics

5.12.10.1 General considerations

Zero or more other observations shall be made about the characteristics of the Medical Device. This shall be done using an Observation class as described in section 5.12.4.

5.12.10.2 Restricted Use Count (number)

If the medical device’s label indicates a limited number of times of use, the number shall be specified using an INT data type.

5.12.10.3 Has Allergens (materials of concern)

It shall be specified, if in accordance with the label or the instruction for use the medical device is containing allergens/materials of concern (Yes/No value). The actual allergens shall then be specified using the ‘Ingredient’ class as described in section 5.13.

5.12.11 Is Sterile

It shall be specified if the package for the medical device is sterile or not when supplied (Yes/No value).

5.12.12 Is Sterilization required

It shall be specified if the medical device shall be sterilized before use (Yes/No value).
5.12.13 Manufactured Item

5.12.13.1 General provisions

The manufactured pharmaceutical item(s) as contained in the ‘Packaged Medicinal Product’ shall be described. This is the actual manufactured item - the tablet, the liquid, the cream contained within the package - as it is delivered from the manufacturer but before any reconstitution for administration to the patient, if applicable.

The reconstituted equivalent is described in the ‘Pharmaceutical Product’ class.

![Diagram of Manufactured Item and immediately related packaging classes]

5.12.13.2 Manufactured Dose Form

This describes the pharmaceutical dose form of the pharmaceutical item as supplied by the manufacturer. A term and a term identifier as defined in ISO/DIS 11239 and the resulting controlled vocabulary shall be specified. It is to be provided using a CD data type.

EXAMPLE Values are: Tablet, Capsule, Oral Solution, Powder for solution for injection.

Note that a medicinal product may have two items, one with a ‘Manufactured Dose Form’ of powder for solution for injection and the other with a Manufactured Dose Form of solvent for solution for injection. These are then to be reconstituted to a solution for injection to be administered to a patient. Solution for injection is the ‘Administrable Dose Form’, which is an attribute of ‘Pharmaceutical Product’.

5.12.13.3 Pack Size

This is the size of the ‘Manufactured Item’. It shall be specified using a PQ data type and the units shall be specified as a symbol and a symbol identifier as defined in ISO/DIS 11240 and the resulting controlled vocabulary.

For many supplied pharmaceutical dose forms with a single active ingredient the value and units in ‘Pack Size’ shall be a simple multiple of the value and units for the ‘Strength’ of the single active ingredient. However, where there are multiple active ingredients, or where the ‘Strength’ is expressed as a quantity per volume rather than a quantity per item, the values and units will be different. See the examples provided in Annex A.

5.12.13.4 Unit of Presentation

This specifies the “real world” units in which the ‘Pack Size’ of the ‘Manufactured Item’ is described. It is a term and a term identifier as defined in ISO/DIS 11239 and its resulting controlled vocabulary. It is to be specified using a CD data type.
For items where their ‘Pack Size’ 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 ‘Pack Size’ (that is ml, mg or some multiple). For solid dose forms and other items that are measured by counting integer quantities the unit for ‘Pack Size’ shall be “Unit” and the ‘Presentation Unit’ shall be the item that is counted (e.g. tablets, capsules).

**Figure 24 – Pack Size & Presentation Unit Examples (some attributes have been omitted for clarity)**

Units of Presentation and Manufactured Dose Form for a Manufactured Item are not necessarily the same Units of Presentation and Administrable Dose Form for a Pharmaceutical Product. For instance, a product may be supplied as two items, one a powder for solution for injection, and the other a solvent for solution for injection. Both of these items may have a ‘Unit of Presentation’ of Cartridge / Vial. However, once reconstituted the unit of presentation may be millilitres and does not require an explicit value since it is captured in the Pack Size. The Administrable Dose Form is Solution for Injection.

**Figure 25 – Pack Size & Presentation Unit Examples (some attributes have been omitted for clarity)**

### 5.12.13.5 Physical Characteristics

The physical attributes of the ‘Manufactured Item’ such as height, weight, width, depth, volume, colour and shape shall be provided. One or more images of the ‘Manufactured Item’ shall be also included as applicable.

These attributes are described in detail in section 5.12.3.
5.12.14 Pharmaceutical Product

5.12.14.1 General provisions

The pharmaceutical item(s) resulting from the ‘Packaged Medicinal Product’ shall be described in the form in which they are to be administered to the patient in accordance with the product labelling or summary of product characteristics.

The ‘Manufactured Item’ as packaged for distribution or sale and before reconstitution, if applicable, is described in the ‘Manufactured Item’ class.

For many medicinal products, there is no reconstitution step required, however, both the ‘Manufactured Item’ and ‘Pharmaceutical Product’ shall be specified.

![Figure 26 – Pharmaceutical Product and immediately related packaging classes](image)

5.12.14.2 PhPID

This field shall carry the relevant identifiers as defined by ISO/DIS 11616. It provides a uniform representation of the pharmaceutical product using the ‘Substance(s)/Specified Substance(s)’, their ‘(Reference) Strength(s)’, the ‘Administrable dose form’ and any associated ‘Medical device(s)’.

5.12.14.3 Administrable Dose Form

This shall describe the pharmaceutical dose form as to be administered to the patient in accordance with the terms laid down in the marketing authorization. It is after it has undergone any necessary reconstitution. A term and a term identifier as defined by ISO/DIS 11239 and its resulting controlled vocabulary shall be used. It is to be specified using a CD data type.

EXAMPLE Values are: Tablet, Capsule, Oral Solution, Suspension.

NOTE A medicinal product may have two manufactured items, one with a ‘Manufactured Dose Form’ of ‘powder for solution for injection’ and the other with a ‘Manufactured Dose Form’ of ‘solvent for solution for injection’. These are then reconstituted to an ‘Administrable Dose Form’ ‘solution for injection’ before administered to a patient.

5.12.14.4 Pack Size

This is the ‘Pack Size’ of the ‘Pharmaceutical Product’. It shall be specified using a PQ data type and the unit symbol and unit identifier as defined by ISO/DIS 11240 and its resulting controlled vocabulary.
For many pharmaceutical dose forms with single ingredients, the value and units in ‘Pack Size’ will be a simple multiple of the value and units for the ‘Strength’ of the single ingredient. However, where there are multiple ingredients, or where the strength is expressed as a quantity per volume rather than a quantity per item, the values and units will be different. See the examples in section 5.12.13.4.

5.12.14.5 Unit of Presentation

This specifies the “real world” units in which the ‘Pack Size’ of the ‘Pharmaceutical Product’ is described. A specified term and a term identifier as defined by ISO/DIS 11239 and its resulting controlled vocabulary shall be used. It is to be specified using a CD data type.

For items where their ‘Pack Size’ 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 ‘Pack Size’ (that is ml, mg or some multiple). For solid dose forms and other items that are measured by counting integer quantities the unit for ‘Pack Size’ shall be “Unit” and the ‘Presentation Unit’ shall be the item that is counted (e.g. Tablets, Capsules). See the examples in Annex A.

‘Units of Presentation’ for a ‘Pharmaceutical Product’ are not necessarily the same as for a ‘Manufactured Item’. See the examples in section 5.12.13.4.

5.12.14.6 Onset of Action

The length of time for a pharmaceutical product to start to “work” shall be specified, where applicable, using a term and a term identifier from a controlled vocabulary.

EXAMPLE Quick acting, short acting, intermediate acting insulin.

5.12.14.7 Product Classification

A list of groupings or categories in accordance with an adequate product and/or pharmacological classification system shall be specified. It shall be specified using a CD data type and using one or more classification systems.

EXAMPLE Diuretikum, Antihypertensivum, Antiemeticum, Advanced Therapy Medicinal Product, Vaccine.

5.12.15 Route of Administration

5.12.15.1 General provisions

The route(s) of administration as authorized in accordance with the terms outlined in the marketing authorizations shall be specified.

Figure 27 – Route of Administration and immediately related packaging classes

5.12.15.2 Route of Administration

‘Route of Administration’ shall use the terms and term identifiers as defined in ISO/DIS 11239 and its resulting controlled vocabulary. A CD data type shall be used.
5.12.15.3 Max Dose per Route

This shall specify the maximum single dose quantity that may be given for a first-in-human clinical trial in a single dose by the specified ‘Route of Administration’. This shall be specified using an RTO<PQ,PQ> data type.

It is only applicable for investigational products as described in section 6.

5.12.16 Indications

5.12.16.1 General provisions

The authorized therapeutic use of the medicinal product in line with the terms and conditions as outlined in the marketing authorizations shall be specified.

![Diagram of Indications and Pharmaceutical Product]

**Figure 28 – Indications and immediately related packaging classes**

5.12.16.2 Indication

The authorized indication shall be specified using a controlled term and controlled term identifier of a controlled vocabulary, as applicable. This shall be specified using a CD data type.

The authorized indication as described in the summary of product characteristics or the product labelling shall be also described using the Original Text part of the CD data type.

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

5.12.16.3 Therapeutic Use

The authorized therapeutic use shall be specified using a term and a term identifier from a controlled vocabulary as applicable.

EXAMPLE Prophylaxis, diagnosis, treatment.

5.12.16.4 Target Population

The target population for which the medicinal product is indicated shall be specified using a term and a term identifier from a controlled vocabulary, as applicable.

EXAMPLE For adults, children, elderly.

5.12.16.5 Target Population Age Range/Age Group

The age range or age group of the target population as authorized for the medicinal product shall be specified based on a value drawn from an international reference terminology.
EXAMPLE For children older than 12 months and younger than 4 years.

5.12.16.6 Gender

The target gender as authorized for the medicinal product shall be specified using the ISO/IEC 5218:2004 and held in a CD data type.

EXAMPLE For the treatment of men with prostate cancer has gender code male.

5.12.16.7 Underlying disease(s)

The underlying disease as referenced in the summary of product characteristics or the product labelling shall be specified using a term and a term identifier from a controlled vocabulary, as applicable.

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

5.13 Ingredient

5.13.1 General considerations

This describes the constituents of the medicinal product i.e. the ‘Manufactured Item’ and the ‘Pharmaceutical Product’ based on the terms and term identifiers as defined by ISO/DIS 11238 and its resulting controlled vocabulary.

There shall be one instance of the ‘Ingredient’ class for each actual ingredient, but the class itself only acts to connect together the appropriate set of substances and specified substances and the strength thereof.

Figure 29 – Ingredient and immediately related classes

5.13.2 Substances

5.13.2.1 General provisions

The ‘Substance’ as contained in the ‘Manufactured Item’ and the ‘Pharmaceutical Product’ shall be described using a term and a term identifier as defined in ISO/DIS 11238 and its resulting controlled vocabulary.

5.13.2.2 Role

The role of the ‘Substance’ shall be described using a term and a term identifier of a controlled vocabulary. It shall be specified using a CD data type.

EXAMPLE The substance role may be Active Substance, Adjuvant, Excipient, Coating, Ink.
5.13.2.3 Substance

The ‘Substance’ shall be described using a term and a term identifier as defined in ISO/DIS 11238 and its resulting controlled vocabulary. It shall be specified using a CD data type.

If a ‘Specified Substance’ is given, the ‘Substance’ shall be a proper general version of the ‘Specified Substance’.

5.13.2.4 Substance Strength

The strength of the ‘Substance’ shall be specified as a quantity of the substance present in a given quantity of the ‘Manufactured Item’ or ‘Pharmaceutical Product’. It shall be specified using the Strength class see section 5.13.5. The symbol and the symbol identifier as defined in ISO/DIS 11240 and its resulting controlled vocabulary shall be specified. Where the strength is defined on the basis of a ‘Unit of Presentation’, the term and term identifier shall be used as defined in ISO/DIS 11239 and its resulting controlled vocabulary.

