TECHNICAL SPECIFICATION

ISO/TS 19256

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Health informatics — Requirements for medicinal product dictionary systems for health care

Informatique de santé — Exigences pour les systèmes de dictionnaires de produits médicaux pour les soins de santé

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Foreword

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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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

Introduction

This introduction contains the following topics:

a) What is a Medicinal Product Dictionary system?

b) What are the use cases and who are the stakeholders?

c) What are the benefits for the different stakeholders?

d) What are the core functional requirements for an MPD-system for healthcare?

The main target audience is the developers and service providers of MPD-systems, and those who contract such developers and service providers.

The goal of MPD Systems is to offer various parties in healthcare a complete overview of available medicinal products in such a way the (elements of the) concepts and the descriptions and medicinal product identifiers can be used in a variety of other healthcare information systems. The principle for this Technical Specification is that the global unique IDs of IDMP (Identification of Medicinal Products) shall be maintained in any MPD-system.

Medicinal products play an important role in healthcare. There are many (thousands of) medicinal products and each medicinal product has many characteristics (attributes), both defining and non-defining. The development and use of medicinal products is highly regulated; currently the way to define information about them is guided by the ISO IDMP standards. Furthermore, many healthcare providers, institutions and enterprises are involved in the use of medicinal products. Each of these actors uses information systems in which information on medicinal products is stored and exchanged. These information systems need an MPD-system to accurately and consistently identify medication concepts in the form(s) that fulfill their use cases.

An MPD-system establishes a consistent representation of medication concepts (set of identifiers) at various levels of detail and with meaningful relationships between the concepts, in order to support parts of several processes in healthcare in which medication plays a role. This Technical Specification describes a Medicinal Product Dictionary system in that way, that the concepts, identifiers and the relationships form a kind of structure that supports the use cases; together with the description of how this structure supports the use cases and what is needed for that. The MPD-system is further described from within an architecture in which it is connected to other parts of healthcare information systems.

Cultural differences in the practice and delivery of care and national legislation require electronic MPD-systems that meet specific local, regional or national needs. Each MPD-system is designed to support a particular set of use cases, which helps to determine the functional requirements which must be met by such systems. These functional requirements will then, in turn, determine the specific collection of ‘medication abstractions’ which must be identified, defined and related to each other within the MPD-system. Each ‘medicinal product’ in the MPD-system is described in terms of a specific subset of all possible defining and non-defining information elements, which together enable it to support one or more specific use case(s). The concepts are formally defined in terms of their characteristics and relationships with other concepts according to the ISO IDMP Standards, in particular ISO 11615, ISO 11616 and ISO 11238. Relationships between each of these medicinal product entries give the MPD-system the potential to support interoperability between use cases, processes, information systems, organizations and jurisdictions.

The anticipated stakeholders of this Technical Specification include healthcare providers that have responsibilities in selecting appropriate MPD-systems, software vendors, governments, pharmaceutical companies, wholesalers, payers, drugs regulatory authorities, and patients / patients’ organizations.

In general, this Technical Specification supports the following business goals:

- It provides information to MPD-system developers, to help them design MPD-systems which are better able to meet the ISO IDMP standards and the needs of multiple use cases;

- It facilitates accuracy and consistency of the use of concepts and terms according to the ISO IDMP standards in the MPD-systems;
- It increases the potential for consistency between MPD-systems around the world;
- It reduces redundancy of data collection and governance;
- It provides the foundations for future international standards, which help to enable interoperability between medication use cases, information systems, and jurisdictions involved in cross-border healthcare;
- It might reduce the cost of developing and maintaining medicinal product dictionaries systems.

The Technical Specification is partly based on the following terminologies / databases:

- The Australian Medicinal Terminology (AMT);
- NHS dictionary of medicines and devices (DM+D);
- Singapore Drug Database;
- SNOMED CT;
- Dutch G-Standaard from Z-Index (and Pharmabase from Healthbase) (NEN 7507);
- ISO/TR 22790, *Health informatics — Functional characteristics of prescriber support systems*.

Health informatics — Requirements for medicinal product dictionary systems for health care

1 Scope

This Technical Specification defines the required characteristics for any MPD-system to support use cases in healthcare.

These characteristics include the medication concepts, identifiers and relationships to form a kind of structure that supports the use cases.

