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

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

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Foreword

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

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

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

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

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

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

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

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Introduction

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

These sets of standards and technical specifications comprise:

— ISO 11615

— ISO/TS 20443;

— ISO 11616;

— ISO/TS 20451;

— ISO 11238;

— ISO/TS 19844;

— ISO 11239;

— ISO/TS 20440;

— ISO 11240.

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

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

— regulatory medicines authority to regulatory medicines authority;

— pharmaceutical company to regulatory medicines authority;

— sponsor of a clinical trial to regulatory medicines authority;

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

— regulatory medicines authority to worldwide-maintained data sources.

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

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

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

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

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

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

— to specify data elements, structures and relationships between the data elements which are required to uniquely and with certainty identify Medicinal Products for human use;

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

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

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

1 Scope

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

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

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

2 Normative references

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

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

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

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

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

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

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

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

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

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

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

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

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

HL7 Version 3 Standard, Structured Product Labelling

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

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

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

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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

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

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

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

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

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

[SOURCE: ENV 12610:1997]

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

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

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

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

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

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

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

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

3.1.10
characteristic
abstraction of a property of an object

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[SOURCE: ISO 11404:2007, 3.12]

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

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

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

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

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

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

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

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

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

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

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

[SOURCE: ENV 12610:1997]

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

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

[SOURCE: ENV 12610:1997]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.1.38
manufacturer
organisation that holds the authorisation for the manufacturing process

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[SOURCE: ENV 13607 and ENV 12610]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

— collecting and managing data on the safety of medicines;

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

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

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

— communicating with stakeholders;

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

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

— patients as the users of medicines;

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

— pharmaceutical companies, and companies importing or distributing medicines.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.2 Abbreviated terms

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

4 Message exchange format

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

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