5.13.3 Specified Substances

5.13.3.1 General considerations

The attributes for the ‘Specified Substances’ class are the same as those described above for ‘Substances’ except that they refer to a specified substance as defined in ISO/DIS 11238.

If a ‘Substance’ is described, the ‘Specified Substance’ shall be a proper manufactured version of a substance.

5.13.3.2 Role

The role of the ‘Specified Substance’ shall be described using a term and a term identifier of a controlled vocabulary. It shall be specified using a CD data type.

EXAMPLE The specified substance role may be Active Substance, Adjuvant, Excipient, Coating, Ink.

5.13.3.3 Specified Substance

The ‘Specified Substance’ shall be described using a term and a term identifier as defined in ISO/DIS 11238 and its resulting controlled vocabulary. It shall be specified using a CD data type.

If a ‘Specified Substance’ is given, the ‘Substance’ shall be a proper general version of the ‘Specified Substance’.

5.13.3.4 Specified Substance Strength

The strength of the ‘Specified Substance’ shall be indicated as a quantity of the substance present in a given quantity of the ‘Manufactured Item’ or ‘Pharmaceutical Product’. The symbol and the symbol identifier as defined in ISO/DIS 11240 and its resulting controlled vocabulary shall be specified. Where the strength is defined on the basis of a ‘Unit of Presentation’, the term and term identifier shall be used as defined in ISO/DIS 11239 and its resulting controlled vocabulary. This attribute is optional.

It shall be specified using the ‘Strength’ class see section 5.13.5.
5.13.4 Reference Strength

5.13.4.1 General provisions

This makes use of a child of ‘Substances’ or ‘Specified Substances’ class to describe a substance and/or specified substance that is used as a reference for expression of strength. It shall be indicated using the ‘Strength’ class see section 5.13.5.

5.13.4.2 Reference Substance

The value for the ‘Reference Substance’ shall be described using a term and a term identifier as defined in ISO/DIS 11238 and its resulting controlled vocabulary. It shall be specified using a CD data type.

5.13.4.3 Reference Substance Strength

The strength of the ‘Reference Substance’ shall be specified as a quantity of the substance as referred to in order to express a given quantity of the ‘Manufactured Item’ or ‘Pharmaceutical Product’. The symbol and the symbol identifier as defined in ISO/DIS 11240 and its resulting controlled vocabulary shall be specified. Where the strength is defined on the basis of a ‘Unit of Presentation’, the term and term identifier shall be used as defined in ISO/DIS 11239 and its resulting controlled vocabulary. It shall be specified using the ‘Strength’ class see section 5.13.5.

5.13.4.4 Reference Specified Substance

The value for the ‘Reference Specified Substance’ shall be described using a term and a term identifier as defined in ISO/DIS 11238 and its resulting controlled vocabulary. It shall be specified using a CD data type.

5.13.4.5 Reference Specified Substance Strength

The strength of the ‘Reference Specified Substance’ shall be specified as a quantity of the specified substance as referred to in order to express a given quantity of the ‘Manufactured Item’ or ‘Pharmaceutical Product’. The symbol and the symbol identifier as defined in ISO/DIS 11240 and its resulting controlled vocabulary shall be specified. Where the strength is defined on the basis of a ‘Unit of Presentation’, the term and term identifier shall be used as defined in ISO/DIS 11239 and its resulting controlled vocabulary. It shall be specified using the ‘Strength’ class see section 5.13.5.

5.13.5 Strength

5.13.5.1 Range

The actual value and units of the strength shall be specified using an RTO<PQ,PQ> data type, which requires data to be given as a numerator and a denominator, each with units, and for the numerator to be an interval. This allows both a low and a high value to be specified as well as upper and lower ranges. If both low and high values are the same, the interval is equivalent to a single value. If the low value is zero or not valued, the range is interpreted as not greater than the high value. Similarly if the high value is zero or not valued the range is interpreted as not less than the low value. The symbol and the symbol identifier as defined in ISO/DIS 11240 and its resulting controlled vocabulary shall be specified. Where the strength is defined on the basis of a ‘Unit of Presentation’, the term and term identifier shall be used as defined in ISO/DIS 11239 and its resulting controlled vocabulary.

5.13.5.2 Measurement Point

The point where a measurement is made shall be specified, as applicable. It shall be specified using a CD data type.
5.13.5.3 Country

The country or countries for which the Range and Measurement Point are valid may be specified. The values shall be specified using a CD data type and using values from ISO 3166-1-alpha-2 code elements.
6 Identifying Characteristics for Investigational Medicinal Products

6.1 Conceptual Overview

6.1.1 General considerations

This section describes investigational medicinal products (IMP) that are not authorized for marketing and subject to an investigation in one or more clinical trials.

IMP refers to a medicinal product being tested in a clinical trial, including e.g. each comparator and each placebo as defined in the clinical trial protocol.

Whilst 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.

Figure 30 – Investigational Product Conceptual Drawing and immediately related classes

The main concepts identifying characteristics of an investigational medicinal product modelled in Figure 30 and described in 6.1.2 to 6.1.10 shall apply.
6.1.2 Sponsor

The organisation that undertakes the clinical trial

6.1.3 Clinical Trial Authorization

The clinical trial authorization as issued by a medicines regulatory authority, which permits a sponsor to conduct a clinical trial in a specific jurisdiction.

6.1.4 Investigational Medicinal Product Name or Code

The name or code of an investigational medicinal product together with an analysis of the name into various parts.

6.1.5 IMPID

The criteria for the unique identification of an investigational medicinal product.

6.1.6 IPCID

The criteria for the unique identification of a packaged investigational medicinal product.

6.1.7 Packaged Investigational Medicinal Products

The description of the packaging of the medicine both as supplied for distribution for the purpose of the conduct of a clinical trial and as reconstituted for administration (pharmaceutical product) to the patients enrolled in a clinical trial, if applicable.

6.1.8 Ingredients

The set of substances and specified substances of which both the manufactured (manufactured item) and administrable medicine (pharmaceutical product) is composed.

6.1.9 PhPID

The link to the ISO/DIS 11616 standard.

6.1.10 IBAID_1 and IBAID_2

The criteria for the unique identification of a batch/lot of an investigational medicinal product.

6.2 Primary Identifiers

6.2.1 Specified identifiers

To satisfy the requirements as described in section 3.1.39, the following four primary identifiers shall be specified:

- IMPID – Investigational Medicinal Product Identifier
- IPCID – Investigational Medicinal Product Package Identifier
- IBAID_1 – Investigational Medicinal Product Batch Identifier
- IBAID_2 – Investigational Medicinal Product Package Batch Identifier
These shall be associated with the ‘Pharmaceutical Product Identifier’ (PhPID) as specified in ISO/DIS 11616. The relationship between these different identifiers is shown in Figure 31 and is further defined in the following sections.

![Figure 31 – Relationship of Core Identifiers (other attributes have been omitted for clarity)](image)

6.2.2 Defining Attributes for Investigational Medicinal Product Identifier Attribute Set (IMPID)

6.2.2.1 Attribute Set

For each investigational medicinal product, a unique investigational medicinal product identifier (IMPID) shall be assigned. The IMPID shall be allocated in addition to any existing identifier ascribed by a medicines regulatory authority in a jurisdiction or sponsors 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 be specified using an II data type.

![Figure 32 – Investigational MPID Attribute Set and immediately related classes](image)

The IMPID shall use a common attribute set related to an investigational medicinal product, which when all of them have a value, defines a specific IMPID concept:

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

A separate unique IMPID shall be assigned whenever any of the pre-defined attribute sets of an investigational medicinal product are different in any way that is relevant to the medicines regulatory process.

This process may result in changes to IMPID when existing regulatory identifiers would not change. The standard shall NOT require such existing regulatory identifiers to be changed in step with the IMPID. Each jurisdiction may continue with its existing working practices for existing identifiers.

Formalising the rules for when a new IMPID shall be generated allows the generation to be automated applying the appropriate notification of changes.

The IMPID code segments shall be generated using the following code segments.

6.2.2.2 Country Code Segment

This code segment shall reflect the country code (jurisdiction(s)) where the clinical trial protocol is submitted to a medicines regulatory authority. The ISO 3166-1-alpha-2 code shall be used. If the clinical trial is authorized in more than one country of a jurisdiction, all country codes shall be specified. It shall be defined using a CD data type.

6.2.2.3 Clinical Trial Protocol Number Code Segment

This code segment shall reflect the clinical trial protocol number as assigned by the medicines regulatory authority, which authorized the conduct of the clinical trial in a jurisdiction. The identifier allocated for the protocol under which the clinical trial is being conducted shall be described using an II data type.

This code segment shall reflect a code assigned to the investigational medicinal product. It shall apply the following defining attribute set:

- Substances(active)/specified substances (e.g., adjuvant)
- Medical device where it is a part of an investigational medicinal product
- Indication(s) studied in the clinical trial

6.2.3 Defining Attributes for Investigational Medicinal Product Package Identifier (IPCID):

6.2.3.1 Package Identifier

For each investigational medicinal product, an investigational package identifier (IPCID) shall be assigned.
The IPCID shall use a common attribute set related to a package of an investigational medicinal product, which when all of them have a value, define a specific IPCID concept:

- IMPID Attribute Set
- Package Description Code segment

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

A separate unique IPCID shall be assigned whenever any of the pre-defined attribute sets of an investigational medicinal product are different in any way that is relevant to the medicines regulatory process.

This process may result in changes to IPCID when existing regulatory identifiers would not change. The standard shall 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.

Formalising the rules for when a new IPCID shall be generated allows the generation to be automated applying the appropriate notification of changes.

6.2.3.2 Package Description Code Segment

This code segment shall reflect a code assigned to each package presentation of an investigational medicinal product. It is shall apply to the ‘Packaged Item’ attribute set.

6.3 Defining Attributes for Investigational Medicinal Product Batch Identifier (IBAID_1)

6.3.1 Specified attributes

For each investigational medicinal product, a batch identifier (IBAID_1) shall be assigned. The IBAID_1 shall be based on the batch number allocated by the manufacturer or sponsor.
The IBAID_1 shall apply a common attribute set related to an investigational medicinal product, which when all of them have a value, define a specific IBAID_1 concept:

- 'IMPID Attribute Set'
- 'Batch Code Segment'

Any change of the values related to these code segments shall result in the assignment of a new IBAID_1.

### 6.3.2 Batch Code Segment

This code segment shall reflect the batch or lot number assigned by the manufacturer or the sponsor. It shall apply the following defining attribute set:

- Batch or lot number
- Expiration Date (optional attribute)

### 6.4 Defining Attributes for Investigational Medicinal Product Batch Identifier (IBAID_2)

For each investigational medicinal product, a batch identifier (IBAID_2) shall be assigned. The IBAID_2 shall use the batch number allocated by the manufacturer or the sponsor.

The IBAID_2 shall be 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:

- 'PCID Attribute Set'
- Batch Code Segment as described in section 6.3.2.
6.5 Version

6.5.1 General considerations

The characteristics of investigational medicinal products as defined in this standard shall be versioned. This refers to the fact that at the given effective date, some characteristics of the investigational medicinal product have changed. These characteristics are not different to a sufficient extent to warrant the assignment of a new Primary Identifier Attribute Set as specified in section 5.2.