In order to support the use cases, an MPD-system needs to:

- be comprehensive and exhaustive as far as possible – unless all medicinal products that are in scope are included, other systems cannot fully rely on the MPD-system to supply the necessary information, and some amount of duplicated registration of information will still be necessary;
- contain the information in a consistent and appropriate structure according to the ISO IDMP Standards (as described in this Technical Specification) and with an appropriate level of detail.

Outside the scope of this Technical Specification are:

- the functionality of health, clinical and/or pharmacy systems;
- the other kinds of content of health, clinical or pharmacy systems that are needed to support the whole process of healthcare providers, like:
    - o the wide range of knowledge about medicines, which would be handled in drug knowledge databases and decision support systems,
    - o the medication record,
    - o the dose instructions;
- in terms of products:
    - o traditional Chinese medicines,
    - o medical devices, such as for medication administration [this Technical Specification focuses on administration devices that are intended for correct administration of the medicinal product only (see ISO 11615)],

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

    - o veterinary medicines.

The purpose of this Technical Specification is to provide a set of functional requirements for systems handling details about medicinal products and the relationships between them for the purpose of supporting healthcare.

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

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

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

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

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

ISO/TS 16791, *Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers*

ISO 17523, *Health informatics — Requirements for electronic prescriptions*

3 Terms and definitions

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

3.1
administration
act of (self-)administering a (prescribed) medicinal product to the patient, using an administration method, and via a defined route, and recording that the act has actually happened at a particular date and time

3.2
administration method
general method by which a pharmaceutical product is intended to be administered to the patient

EXAMPLE Application, inhalation, injection.

Note 1 to entry: The administration method is a general term that is used to group related pharmaceutical dose form concepts, and is not intended to describe a precise method or route of administration.

[SOURCE: ISO 11239:2012, 3.1.3]

3.3
administration device
equipment intended for correct administration of the Medicinal Product

EXAMPLE Applicator, needle, oral syringe.

Note 1 to entry: An administration device can be an integral part of an immediate container or a closure.

[SOURCE: ISO 11239:2012, 3.1.2, modified]

3.4
attribute
characteristic of an object or entity

Note 1 to entry: In the context of this Technical Specification: a specific characteristic of a data element.

[SOURCE: ISO/IEC 11179-1:2015, 3.1.1, modified]

3.5
authorized product
medicinal product that has a marketing authorization

3.6
concept
unit of knowledge created by a unique combination of characteristics

[SOURCE: ISO 1087-1:2000, 3.2.1, modified]

3.7
context
related conditions and situations that provide a useful understanding and meaning of a subject

[SOURCE: ISO/TR 17119:2005, 2.4]

3.8
data
reinterpretable representation of information in a formalized manner suitable for communication, interpretation or processing

[SOURCE: ISO/IEC 2382:2015, 2121272, modified]

3.9
dispensing
process by which an individual healthcare provider takes in a prescription, assesses that prescription, selects the prescribed medicinal product and delivers that medicinal product to the subject of care or their representative

Note 1 to entry: In most cases, but not necessarily always, the individual healthcare provider concerned will be a Pharmacist.

[SOURCE: IHE Pharmacy - Technical Framework Specification]

3.10
dispense record
record of dispensed medicinal product and dispense process

Note 1 to entry: Dispensed medicinal product includes the actual product dispensed identifiers, brand, type, form, quantity etc. Dispense process record includes details of the delivery method, date and recipient (where this is not the subject of care) and the dispenser. The ability to record a comment where assessments of prescriptions are undertaken might also be part of this record.

3.11
dispenser
healthcare professional responsible for filling/dispensing prescriptions

Note 1 to entry: The dispenser is usually a pharmacist but can be other individuals according to local jurisdiction.

[SOURCE: ISO 21549-7:—, 3.5, modified]

3.12
dose form
pharmaceutical dose form

physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient

Note 1 to entry: Pharmaceutical dose form can refer to the administered dose form or the packaged dose form, depending on the product it is describing.