![Figure 36 – Version and immediately related classes]

6.5.2 Effective Date

The date of the authorization or the latest update of the investigational medicinal product information (based on the clinical trial application and the investigators brochure), which serves as the reference for the unique identification of investigational medicinal products and their characteristics, shall be specified. The date shall be specified using a TS.Date data type.

6.5.3 Regulated Document

The reference number of the regulatory decision document related to the granting of the authorization or the latest update of the clinical trial application shall be specified. The reference document ID shall be specified using an II data type.

6.6 Medicinal Product Name (Investigational)

6.6.1 General considerations

The name or code routinely used by a sponsor to identify the IMP in the clinical trial shall be specified. The name or code shall be specified using a CD data type.

In addition to the investigational medicinal product name or code, an analysis of the name parts shall be provided in a structured format as applicable. Where applicable, these name/code parts shall also be described for all official languages in a jurisdiction.

The ‘Name’ and its elements and ‘Language’ are actually all part of the EN data type as provided by ISO 21090. They are defined in full here for clarity. Implementations shall use the EN data type.

There may be multiple instances of this class to cover multiple languages in a jurisdiction and the multiple countries for which the investigational medicinal product has a name.

The ‘Medicinal Product Name’ class as described in section 5.6 shall be used.
6.6.2 Code

If the sponsor has assigned a code to the IMP for the purpose of the trial the code value shall be specified.

6.7 Clinical Trial Authorization

6.7.1 General considerations

A clinical trial authorization is issued by the appropriate regulatory medicines authority. In compliance with the laws and regulations applicable in a jurisdiction, an authorization is required before an investigational medicinal product may be studied in a clinical trial.

6.7.2 Clinical Trial Registration Number

The registration number (identifier) for a clinical trial in a jurisdiction shall be specified, where applicable.
6.7.3 Investigation Code

The code for an investigational medicinal product as assigned in a jurisdiction for a clinical trial of a set of clinical trials shall be specified.

6.7.4 Country

The jurisdiction(s) in which the clinical trial authorization was granted shall be described using ISO 3166-1 alpha-2 codes. It shall be defined using a CD data type.

6.7.5 Protocol Number

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

6.7.6 Max Duration

This shall specify the maximum period of treatment of a subject according to the clinical trial protocol. It shall be specified using a PQ.Time data type.

6.7.7 Max Dose per Period

This shall specify the maximum dose quantity that may be given in either a day, or in total over an undefined period. This shall be specified using an RTO<PQ,PQ> data type.

6.7.8 Max Single Dose

This shall specify the maximum dose quantity that may be given for a first-in-human clinical trial in a single dose. This shall be specified using an RTO<PQ,PQ> data type.

6.7.9 Max First Dose per Period

This shall specify the maximum first dose quantity that may be given for a first-in-human clinical trial either in a day, or in total over an undefined period. This shall be specified using an RTO<PQ,PQ> data type.

6.7.10 Authorization Date

The date when the clinical trial authorization was granted by a regulatory medicines authority in a jurisdiction shall be provided. A complete date consisting of day, month and year shall be specified using the ISO date format [ISO 8601].

6.7.11 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 date consisting of day, month and year shall be specified using the ISO date format [ISO 8601].

6.7.12 Is Paediatric?

This shall be set to TRUE or FALSE as appropriate. It shall be specified using a BL data type.

6.7.13 Product Classification

If the investigational medicinal product designated in the indication(s) as an orphan drug this shall be set to the value or values of the orphan drug designation reference number(s) within the Product Classification.
6.7.14 Local Clinical Trial Authorization

6.7.14.1 Attribute considerations

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.

6.7.14.2 Local Clinical Trial Registration Number

The registration number (identifier) for a clinical trial as assigned by the regulatory medicines authority locally shall be specified.

6.7.14.3 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.

6.7.14.4 Country

The jurisdiction(s) in which the clinical trial authorization was granted shall be described using ISO 3166-1 alpha-2 codes. It shall be defined using a CD data type.

6.7.14.5 Local Authorization Date

The date when the clinical trial authorization was granted locally by a regulatory medicines authority shall be provided. A complete date consisting of day, month and year shall be specified using the ISO date format [ISO 8601].

6.7.14.6 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 date consisting of day, month and year shall be specified using the ISO date format [ISO 8601].

6.8 Sponsor

6.8.1 General considerations

This section refers to the details of the sponsor of a clinical trial and the investigational medicinal product studied.
6.8.2 Organisation

Details in relation to the organisation that is the ‘Sponsor’ shall be specified as an ‘Organisation’ class as described in section 5.10.

6.8.3 Status

This shall specify the Sponsor to be either ‘Commercial’ or ‘Non-Commercial’. This is specified using an appropriate value set and a CD data type.

6.8.4 Legal Representative of the Sponsor

Details of the ‘Legal Representative of the Sponsor’ shall be specified as an ‘Organisation’ class as described in section 5.10.

6.9 Manufacturing Authorization

6.9.1 General considerations

Details of the manufacturing authorization granted by a regulatory medicines authority shall be specified for the investigational medicinal product, where applicable.

6.9.2 Manufacturing Authorization Holder

Details in relation to the organisation that holds the manufacturing authorizations shall be specified as an ‘Organisation’ class described in section 5.10.

6.9.3 Manufacturing Authorization Date

The date when the manufacturing authorization was issued by the regulatory authority shall be specified using the ISO 8601 date format.

6.9.4 Manufacturing Authorization Authority

Details in relation to the organisation that granted the manufacturing authorization shall be specified as an ‘Organisation’ class described in section 5.10.
6.10 Medicines Regulatory Authority

The medicines regulatory authority, which authorized the clinical trial in which the medicinal product is investigated, shall be specified as an ‘Organisation’ class described in section 5.10.

6.11 Packaged Medicinal Product

The description of a packaged investigational 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), as applicable. Details as described in section 5.12 shall be described.

As regards ‘Indication’ the indication(s) as authorized in the context of the clinical trial shall be specified.
ANNEX A
(informative)

Examples

A.1 Fictional Authorized Medicinal Product, INFLUENZAVAC, in accordance with the approved product labelling

Tabular view

Table A.1 shows a fictional example of an Authorized Medicinal Product, INFLUENZAVAC, in accordance with the approved product labelling
Table A.1 — Example, INFLUENZAVAC in accordance with the approved product labelling

<table>
<thead>
<tr>
<th>Invented Name</th>
<th>INFLUENZAVAC suspension and emulsion for emulsion for injection, Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language</td>
<td>English</td>
</tr>
<tr>
<td>Marketing Number</td>
<td>EU/H/08452001</td>
</tr>
<tr>
<td>Marketing Holder</td>
<td>COMPANY A, Street, Number 5, Paris, France</td>
</tr>
<tr>
<td>Marketing Identifier</td>
<td>454</td>
</tr>
<tr>
<td>Country</td>
<td>EU</td>
</tr>
<tr>
<td>Legal Status of Supply</td>
<td>Medicinal product subject to medical prescription</td>
</tr>
<tr>
<td>Regulator</td>
<td>REGULATOR A</td>
</tr>
<tr>
<td>Regulator ID</td>
<td>777</td>
</tr>
<tr>
<td>Marketing Expiry Date</td>
<td>01.01.2013</td>
</tr>
<tr>
<td>Date of Marketing</td>
<td>01.03.2008</td>
</tr>
<tr>
<td>Status of the marketing</td>
<td>Active</td>
</tr>
<tr>
<td>GTIN</td>
<td>12345678901234</td>
</tr>
<tr>
<td>Procedure Type</td>
<td>Initial marketing</td>
</tr>
<tr>
<td>Procedure Reference Code</td>
<td>123 XYZ centralised procedure</td>
</tr>
<tr>
<td>Procedure ID</td>
<td>9870</td>
</tr>
<tr>
<td>Document ID</td>
<td>1234/2008</td>
</tr>
<tr>
<td>Date</td>
<td>01.01.2008</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>MANUFACTURER A, Street, Number 8, Florence, Italy</td>
</tr>
<tr>
<td>Medicines Regulatory Authority</td>
<td>REGULATOR A, L Street, Number 13, Brussels, Belgium</td>
</tr>
<tr>
<td>Package Description</td>
<td>One vial (type I glass) of 2.5 ml suspension with a stopper (butyl rubber)</td>
</tr>
<tr>
<td></td>
<td>One vial (type I glass) of 2.5 ml emulsion with a stopper (butyl rubber)</td>
</tr>
<tr>
<td>Batch number</td>
<td>3456</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>09.2011</td>
</tr>
<tr>
<td>Outer Packaging</td>
<td>Carton</td>
</tr>
<tr>
<td>Indication(s)</td>
<td>Prophylaxis of influenza in an officially declared pandemic situation</td>
</tr>
<tr>
<td>Manufactured item</td>
<td>Suspension: multidose vial containing the antigen</td>
</tr>
<tr>
<td></td>
<td>Emulsion: multidose vial containing the adjuvant</td>
</tr>
<tr>
<td></td>
<td>Suspension vial:</td>
</tr>
<tr>
<td></td>
<td>Split influenza virus, inactivated, containing antigen* equivalent to:</td>
</tr>
<tr>
<td></td>
<td>A/Nevada/9/2009 (H1N1)v-like strain (Z-999Z)</td>
</tr>
<tr>
<td></td>
<td>Polysorbate 80, Octoxyynol 10, Thiomersal, Sodium chloride (NaCl)</td>
</tr>
<tr>
<td></td>
<td>Disodium hydrogen phosphate (Na2HPO4), Potassium dihydrogen phosphate (KH2PO4), Potassium chloride (KCl), Magnesium chloride (MgCl2), Water for injections</td>
</tr>
<tr>
<td></td>
<td>Emulsion vial:</td>
</tr>
<tr>
<td></td>
<td>SA09 adjuvant composed of squalene (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams)</td>
</tr>
<tr>
<td></td>
<td>Sodium chloride (NaCl)</td>
</tr>
<tr>
<td></td>
<td>Disodium hydrogen phosphate (Na2HPO4),Potassium dihydrogen phosphate (KH2PO4), Potassium chloride (KCl), Water for injections</td>
</tr>
<tr>
<td>Pharmaceutical Product</td>
<td>Emulsion for injection after mixing, 1 dose (0.5 ml) contains:</td>
</tr>
<tr>
<td></td>
<td>Split influenza virus, inactivated, containing antigen* equivalent to:</td>
</tr>
<tr>
<td></td>
<td>A/Nevada/9/2009 (H1N1)v-like strain (Z-9992) 3.75 micrograms**</td>
</tr>
<tr>
<td></td>
<td>* propagated in eggs, ** haemagglutinin</td>
</tr>
<tr>
<td></td>
<td>Polysorbate 80, Octoxyynol 10, Thiomersal, Sodium chloride (NaCl)</td>
</tr>
<tr>
<td></td>
<td>Disodium hydrogen phosphate (Na2HPO4), Potassium dihydrogen phosphate (KH2PO4), Potassium chloride (KCl), Magnesium chloride (MgCl2), SA09 adjuvant composed of squalene (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams), Sodium chloride (NaCl),Disodium hydrogen phosphate (Na2HPO4),Potassium dihydrogen phosphate (KH2PO4), Potassium chloride (KCl), Water for injections</td>
</tr>
<tr>
<td>Product classification</td>
<td>Vaccine</td>
</tr>
<tr>
<td>Route of administration</td>
<td>intramuscular injection</td>
</tr>
<tr>
<td>Pharmaceutical Dose Form</td>
<td>Suspension and emulsion for emulsion for injection</td>
</tr>
</tbody>
</table>
A.2 Model view

The Figures that follow show the representation of the example 0 using objects derived from the model. Because of limitations of paper size the overview in Figure A.1 is broken into four quadrants for display in Figures A.2 to A.5.

Figure A.1 — Example, INFLUENZAVAC, overview model
Figure A.2 — Example, INFLUENZAVAC, top left quadrant
Figure A.3 — Example INFLUENZAVAC, top right quadrant
Figure A.4 — Example INFLUENZAVAC, bottom left quadrant
Figure A.5 — Example INFLUENZAVAC, bottom right quadrant
A.3 Fictional Authorized Medicinal Product, LITHDRUG®, in accordance with the approved product labelling

Table A.2 shows a fictional example of an Authorized Medicinal Product, LITHDRUG®, in accordance with the approved product labelling

<table>
<thead>
<tr>
<th>Invented Name</th>
<th>LITHDRUG® (Lithium Carbonate, Pharmacopoeia), Extended-Release Tablets 300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language</td>
<td>English</td>
</tr>
<tr>
<td>Marketing Number</td>
<td>6ZX68-44K2-1</td>
</tr>
<tr>
<td>Marketing Holder</td>
<td>COMPANY Z, Street, Number 599, New York, US</td>
</tr>
<tr>
<td>Marketing Holder Identifier</td>
<td>4545</td>
</tr>
<tr>
<td>Country</td>
<td>US</td>
</tr>
<tr>
<td>Legal Status of Supply</td>
<td>Medicinal product subject to medical prescription</td>
</tr>
<tr>
<td>Regulator</td>
<td>REGULATOR Z</td>
</tr>
<tr>
<td>Regulator Identifier</td>
<td>0001</td>
</tr>
<tr>
<td>Marketing Expiry Date</td>
<td>01.03.2013</td>
</tr>
<tr>
<td>Date of Marketing</td>
<td>09.09.2009</td>
</tr>
<tr>
<td>Status of the marketing</td>
<td>Active</td>
</tr>
<tr>
<td>GTIN</td>
<td>987654321111111</td>
</tr>
<tr>
<td>Procedure Type</td>
<td>Renewal marketing</td>
</tr>
<tr>
<td>Procedure Reference Code</td>
<td>123  ANDA procedure</td>
</tr>
<tr>
<td>Procedure ID</td>
<td>KH12121</td>
</tr>
<tr>
<td>Document ID</td>
<td>999/2006</td>
</tr>
<tr>
<td>Date</td>
<td>01.01.2006</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>MANUFACTURER Z, Street, Number 765, Phoenix, US</td>
</tr>
<tr>
<td>Medicines Regulatory Authority</td>
<td>REGULATOR Z, Street, Number 7, Washington D.C., US</td>
</tr>
<tr>
<td>Package Description</td>
<td>Bottle of 100</td>
</tr>
<tr>
<td>Batch number</td>
<td>12366</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>9.2012</td>
</tr>
<tr>
<td>Outer Packaging</td>
<td>Carton</td>
</tr>
<tr>
<td>Indication(s)</td>
<td>Acute Mania</td>
</tr>
<tr>
<td>Manufactured item</td>
<td>Lithium Carbonate, Pharmacopoeia)</td>
</tr>
<tr>
<td></td>
<td>Extended-Release Tablets, 300 mg, peach colored imprinted “LITHIUMDRUG” 300</td>
</tr>
<tr>
<td>Pharmaceutical Product</td>
<td>Lithium Carbonate, Pharmacopoeia</td>
</tr>
<tr>
<td></td>
<td>Extended-Release Tablets, 300 mg</td>
</tr>
<tr>
<td>Product classification</td>
<td>Antipsychotic</td>
</tr>
<tr>
<td>Route of administration</td>
<td>oral</td>
</tr>
<tr>
<td>Pharmaceutical Dose Form</td>
<td>Extended-Release Tablet</td>
</tr>
</tbody>
</table>
A.4 Fictional Authorized Medicinal Product, INHALDRUG HFA, in accordance with the approved product labelling

Table A.3 shows a fictional example of an Authorized Medicinal Product, INHALDRUG HFA, in accordance with the approved product labelling

<table>
<thead>
<tr>
<th>Invented Name</th>
<th>INHALDRUG HFA (fluticasone propionate) aerosol, metered, company K</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language</td>
<td>English</td>
</tr>
<tr>
<td>Marketing Number</td>
<td>9ZX99-67L2-1</td>
</tr>
<tr>
<td>Marketing Holder</td>
<td>COMPANY K, Street, Number 1, Dublin, Ireland</td>
</tr>
<tr>
<td>Marketing Holder Identifier</td>
<td>0876</td>
</tr>
<tr>
<td>Country</td>
<td>Ireland</td>
</tr>
<tr>
<td>Legal Status of Supply</td>
<td>Medicinal product subject to medical prescription</td>
</tr>
<tr>
<td>Regulator</td>
<td>REGULATOR K</td>
</tr>
<tr>
<td>Regulator ID</td>
<td>0099</td>
</tr>
<tr>
<td>Marketing Date</td>
<td>1.1.2008</td>
</tr>
<tr>
<td>Marketing Expiry Date</td>
<td>01.12.2012</td>
</tr>
<tr>
<td>Date of Marketing</td>
<td>1.02.2008</td>
</tr>
<tr>
<td>Status of the marketing</td>
<td>Active</td>
</tr>
<tr>
<td>GTIN</td>
<td>111156789111234</td>
</tr>
<tr>
<td>Procedure Type</td>
<td>Initial marketing</td>
</tr>
<tr>
<td>Procedure Reference Code</td>
<td>Decentralised procedure</td>
</tr>
<tr>
<td>Procedure ID</td>
<td>KK121887</td>
</tr>
<tr>
<td>Date</td>
<td>4.9.2007</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>MANUFACTURER K, Street, Number 88, City, Country</td>
</tr>
<tr>
<td>Manufacturer ID:</td>
<td>0765</td>
</tr>
<tr>
<td>Manufacturing Date</td>
<td>1.8.2007</td>
</tr>
<tr>
<td>Medicines Regulatory Authority</td>
<td>REGULATOR K, A Street, Number 19, Dublin, Ireland</td>
</tr>
<tr>
<td>Package Description</td>
<td>INHALDRUG HFA 44 mcg Inhalation Aerosol is supplied in 10.6-g pressurized aluminium canisters containing 120 metered actuations in boxes of 1</td>
</tr>
<tr>
<td>Batch Number</td>
<td>2LL</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>10 2011</td>
</tr>
<tr>
<td>Outer Packaging</td>
<td>Carton</td>
</tr>
<tr>
<td>Indication(s)</td>
<td>Maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older</td>
</tr>
<tr>
<td>Manufactured item</td>
<td>Aerosol, metered. Each unit contains a microcrystalline suspension of fluticasone propionate (micronized) in propellant HFA-134a (1,1,1,2-tetrafluoroethane)</td>
</tr>
<tr>
<td>Pharmaceutical Product</td>
<td>Aerosol, metered. Each unit contains a microcrystalline suspension of fluticasone propionate (micronized) in propellant HFA-134a (1,1,1,2-tetrafluoroethane). It contains no other excipients</td>
</tr>
<tr>
<td>Product classification</td>
<td>Antiasthmaticum</td>
</tr>
<tr>
<td>Route of administration</td>
<td>RESPIRATORY (INHALATION), ORAL</td>
</tr>
<tr>
<td>Pharmaceutical Dose Form</td>
<td>Aerosol, metered</td>
</tr>
</tbody>
</table>
A.5 Fictional Authorized Medicinal Product, COMBIDRUGTM GYN, in accordance with the approved product labelling

Table A.4 shows a fictional example of an Authorized Medicinal Product, COMBIDRUGTM GYN, in accordance with the approved product labelling

Table A.4 — Example, COMBIDRUGTM GYN in accordance with the approved product labelling

<table>
<thead>
<tr>
<th>Invented Name</th>
<th>COMBIDRUGTM GYN Clotrimazol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language</td>
<td>English</td>
</tr>
<tr>
<td>Marketing Number</td>
<td>1ZX99-617L-4</td>
</tr>
<tr>
<td>Marketing Holder</td>
<td>COMPANY B, M Street, Number 111, London, UK</td>
</tr>
<tr>
<td>Marketing Holder Identifier</td>
<td>0908</td>
</tr>
<tr>
<td>Legal Status of Supply</td>
<td>Medicinal product subject to medical prescription</td>
</tr>
<tr>
<td>Regulator</td>
<td>REGULATOR B, K Street, Number 49, London, UK</td>
</tr>
<tr>
<td>Regulator ID</td>
<td>0087</td>
</tr>
<tr>
<td>Marketing Expiry Date</td>
<td>01.12.2014</td>
</tr>
<tr>
<td>Date of Marketing</td>
<td>5.5.2009</td>
</tr>
<tr>
<td>Status of the marketing</td>
<td>Active</td>
</tr>
<tr>
<td>GTIN</td>
<td>99995678911234</td>
</tr>
<tr>
<td>Procedure Type</td>
<td>Renewed marketing</td>
</tr>
<tr>
<td>Procedure Reference Code</td>
<td>334REW procedure</td>
</tr>
<tr>
<td>Procedure ID</td>
<td>JH121887</td>
</tr>
<tr>
<td>Document ID</td>
<td>6786/20010</td>
</tr>
<tr>
<td>Date</td>
<td>01.01.2010</td>
</tr>
<tr>
<td>Procedure</td>
<td>MRP</td>
</tr>
<tr>
<td>Procedure Reference</td>
<td>UK/H/02T1/009</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>MANUFACTURER B, L Street, Number 123, Manchester, UK</td>
</tr>
<tr>
<td>Medicines Regulatory Authority for Manufacturing</td>
<td>REGUL ATOR B, K Street, Number 49, London, UK</td>
</tr>
<tr>
<td>Manufacturing Date</td>
<td>6.6.2009</td>
</tr>
<tr>
<td>Manufacturer ID:</td>
<td>0222</td>
</tr>
<tr>
<td>Package Description</td>
<td>1 vaginal tablet / content of 1 applicator of vaginal cream (about 5 g)</td>
</tr>
<tr>
<td>Packaging</td>
<td>Carton with Vaginal Cream in 5 g aluminium tube, applicator, Vaginal tablet in PVC-Aluminium foil</td>
</tr>
<tr>
<td>Batch Number:</td>
<td>2BB</td>
</tr>
<tr>
<td>Expiry Date:</td>
<td>10 2012</td>
</tr>
<tr>
<td>Indication(s)</td>
<td>Infections of the genital region (vaginitis) and infectious vaginal discharge caused by fungi (usually Candida), trichomonads and superinfections caused by clotrimazole-sensitive Bacteria</td>
</tr>
</tbody>
</table>
| Manufactured Item      | **Vaginal Tablet**: 500 mg clotrimazole (active substance), Calcium lactate pentahydrate, crospovidone silica, colloidal anhydrous, lactose, monohydrate, magnesium stearate, maize starch, hypromellose, microcrystalline, cellulose, lactic acid (Excipients)  
**Vaginal Cream**: 500 mg clotrimazole (active substance), alcohol, cetyl palmitate, cetostearyl alcohol, purified water, polysorbate 60, sorbitan stearate, octyldodecanol (Excipients) |
| Pharmaceutical Product | **Vaginal Tablet**: 500 mg clotrimazole (active substance), Calcium lactate pentahydrate, crospovidone silica, colloidal anhydrous, lactose, monohydrate, magnesium stearate, maize starch, hypromellose, microcrystalline, cellulose, lactic acid (Excipients)  
**Vaginal Cream**: 500 mg clotrimazole (active substance), alcohol, cetyl palmitate, cetostearyl alcohol, purified water, polysorbate 60, sorbitan stearate, octyldodecanol (Excipients) |
| Product classification | Antimycotic                                  |
| Route of administration | Vaginal use                                 |
| Pharmaceutical Dose Form | Vagina tablet; vaginal cream                |
ANNEX B
(informative)

Technical Realisation

B.1 General principles

This Annex shows the full class model both as diagrams and as a list of attributes with data types. The Model diagram for the regular Marketed products is shown first, followed by that for the Investigational products, before a full listing of all the classes and attributes in alphabetic order. Many of the classes are shared between the two drawings.

B.2 Full class model

B.2.1 Marketed products model view

The Figures that follow show the model representation of regular marketed products. Because of limitations of paper size the overview in Figure B.1 is broken into four quadrants for display in Figures B.2 to B.5.

Figure B.1 — Marketed products, overview model
Figure B.2 — Class model: Marketed products, top left quadrant
Figure B.3 — Class model: Marketed products, top right quadrant
Figure B.4 — Class model: Marketed products, bottom left quadrant
B.2.2 Investigational products, model view

The Figures that follow show the model representation of Investigational Products. Because of limitations of paper size the overview Figure B.6 is broken into four quadrants for display in Figures B7 to B.10.

Figure B.6 — Investigational products, overview model
Figure B.7 — Class Model: Investigational Products, top left quadrant
Figure B.8 — Class Model: Investigational Products, top right quadrant
Figure B.9 — Class Model: Investigational Products, lower left quadrant
Figure B.10 — Class Model: Investigational Products, lower right quadrant
B.3 Class and Attribute Listing

B.3.1 Clinical Trial

Table C.1 — Clinical Trial

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration Number</td>
<td>«defining attribute»</td>
<td>II</td>
</tr>
<tr>
<td>Jurisdictional Investigation Code</td>
<td>«defining attribute»</td>
<td>II</td>
</tr>
<tr>
<td>Local Clinical Trial</td>
<td>«defining attribute»</td>
<td>Local Clinical Trial</td>
</tr>
<tr>
<td>Investigation Code</td>
<td>«defining attribute»</td>
<td>ST.NT</td>
</tr>
<tr>
<td>Country</td>
<td>«defining attribute»</td>
<td>CD</td>
</tr>
<tr>
<td>[1..*]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol Number</td>
<td>«defining attribute»</td>
<td>ST.NT</td>
</tr>
<tr>
<td>Max Duration</td>
<td>«defining attribute»</td>
<td>PQ.Time</td>
</tr>
<tr>
<td>Max Dose per Period</td>
<td>«defining attribute»</td>
<td>RTO&lt;PQ,PQ&gt;</td>
</tr>
<tr>
<td>Max Single Dose</td>
<td>«defining attribute»</td>
<td>RTO&lt;PQ,PQ&gt;</td>
</tr>
<tr>
<td>Max First Dose per Period</td>
<td>«defining attribute»</td>
<td>RTO&lt;PQ,PQ&gt;</td>
</tr>
<tr>
<td>Date</td>
<td>«optional attribute»</td>
<td>TS.Date</td>
</tr>
<tr>
<td>Anticipated End Date</td>
<td>«optional attribute»</td>
<td>TS.Date</td>
</tr>
<tr>
<td>Is Paediatric</td>
<td>«optional attribute»</td>
<td>BL</td>
</tr>
<tr>
<td>Product Classification</td>
<td>«defining attribute»</td>
<td>CD</td>
</tr>
</tbody>
</table>
B.3.2 Indications

Table C.2 — Indications

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
<td>«defining attribute»</td>
<td>Indication Vocab</td>
</tr>
<tr>
<td>Therapeutic Use</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td>Target Population</td>
<td>«defining attribute»</td>
<td>CD</td>
</tr>
<tr>
<td>Target Age</td>
<td>«defining attribute»</td>
<td>IVL&lt;PQ.Time&gt;</td>
</tr>
<tr>
<td>Gender</td>
<td>«defining attribute»</td>
<td>CD</td>
</tr>
<tr>
<td>Underlying disease</td>
<td>«defining attribute»</td>
<td>CD</td>
</tr>
</tbody>
</table>

B.3.3 Ingredient

The set of Substances and Specified Substances that go together to make up the product.

Table C.3 — Ingredient

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance [0..*]</td>
<td>«defining attribute»</td>
<td>Substances</td>
</tr>
<tr>
<td>Specified Substance [0..*]</td>
<td>«defining attribute»</td>
<td>Substances</td>
</tr>
</tbody>
</table>

B.3.4 IMPID Attribute Set

A set of attributes which when they have a value define a specific Investigational MPID concept.

Some of the attributes are defining attributes and, if present a change will result in a change in MPID. Other attributes are optional and changes to the values of these will NOT result in a new MPID.
Table C.4 — IMPID Attribute Set

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMPID</td>
<td>«assigned attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>II</td>
<td></td>
</tr>
<tr>
<td>Version</td>
<td>«assigned attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Version</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>«defining attribute»</td>
<td>ISO Country Codes</td>
</tr>
<tr>
<td>Package Description</td>
<td>«optional attribute»</td>
<td>PCID Attribute Set</td>
</tr>
<tr>
<td>Other characteristics</td>
<td>«defining attribute»</td>
<td>Other Characteristics</td>
</tr>
<tr>
<td>[0..*]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>«defining attribute»</td>
<td>Medicinal Product Name</td>
</tr>
<tr>
<td>Sponsor</td>
<td>«defining attribute»</td>
<td>Sponsor</td>
</tr>
<tr>
<td>Protocol Number</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td>Product Name</td>
<td>«defining attribute»</td>
<td>CD</td>
</tr>
<tr>
<td>Product Classification</td>
<td>«defining attribute»</td>
<td>Classification System</td>
</tr>
<tr>
<td>Indication</td>
<td>«defining attribute»</td>
<td>Indication Vocab</td>
</tr>
<tr>
<td>[1..*]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B.3.5 Investigational Medicinal Product Batch Identifier

Carries the batch number and the expiration date when created a medicinal product level.

Table C.5 — Investigational Medicinal Product Batch Identifier

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBAID_1</td>
<td>«assigned attribute»</td>
<td>Product Level batch identification</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td></td>
</tr>
<tr>
<td>Batch id</td>
<td>«defining attribute»</td>
<td>Manufacturer’s batch identification at product level.</td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>Expiration Date</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td>[0..1]</td>
<td>TS.Date</td>
<td></td>
</tr>
</tbody>
</table>

B.3.6 Investigational Medicinal Product Name

Provides a structured description of the name of the medicinal product.
Table C.6 — Investigational Medicinal Product Name

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>«defining attribute»</td>
<td>ST</td>
</tr>
<tr>
<td>Code</td>
<td>«defining attribute»</td>
<td>ST.NT</td>
</tr>
<tr>
<td>Language</td>
<td>«defining attribute»</td>
<td>ISO Language Codes</td>
</tr>
<tr>
<td>Country</td>
<td>«defining attribute»</td>
<td>ISO Country Codes</td>
</tr>
<tr>
<td>InventedNamePart</td>
<td>«optional attribute»</td>
<td>ST</td>
</tr>
<tr>
<td>ScientificNamePart</td>
<td>«optional attribute»</td>
<td>ST</td>
</tr>
<tr>
<td>StrengthNamePart</td>
<td>«optional attribute»</td>
<td>ST</td>
</tr>
<tr>
<td>PharmaceuticalFormPart</td>
<td>«optional attribute»</td>
<td>ST</td>
</tr>
<tr>
<td>IntendedUsePart</td>
<td>«optional attribute»</td>
<td>ST</td>
</tr>
<tr>
<td>ContainerPart</td>
<td>«optional attribute»</td>
<td>ST</td>
</tr>
<tr>
<td>DevicePart</td>
<td>«optional attribute»</td>
<td>ST</td>
</tr>
<tr>
<td>TrademarkOrCompanyPart</td>
<td>«optional attribute»</td>
<td>ST</td>
</tr>
<tr>
<td>Year</td>
<td>«optional attribute»</td>
<td>ST</td>
</tr>
</tbody>
</table>

B.3.7 Investigational Medicinal Product Package Batch Identifier

Carries the batch number and the expiration date when created a medicinal product package level.

Table C.7 — Investigational Medicinal Product Package Batch Identifier

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBAID_2</td>
<td>«assigned attribute»</td>
<td>Pack Level batch identification</td>
</tr>
<tr>
<td>Batch id</td>
<td>«defining attribute»</td>
<td>Manufacturer's batch identification at pack level.</td>
</tr>
<tr>
<td>Expiration Date</td>
<td>«defining attribute»</td>
<td>TS.Date</td>
</tr>
</tbody>
</table>
B.3.8 IPCID Attribute Set

This is the product in its packaging. This class acts as a "parent" for more detailed descriptive classes.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPCID</td>
<td>«assigned attribute»</td>
<td>II</td>
</tr>
<tr>
<td>Other Characteristics</td>
<td>«defining attribute»</td>
<td>Other Characteristics</td>
</tr>
<tr>
<td>[0..*]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Character</td>
<td>«optional attribute»</td>
<td>Physical Characteristics</td>
</tr>
<tr>
<td>[0..1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marketing</td>
<td>«defining attribute»</td>
<td>Marketing</td>
</tr>
<tr>
<td>Outer Packaging</td>
<td>«optional attribute»</td>
<td>Outer Packaging</td>
</tr>
<tr>
<td>Package Item</td>
<td>«defining attribute»</td>
<td>Package Item</td>
</tr>
</tbody>
</table>

B.3.9 Local Clinical Trial

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration Number</td>
<td>«defining attribute»</td>
<td>II</td>
</tr>
<tr>
<td>Investigation Code</td>
<td>«defining attribute»</td>
<td>II</td>
</tr>
<tr>
<td>Country</td>
<td>«defining attribute»</td>
<td>CD</td>
</tr>
<tr>
<td>Date</td>
<td>«defining attribute»</td>
<td>TS.Date</td>
</tr>
<tr>
<td>Anticipated End Date</td>
<td>«defining attribute»</td>
<td>TS.Date</td>
</tr>
</tbody>
</table>

B.3.10 Local Marketing Information

Describes marketing authorization applicable to a specific region
<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>id</td>
<td>«assigned attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>II</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ISO Country Codes</td>
<td></td>
</tr>
<tr>
<td>Legal Status Of Supply</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CD</td>
<td></td>
</tr>
<tr>
<td>Marketing Start</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TS.Date</td>
<td></td>
</tr>
<tr>
<td>Marketing Stop</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TS.Date</td>
<td></td>
</tr>
<tr>
<td>GTIN</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CD</td>
<td></td>
</tr>
</tbody>
</table>

**B.3.11 Manufactured Item**

This is the medicine as supplied by the manufacturer.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufactured Dose Form</td>
<td>«defining attribute»</td>
<td>The physical form that the product is supplied in.</td>
</tr>
<tr>
<td></td>
<td>Dose Form Vocab</td>
<td>Note that (for example) &quot;Tablet&quot; is both a Dose Form and a Presentation Unit. These are different concepts that happen to use the same word.</td>
</tr>
<tr>
<td>Pack Size [0..1]</td>
<td>«defining attribute»</td>
<td>The quantity contained within the item. For liquids and creams this is expressed in units of milligrams or millilitres or other appropriate definable unit. For solid dose forms such as tablets, capsules and pessaries the size will be the number of units present in a single item. So in such cases this will usually be 1 unit. The nature of this unit is given in the Presentation Unit attribute. In some cases size may be omitted. This is when the product is specified by its size when reconstituted rather than as supplied. Antibiotics supplied as a powder for suspension are an example.</td>
</tr>
<tr>
<td></td>
<td>PQ</td>
<td></td>
</tr>
<tr>
<td>Unit of Presentation</td>
<td>«defining attribute»</td>
<td>The unit used to specify the size when the product is a solid dose form. In other cases this will be the same as the unit used for Size.</td>
</tr>
<tr>
<td></td>
<td>Presentation Unit Vocab</td>
<td></td>
</tr>
<tr>
<td>Ingredient Set [0..*]</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ingredient</td>
<td></td>
</tr>
<tr>
<td>Physical Character [0..1]</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physical Characteristics</td>
<td></td>
</tr>
</tbody>
</table>
B.3.12 Manufacturing

Details of a manufacturing authorization by a regulatory authority for a medicinal product

Table C.12 — Manufacturing

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holder</td>
<td>«defining attribute»</td>
<td>Name of the manufacturing authorization holder</td>
</tr>
<tr>
<td></td>
<td>Organisation</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TS</td>
<td></td>
</tr>
<tr>
<td>Authority</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Organisation</td>
<td></td>
</tr>
</tbody>
</table>

B.3.13 Marketing

This is issued by the applicable medicines regulatory authority in a jurisdiction to grant permission to place a medicinal product on the market.
### Table C.13 — Marketing

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marketing Authorization Number</td>
<td>«assigned attribute» I II</td>
<td>A unique identifier for the marketing authorization issued by the regulatory body</td>
</tr>
<tr>
<td>Holder</td>
<td>«defining attribute» Organisation</td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>«defining attribute» Marketing Procedure</td>
<td></td>
</tr>
<tr>
<td>Country [1..*]</td>
<td>«defining attribute» ISO Country Codes</td>
<td></td>
</tr>
<tr>
<td>Legal Status Of Supply</td>
<td>«defining attribute» Legal Status Vocab</td>
<td></td>
</tr>
<tr>
<td>First Date</td>
<td>«defining attribute» TS.Date</td>
<td></td>
</tr>
<tr>
<td>Renewal Date</td>
<td>«optional attribute» TS.Date</td>
<td></td>
</tr>
<tr>
<td>Variation Date</td>
<td>«optional attribute» TS.Date</td>
<td></td>
</tr>
<tr>
<td>Withdrawal Date</td>
<td>«optional attribute» TS.Date</td>
<td></td>
</tr>
<tr>
<td>Expiry Date</td>
<td>«optional attribute» TS.Date</td>
<td>Indicates when this Marketing expires.</td>
</tr>
<tr>
<td>Status</td>
<td>«optional attribute» Marketing Authorization Status Vocab</td>
<td>Indicates the current status of this Marketing</td>
</tr>
<tr>
<td>Previous Status</td>
<td>«optional attribute» Marketing Authorization Status Vocab</td>
<td>The Marketing Status prior to the current status.</td>
</tr>
<tr>
<td>Status Change Date</td>
<td>«optional attribute» TS.Date</td>
<td>Date when status last changed</td>
</tr>
<tr>
<td>Local Marketing Information</td>
<td>«optional attribute» Local Marketing Information</td>
<td></td>
</tr>
<tr>
<td>Manufacturing</td>
<td>«defining attribute» Manufacturing</td>
<td></td>
</tr>
<tr>
<td>Regulator</td>
<td>«defining attribute» Organisation</td>
<td></td>
</tr>
<tr>
<td>GTIN</td>
<td>«optional attribute» CD</td>
<td></td>
</tr>
<tr>
<td>Authorized Combined Pharmaceutical Dose Form</td>
<td>«optional attribute» CD</td>
<td></td>
</tr>
</tbody>
</table>
B.3.14 Marketing Procedure

Identifies the formal procedure used to grant or amend the marketing authorization.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Type</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Marketing Procedure Type Vocab</td>
<td></td>
</tr>
<tr>
<td>Procedure Reference Code</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CD</td>
<td></td>
</tr>
<tr>
<td>Procedure id</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>II</td>
<td></td>
</tr>
<tr>
<td>Document id</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>II</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TS.Date</td>
<td></td>
</tr>
</tbody>
</table>

B.3.15 Medical Device

This is a device that is part of a pharmaceutical product
### Table C.15 — Medical Device

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDI</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>I</td>
<td></td>
</tr>
<tr>
<td>Name</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>Trade Name</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST:NT</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td>«defining attribute»</td>
<td>Organisation</td>
</tr>
<tr>
<td>Model Number</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST:NT</td>
<td></td>
</tr>
<tr>
<td>Nomenclature</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST:NT</td>
<td></td>
</tr>
<tr>
<td>Physical Characteristics</td>
<td>«optional attribute»</td>
<td>Physical Characteristics</td>
</tr>
<tr>
<td>Other Characteristics</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other Characteristics</td>
<td></td>
</tr>
<tr>
<td>Restricted Use Count</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>int</td>
<td></td>
</tr>
<tr>
<td>Has Allergens</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BL</td>
<td></td>
</tr>
<tr>
<td>Ingredient Set</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ingredient</td>
<td></td>
</tr>
<tr>
<td>Is Sterile</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BL</td>
<td></td>
</tr>
<tr>
<td>Is Sterilization Required</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BL</td>
<td></td>
</tr>
</tbody>
</table>

### B.3.16  Medicinal Product Batch Identifier

Carries the batch number and the expiration date when created a medicinal product level.
Table C.16 — Medicinal Product Batch Identifier

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>BAID_1</td>
<td>«assigned attribute»</td>
<td>Product Level batch identification</td>
</tr>
<tr>
<td>Batch id</td>
<td>«defining attribute»</td>
<td>Manufacturer’s batch identification at product level.</td>
</tr>
<tr>
<td>Expiration Date</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td>[0..1]</td>
<td>TS.Date</td>
<td></td>
</tr>
</tbody>
</table>

**B.3.17 Medicinal Product Name**

Provides a structured description of the name of the medicinal product

Table C.17 — Medicinal Product Name

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>Language</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ISO Language Codes</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ISO Country Codes</td>
<td></td>
</tr>
<tr>
<td>InventedNamePart</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>ScientificNamePart</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>StrengthNamePart</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>PharmaceuticalFormPart</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>IntendedUsePart</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>ContainerPart</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>DevicePart</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>TrademarkOrCompanyPart</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>Year</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ST</td>
<td></td>
</tr>
</tbody>
</table>
B.3.18 Medicinal Product Package Batch Identifier

Carries the batch number and the expiration date when created a medicinal product package level.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>BAID_2</td>
<td>«assigned attribute» II</td>
<td>Pack Level batch identification</td>
</tr>
<tr>
<td>Batch id</td>
<td>«defining attribute» ST</td>
<td>Manufacturer's batch identification at pack level.</td>
</tr>
<tr>
<td>Expiration Date</td>
<td>«defining attribute» TS.Date</td>
<td></td>
</tr>
</tbody>
</table>

B.3.19 MPID Attribute Set

A set of attributes which when they have a value define a specific MPID concept.

Some of the attributes are defining attributes and, if present a change will result in a change in MPID. Other attributes are optional and changes to the values of these will NOT result in a new MPID.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPID</td>
<td>«assigned attribute»</td>
<td></td>
</tr>
<tr>
<td>Version</td>
<td>«assigned attribute»</td>
<td></td>
</tr>
<tr>
<td>Country [0..*]</td>
<td>«defining attribute»</td>
<td>ISO Country Codes</td>
</tr>
<tr>
<td>Marketing Authorization</td>
<td>«optional attribute»</td>
<td>Marketing</td>
</tr>
<tr>
<td>Marketing Authorization Holder</td>
<td>«defining attribute»</td>
<td>Organisation</td>
</tr>
<tr>
<td>Package Description</td>
<td>«optional attribute»</td>
<td>PCID Attribute Set</td>
</tr>
<tr>
<td>Other characteristics [0..*]</td>
<td>«defining attribute»</td>
<td>Other Characteristics</td>
</tr>
<tr>
<td>Name</td>
<td>«defining attribute»</td>
<td>Medicinal Product Name</td>
</tr>
</tbody>
</table>

B.3.20 Organisation

A general class to represent details of an organisation
Table C.20 — Organisation

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>id</td>
<td>«assigned attribute»</td>
<td>II</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unique identifier for the organisation</td>
</tr>
<tr>
<td>Name</td>
<td>«defining attribute»</td>
<td>EN.ON</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Name of the organisation</td>
</tr>
<tr>
<td>Address</td>
<td>«defining attribute»</td>
<td>AD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Address of the organisation.</td>
</tr>
</tbody>
</table>

B.3.21 Other Characteristics

A class to define a pair of a code that identifies a specific characteristic and the applicable value of that characteristic.

Table C.21 — Other Characteristics

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Code</td>
<td>«defining attribute»</td>
<td>CD</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Value</td>
<td>«defining attribute»</td>
<td>ANY</td>
</tr>
<tr>
<td>[0..1]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B.3.22 Outer Packaging

This is the package as seen and handled by end users

Table C.22 — Outer Packaging

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>«defining attribute»</td>
<td>Material Vocab</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alternates</td>
<td>«defining attribute»</td>
<td>Substance Alternates</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B.3.23 Package Item

These are the distinct kinds of items that make up the package. There will only be more than one instance of this class if the Package Medicinal Product is a kit or includes an administration device.
### Table C.23 — Package Item

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>«defining attribute» Package Item Type Vocab</td>
<td>This describes the type of Package Item that is being described. For instance a Pharmaceutical Item, or a Container. The possible values are held in the Package Item Type enumeration.</td>
</tr>
<tr>
<td>Package Type</td>
<td>«defining attribute» Packageing Type Vocab</td>
<td></td>
</tr>
<tr>
<td>Items in Package</td>
<td>«defining attribute» INT</td>
<td>A Package Item may contain several identical items. For instance 2 tubes of cream or 3 inhalers. This attribute specifies that number.</td>
</tr>
<tr>
<td>Physical Character</td>
<td>«optional attribute» Physical Characteristics</td>
<td></td>
</tr>
<tr>
<td>[0..1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Packaging</td>
<td>«defining attribute» Package Item Part</td>
<td></td>
</tr>
<tr>
<td>Manufactured Item</td>
<td>«defining attribute» Manufactured Item</td>
<td></td>
</tr>
<tr>
<td>ReconstituteTo</td>
<td>«defining attribute» Pharmaceutical Product</td>
<td></td>
</tr>
<tr>
<td>Sub Package Item</td>
<td>«optional attribute» Package Item</td>
<td></td>
</tr>
</tbody>
</table>

### B.3.24 Package Item Part

This is the inner packaging and / or parts of an administration device. Most importantly it identifies the material directly in contact with the medicine.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sub-Package Item Part</td>
<td>«optional attribute»</td>
<td></td>
</tr>
<tr>
<td>Component Part</td>
<td>«defining attribute» Part Item Component Vocab</td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td>«defining attribute» Material Vocab</td>
<td></td>
</tr>
<tr>
<td>Alternate</td>
<td>«defining attribute» Substance Alternates</td>
<td></td>
</tr>
<tr>
<td>UDI</td>
<td>«optional attribute» CD</td>
<td></td>
</tr>
</tbody>
</table>
B.3.25 PCID Attribute Set

This is the product in its packaging. This class acts as a "parent" for more detailed descriptive classes.

Table C.25 — PCID Attribute Set

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCID</td>
<td>«assigned attribute»</td>
<td>II</td>
</tr>
<tr>
<td>Other Characteristics</td>
<td>«defining attribute»</td>
<td>Other Characteristics</td>
</tr>
<tr>
<td>Outer Packaging</td>
<td>«optional attribute»</td>
<td>Outer Packaging</td>
</tr>
<tr>
<td>Package Item</td>
<td>«defining attribute»</td>
<td>Package Item</td>
</tr>
<tr>
<td>Physical Character</td>
<td>«optional attribute»</td>
<td>Physical Characteristics</td>
</tr>
<tr>
<td>Marketing</td>
<td>«defining attribute»</td>
<td>Marketing</td>
</tr>
</tbody>
</table>

B.3.26 Pharmaceutical Product

This is the medicine as reconstituted ready to be given to the patient
Table C.26 — Pharmaceutical Product

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>PhPID</td>
<td>«assigned attribute» PhPID Set</td>
<td>This relationship is to a set of PhPIDs that are themselves defined at different levels of specificity. The relationship is described in more detail in ISO/DIS 11616.</td>
</tr>
<tr>
<td>Administrable Dose Form</td>
<td>«defining attribute» Dose Form Vocab</td>
<td>The physical form that the material takes when it is reconstituted and ready for administration. Note that (for example) &quot;Tablet&quot; is both a Dose Form and a Presentation Unit. These are different concepts that happen to use the same word.</td>
</tr>
<tr>
<td>Pack Size</td>
<td>«defining attribute» PQ</td>
<td>The quantity contained within the item. For liquids and creams this is expressed in units of milligrams or millilitres or other appropriate definable unit. For solid dose forms such as tablets, capsules and pessaries the size will be the number of units present in a single item. So in such cases this will usually be 1 unit. The nature of this unit is given in the Presentation Unit attribute. In some cases size may be omitted. This is when the product is specified by its size as supplied rather than when reconstituted.</td>
</tr>
<tr>
<td>Unit of Presentation</td>
<td>«defining attribute» Presentation Unit Vocab</td>
<td>The unit used to specify the size when the product is a solid dose form. In other cases this will be the same as the unit used for Size.</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>«defining attribute» Route of Administration</td>
<td>The path into the subject taken by the medication.</td>
</tr>
<tr>
<td>Ingredient Set</td>
<td>«defining attribute» Ingredient</td>
<td></td>
</tr>
<tr>
<td>Indication</td>
<td>«defining attribute» Indications</td>
<td></td>
</tr>
<tr>
<td>Onset of Action</td>
<td>«optional attribute» Onset of Action Vocab</td>
<td></td>
</tr>
<tr>
<td>Medical Device</td>
<td>«defining attribute» Medical Device</td>
<td></td>
</tr>
</tbody>
</table>

**B.3.27 Physical Characteristics**

Describes height, width and depth, colour, shape and other similar physical attributes of an item.

It may also include one or more images.

This class is used by a number of other classes as the means of expressing these features.
### Table C.27 — Physical Characteristics

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>«optional attribute»</td>
<td>PQ</td>
</tr>
<tr>
<td>[0..1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Width</td>
<td>«optional attribute»</td>
<td>PQ</td>
</tr>
<tr>
<td>[0..1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depth</td>
<td>«optional attribute»</td>
<td>PQ</td>
</tr>
<tr>
<td>[0..1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volume</td>
<td>«optional attribute»</td>
<td>PQ</td>
</tr>
<tr>
<td>[0..1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td>«optional attribute»</td>
<td>PQ</td>
</tr>
<tr>
<td>[0..1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colour</td>
<td>«optional attribute»</td>
<td>Colour Vocab</td>
</tr>
<tr>
<td>[0..1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shape</td>
<td>«optional attribute»</td>
<td>ST</td>
</tr>
<tr>
<td>[0..1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Image</td>
<td>«optional attribute»</td>
<td>ED.Image</td>
</tr>
<tr>
<td>[0..*]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### B.3.28 Reference Strength

### Table C.28 — Reference Strength

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Substance</td>
<td>«defining attribute»</td>
<td>Substance Vocab</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference Substance Strength</td>
<td>«defining attribute»</td>
<td>Strength</td>
</tr>
<tr>
<td>[0..*]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference Specified Substance</td>
<td>«defining attribute»</td>
<td>Speciaised Substance Vocab</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference Specified Substance</td>
<td>«defining attribute»</td>
<td>Strength</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
B.3.29 Route of Administration

Table C.29 — Route of Administration

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Route of Administration</td>
<td></td>
</tr>
<tr>
<td>Max Dose prer Route</td>
<td>«optional attribute»</td>
<td>PQ</td>
</tr>
</tbody>
</table>

B.3.30 Specified Substances

Table C.30 — Specified Substances

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role</td>
<td>«defining attribute»</td>
<td>Ingredient Role Vocab</td>
</tr>
<tr>
<td>Specified Substance</td>
<td>«defining attribute»</td>
<td>Specified Substance Vocab</td>
</tr>
<tr>
<td>Specified Sustance Strength [0..*]</td>
<td>«defining attribute»</td>
<td>Strength</td>
</tr>
<tr>
<td>Reference Strength [0..1]</td>
<td>«defining attribute»</td>
<td>Reference Strength</td>
</tr>
</tbody>
</table>

B.3.31 Sponsor

The organisation that undertakes the Clinical Trial

Table C.31 — Sponsor

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organisation</td>
<td>«defining attribute»</td>
<td>Name of the manufacturing authorization holder</td>
</tr>
<tr>
<td>Organisation</td>
<td>Organisation</td>
<td></td>
</tr>
<tr>
<td>Legal Representative</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td>Organisation</td>
<td>Organisation</td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td>Sponsor Status</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
B.3.32 Strength

Table C.32 — Strength

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RTO&lt;PQ,PQ&gt;</td>
<td></td>
</tr>
<tr>
<td>Measurement Point</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td>[0..1]</td>
<td>ST</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td>[0..1]</td>
<td>ISO Country Codes</td>
<td></td>
</tr>
</tbody>
</table>

B.3.33 Substance Alternates

The actual substance that the package is composed of.

Table C.33 — Substance Alternates

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
<td>«defining attribute»</td>
<td></td>
</tr>
<tr>
<td>[0..*]</td>
<td>Material Vocab</td>
<td></td>
</tr>
</tbody>
</table>

B.3.34 Substances

This describes the substance and quantity of that substance to be found in a product. A product may have multiple substances and may described by means of "Substances" or "Specified Substances" or both.

There are a number of specialisations of this class which distinguish the possible roles played by substances.

Table C.34 — Substances

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role</td>
<td>«defining attribute»</td>
<td>Ingredient Role Vocab</td>
</tr>
<tr>
<td></td>
<td></td>
<td>as specified by 11238. This is a required attribute.</td>
</tr>
<tr>
<td>Substance</td>
<td>«defining attribute»</td>
<td>Substance Vocab</td>
</tr>
<tr>
<td>Substance Strength</td>
<td>«defining attribute»</td>
<td>Strength</td>
</tr>
<tr>
<td>[0..*]</td>
<td></td>
<td>The strength or concentration of the substance</td>
</tr>
<tr>
<td>Reference Strength</td>
<td>«defining attribute»</td>
<td>Reference Strength</td>
</tr>
</tbody>
</table>

B.3.35 Version

An indication that prior to the given effective date some characteristic of the product changed but was not different to a sufficient extent to warrant a new MPID Attribute Set being identified.
Table C.35 — Version

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Stereotype / Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date</td>
<td>«assigned attribute»</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TS.Date</td>
<td></td>
</tr>
<tr>
<td>Regulated Document</td>
<td>«defining attribute»</td>
<td>II</td>
</tr>
</tbody>
</table>
ANNEX C
(informative)

Strength Examples

C.1 Different uses of the Strength

1) **Equal**
   - **Numerator**: 70 - mg
   - **Denominator**: 100 - ml

2) **Not less than**
   - **Numerator**: 75 - IU
   - **Denominator**: 100 - ml

3) **Not greater than**
   - **Numerator**: 75 - IU
   - **Denominator**: 100 - ml

4) **Range**
   - **Low value**: 100 - ml
   - **High value**: 90 - mg

Figure D.1 — Examples of different uses of Strength

C.2 Use of Strength for different types of medicinal products

Table D.1 — Use of Strength for different types of medicinal products

<table>
<thead>
<tr>
<th>ORAL SOLID</th>
<th>Case</th>
<th>Example</th>
<th>Numerator Value</th>
<th>Numerator Unit</th>
<th>Denominator Value</th>
<th>Unit of Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral solid</td>
<td>25 [unit]</td>
<td>number</td>
<td>[unit]</td>
<td>1</td>
<td>Each</td>
<td></td>
</tr>
</tbody>
</table>
### ORAL LIQUID

<table>
<thead>
<tr>
<th>Case</th>
<th>Example</th>
<th>Numerator Value</th>
<th>Numerator Unit</th>
<th>Denominator Value</th>
<th>Unit of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non injection liquid 1 ml or greater</td>
<td>[unit]/ML</td>
<td>25 [unit]</td>
<td>number</td>
<td>10 ML</td>
<td>number 3 ML</td>
</tr>
<tr>
<td>Non injection liquid less than 1 ml</td>
<td>[unit]/ML</td>
<td>25 [unit]</td>
<td>number</td>
<td>0.1 ML</td>
<td>number (0.1 ML)</td>
</tr>
</tbody>
</table>

### ORAL POWDER

<table>
<thead>
<tr>
<th>Case</th>
<th>Example</th>
<th>Numerator Value</th>
<th>Numerator Unit</th>
<th>Denominator Value</th>
<th>Unit of Measurement / Unit of Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non injection powder for reconstitution with a known volume</td>
<td>[unit]/ML</td>
<td>25 [unit]</td>
<td>number</td>
<td>10 ML</td>
<td>number 10 ML / Each</td>
</tr>
<tr>
<td>Non injection powder for reconstitution with a variable volume</td>
<td>[unit]/Each</td>
<td>25 [unit]</td>
<td>number</td>
<td>1 Each</td>
<td>number 1 Each</td>
</tr>
<tr>
<td>Powder packet</td>
<td>[unit]/Each</td>
<td>25 [unit]</td>
<td>number</td>
<td>1 Each</td>
<td>number 1 Each</td>
</tr>
</tbody>
</table>

### SUPPOSITORY

<table>
<thead>
<tr>
<th>Case</th>
<th>Example</th>
<th>Numerator Value</th>
<th>Numerator Unit</th>
<th>Denominator Value</th>
<th>Unit of Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suppository</td>
<td>[unit]/Each</td>
<td>25 [unit]</td>
<td>number</td>
<td>1 Each</td>
<td>number 1 Each</td>
</tr>
</tbody>
</table>

### INJECTION

<table>
<thead>
<tr>
<th>Case</th>
<th>Example</th>
<th>Numerator Value</th>
<th>Numerator Unit</th>
<th>Denominator Value</th>
<th>Denominator Unit of Measurement / Unit of Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection liquid</td>
<td>[unit]/ML</td>
<td>25 [unit]</td>
<td>number</td>
<td>10 ML</td>
<td>number 10 ML</td>
</tr>
<tr>
<td>Injection powder for reconstitution with known volume</td>
<td>[unit]/ML</td>
<td>25 [unit]</td>
<td>number</td>
<td>10 ML</td>
<td>number 10 ML</td>
</tr>
<tr>
<td>Injection powder for reconstitution with variable volume</td>
<td>[unit]/Each</td>
<td>25 [unit]</td>
<td>number</td>
<td>1 Each</td>
<td>number 1 Each</td>
</tr>
</tbody>
</table>
## INHALER

<table>
<thead>
<tr>
<th>Case</th>
<th>Example</th>
<th>Numerator Value</th>
<th>Numerator Unit</th>
<th>Denominator Value</th>
<th>Unit of Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhaler – powder</td>
<td>[unit]/Each</td>
<td>25 [unit]</td>
<td>[unit]</td>
<td>1</td>
<td>Each</td>
</tr>
<tr>
<td>Inhaler – liquid</td>
<td>[unit]/Each</td>
<td>25 [unit]</td>
<td>[unit]</td>
<td>1</td>
<td>Each</td>
</tr>
<tr>
<td>Inhaler – blister</td>
<td>[unit]/Each</td>
<td>25 [unit]</td>
<td>[unit]</td>
<td>1</td>
<td>Each</td>
</tr>
</tbody>
</table>

## TOPICAL

<table>
<thead>
<tr>
<th>Case</th>
<th>Example</th>
<th>Numerator Value</th>
<th>Numerator Unit</th>
<th>Denominator Value</th>
<th>Unit of Measurement/Unit of Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cream or ointment 1 gm or greater</td>
<td>[unit]/GM</td>
<td>25 [unit]</td>
<td>[unit]</td>
<td>number</td>
<td>GM</td>
</tr>
<tr>
<td>Cream or ointment &lt; 1 gm</td>
<td>[unit]/GM</td>
<td>25 [unit]</td>
<td>[unit]</td>
<td>Number (&lt; 1)</td>
<td>GM</td>
</tr>
<tr>
<td>Gel</td>
<td>[unit]/ML</td>
<td>25 [unit]</td>
<td>[unit]</td>
<td>number</td>
<td>ML</td>
</tr>
<tr>
<td>Lotion</td>
<td>[unit]/ML</td>
<td>25 [unit]</td>
<td>[unit]</td>
<td>number</td>
<td>ML</td>
</tr>
<tr>
<td>Transdermal patch</td>
<td>[unit]/Each</td>
<td>25 [unit]</td>
<td>[unit]</td>
<td>1</td>
<td>Each</td>
</tr>
</tbody>
</table>

## BULK

<table>
<thead>
<tr>
<th>Case</th>
<th>Example</th>
<th>Numerator Value</th>
<th>Numerator Unit</th>
<th>Denominator Value</th>
<th>Unit of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulk chemical liquid</td>
<td>[unit]/ML</td>
<td>25 [unit]</td>
<td>[unit]</td>
<td>ML</td>
<td>ML</td>
</tr>
<tr>
<td>Bulk chemical solid</td>
<td>[unit]/GM</td>
<td>25 [unit]</td>
<td>[unit]</td>
<td>GM</td>
<td>GM</td>
</tr>
</tbody>
</table>
### KIT

<table>
<thead>
<tr>
<th>Case</th>
<th>Example</th>
<th>Numerator Value</th>
<th>Numerator Unit</th>
<th>Denominator Value</th>
<th>Unit of Presentation/Unit of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kit with combination of solid oral dosage forms</td>
<td>[unit]/Each</td>
<td>(\frac{25 \text{ [unit]}}{1 \text{ Each}})</td>
<td>[unit]</td>
<td>1</td>
<td>Each</td>
</tr>
<tr>
<td>Kit with two drugs to be mixed forming liquid</td>
<td>[unit]/ML</td>
<td>(\frac{25 \text{ [unit]}}{10 \text{ ML}})</td>
<td>[unit]</td>
<td>number</td>
<td>ML</td>
</tr>
<tr>
<td>Kit with two drugs to be mixed forming non liquid</td>
<td>[unit]/GM</td>
<td>(\frac{25 \text{ [unit]}}{10 \text{ GM}})</td>
<td>[unit]</td>
<td>number</td>
<td>GM</td>
</tr>
<tr>
<td>Kit with two distinct drugs</td>
<td>Each/Each</td>
<td>(\frac{25 \text{ EACH}}{1 \text{ EACH}})</td>
<td>number</td>
<td>Each</td>
<td>1</td>
</tr>
<tr>
<td>Kits with one drugs and diluents and/or alcohol swabs</td>
<td>Each/Each</td>
<td>(\frac{25 \text{ EACH}}{1 \text{ EACH}})</td>
<td>number</td>
<td>Each</td>
<td>1</td>
</tr>
</tbody>
</table>

### EXCEPTIONS

<table>
<thead>
<tr>
<th>Case</th>
<th>Example</th>
<th>Numerator Value</th>
<th>Numerator Unit</th>
<th>Denominator Value</th>
<th>Unit of Measurement/Unit of Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epinephrine auto injector</td>
<td>[unit]/ML</td>
<td>(\frac{25 \text{ [unit]}}{10 \text{ ML}})</td>
<td>[unit]</td>
<td>number</td>
<td>ML</td>
</tr>
<tr>
<td>Trade name kit refill</td>
<td>[unit]/ML</td>
<td>(\frac{25 \text{ [unit]}}{10 \text{ ML}})</td>
<td>[unit]</td>
<td>number</td>
<td>ML</td>
</tr>
<tr>
<td>Nystatin powder</td>
<td>[unit]/GM</td>
<td>(\frac{25 \text{ [unit]}}{10 \text{ GM}})</td>
<td>[unit]</td>
<td>number</td>
<td>GM</td>
</tr>
</tbody>
</table>

### DEVICE AND MEDICAL SUPPLIES

| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
ANNEX D
(informative)

UML Diagramming

D.1 General considerations

UML is the Unified Modelling Language and is defined and maintained by OMG (the Object Modelling Group). The OMG introduction to UML may be found at http://www.uml.org and there are many tutorials that may be found through an internet search. At present (March 2010) the one on Wikipedia gives a rapid flavour of the language.

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 standard has been kept very simple and some constructs have been avoided for this reason. The following Figures aim to explain the style that has been followed for the benefit of those who are not familiar with any UML at all. This Annex is not a substitute for a proper tutorial.

D.2 Class Diagrams

![Class Diagrams Figure]

This kind of "arrow" says that the Marketing Authorisation "contains" the Local Marketing Authorisation, and if the Marketing Authorisation were to disappear so would the Local Marketing Authorisation.

The 1..* numbers show that a Marketing Authorisation can contain 1 or more Local Marketing Authorisations.

A link with an open arrow head shows that the two classes are related and that the sense of the connection flows in the direction of the arrow. This kind of link tells us nothing about containment of one class within another.

A link with a closed arrow head says that the class the arrow points at is a more general version of the other class. Hence an Organisation is a general form of a Regulator since, along with any organisation a Regulator will have, for instance, a Name and an Address.

Figure E.1 — UML representation of Class Diagrams
D.3 Attributes

The **Substance** attribute in the **Ingredient** class has a data type of **Substance**. This actually is duplicating the information given by showing the link to the Substance class. The Substance data type is the same as the Substance class. Providing this duplication gives some flexibility in diagrams by allowing related classes and attributes to be interchanged depending on the level of information being conveyed.

The strength attribute has a data type of RTO<PQ> which is one of the ISO data types and is described in another Annex.

After the data type is [0..1] which says there can be zero or one of these attributes.

Both attributes are under a stereotype of «defining attribute» which says that if the attribute has a value making a change to that value would produce a new instance of the class.

Colour has a data type of Colour Vocab which is an enumeration class listing the possible values the Colour attribute could take.

D.4 Stereotypes

Attributes may have one of three possible stereotypes:

- «defining attribute>> which says that if the attribute has a value and the value changes then the class described will be a new instance of the class.

- «optional attribute>> says that the attribute may change its value without forcing a new instance of a class. So for instance if the value of Substance changed we would be talking about a new Ingredient, but if the colour Changed we could choose to regard it as the same ingredient.

D.5 Objects

These are two instances of the **Ingredient** class. The values their attributes hold is shown in the box.

The attribute value may be a summary of more complex information. For instance here the Substance attribute has a data type that is a class of Substance which itself will have more attributes. For the purpose of illustration it is adequate to summarise this with the name of a Substance and to ignore the other complexity of the Substance class.
ISO/DIS 21090, *Health Informatics -- Harmonized data types for information interchange* defines a complex set of data types that greatly simplify the modelling required here. The data types used are briefly summarised in Table G.1, but for full details of all the attributes and operations of each data type consult the ISO/DIS 21090.

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>AD</td>
<td>Address. This has attributes for all the parts of an address that may be required.</td>
</tr>
<tr>
<td>ANY</td>
<td>Any ISO data type may be used. This is only used when any possible value should be catered for. In implementations this is then restricted to a practical set of possible alternatives.</td>
</tr>
<tr>
<td>BL</td>
<td>Boolean: i.e. yes, no or unknown.</td>
</tr>
<tr>
<td>BLN</td>
<td>As for Boolean, but Unknown is not allowed.</td>
</tr>
<tr>
<td>CD</td>
<td>Used to convey coded data. It has attributes for the actual code, the display term and its translations as well as the original text string that was used to select the code. Codes may be bound to specific sets of vocabulary and the version information for that vocabulary may also be captured.</td>
</tr>
<tr>
<td>ED.Image</td>
<td>Carries computer graphic images.</td>
</tr>
<tr>
<td>EN</td>
<td>Name. This has an internal structure that allows the name to be presented as a set of named parts.</td>
</tr>
<tr>
<td>EN.ON</td>
<td>A simple for of name restricted to that suitable for organisations. Name parts are not allowed.</td>
</tr>
<tr>
<td>II</td>
<td>Instance Identifier. Allows an identification system to be identified with an OID and then the actual identifier to be stored. This combination of an OID and an identifier may ensure that identifiers are globally unique.</td>
</tr>
<tr>
<td>INT</td>
<td>An integer</td>
</tr>
<tr>
<td>PQ</td>
<td>Physical quantity. This has to have a value and then a code for the units of measure. This code is based on the UCUM system of units.</td>
</tr>
<tr>
<td>PQ.Time</td>
<td>A physical quantity where the units are restricted to those of time.</td>
</tr>
<tr>
<td>RTO&lt;PQ,PQ&gt;</td>
<td>Ratio of two physical quantities. i.e x per y where both x and y may be expressed as a quantity and a unit. PQ may be replaced with the URG&lt;PQ&gt; data type. This allows the specification of a lower and upper limit and hence allows expressions such as &quot;10mg to 15mg per 12 hours&quot;</td>
</tr>
<tr>
<td>ST.NT</td>
<td>String with no translation allowed. The plain ST data type carries translations.</td>
</tr>
<tr>
<td>TS.Date</td>
<td>Time stamp. Identifies a specific point in time. The Date flavour restricts the accuracy to being just the day month and year, but excludes the time within the day.</td>
</tr>
</tbody>
</table>
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[41] Appendix2 Overview of SGML creation

[42] Appendix3 DCL
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[43] Appendix4 Template of SGML
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[44] Appendix5 Data model (Entities and relationships)
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