[SOURCE: ISO 11616:2012, 3.1.10]

3.13
Electronic Health Record
EHR
logical representation of information regarding or relevant to the health of a subject of care

[SOURCE: ISO 18308:2011, 3.20, modified]

3.14
entity
concrete or abstract thing of interest, including associations among things

[SOURCE: ISO/IEC 2382:2015, 2120770]

3.15
identifiers
sequence of characters, capable of uniquely identifying that with which it is associated, within a specified context

[SOURCE: ISO/IEC 11179-1:2015, 3.1.3, modified]

3.16
immediate container
immediate packaging in which a manufactured item or pharmaceutical product is contained and with which it is in direct contact

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

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

Note 2 to entry: A pharmaceutical dose form can fulfill the role of an immediate container, e.g. a capsule containing a powder for inhalation; the capsule in this case is not a container.

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

3.17
Investigational Medicinal Product
pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorized form, used for an unauthorized indication, or used to gain further information about the authorized form

[SOURCE: ISO 11615:2012, 3.1.28]

3.18
Investigational Medicinal Product Identifier
unique identifier allocated to an Investigational Medicinal Product supplementary to any existing identifier as ascribed by a Medicines Regulatory Agency in a jurisdiction or a sponsor of a clinical trial

Note 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.

[SOURCE: ISO 11615:2012, 3.1.31]

3.19
knowledge database
system in which knowledge on a specific topic is specified as set of declarative statements, hierarchical organization of such statements, and relationships between declarative statements, which serves as the underpinning of decision support systems

3.20
marketing authorization holder
organization that holds the authorization for marketing a medicinal product in a jurisdiction

[SOURCE: ISO 11615:2012, 3.1.41]

3.21
marketing authorization number
identifier assigned by a Medicines Regulatory Agency to a medicinal product

[SOURCE: ISO 11615:2012, 3.1.42]

3.22
medication concepts
formally defined medicinal products in terms of their characteristics and relationships with other concepts

3.23
medication history
record keeping of the specificities of the prescribed/dispensed/OTC medicinal product (identification, brand, type, form, quantity, dosage, etc.); this record contains the medication still in use as well as the medication no longer in use

[SOURCE: IHE Pharmacy - Technical Framework Specification, modified]

3.24
medicinal product
any substance or combination of substances that may be administered to human beings (or animals) for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions

Note 1 to entry: A medicinal product can contain one or more manufactured items and one or more pharmaceutical products.

Note 2 to entry: In certain jurisdictions a medicinal product can also be defined as any substance or combination of substances which might be used to make a medical diagnosis.

Note 3 to entry: Medicinal Product MPID XXXX87456 Slaapdiep tablet / Slaapdiep20 mg tablets National – has a name dedicated to a specific jurisdiction. (the code number is just an illustration, not a real identifier).

[SOURCE: ISO 11615:2012, 3.1.49, modified]

3.25
Medicinal Product Dictionary System
system that is specifically designed to support the prescription, dispensing and administration of medications in healthcare based on an accurate listing, description and identification of medicinal products

3.26
Medicinal Product Identifier
unique identifier allocated to a medicinal product supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction

Note 1 to entry: This is for indexing purposes and to contribute to improved patient safety by allowing for the unique identification of medicinal products worldwide.

[SOURCE: ISO 11615:2012, 3.1.50]

3.27
Medicinal Product Package Identifier
unique identifier allocated to a packaged medicinal product supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction

Note 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.

[SOURCE: ISO 11615:2012, 3.1.52]

3.28
packaged medicinal product
medicinal product in a container being part of a package, representing the entirety that has been packaged for sale or supply

[SOURCE: ISO 11615:2012, 3.1.57]

3.29
off label use
use of a medicine for an unapproved indication or in an unapproved age group, or in a unapproved dosage or in an unapproved route of administration

3.30
pharmaceutical product
qualitative and quantitative composition of a medicinal product in the dose form authorized for administration by a regulatory authority, and as represented with any corresponding regulated product information

Note 1 to entry: A medicinal product can contain one or more pharmaceutical products.

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

Note 3 to entry: For example: Pharmaceutical Product PhPID: L4M456897456123 Sweetopam 20mg tablet (the code number is just an illustration, not a real identifier).

[SOURCE: ISO 11616:2012, 3.1.19, modified]

3.31
pharmaceutical product identifier
globally unique identifier assigned to the pharmaceutical product(s)

[SOURCE: ISO 11616:2012, 3.1.22]

3.32
pharmacovigilance
process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines

[SOURCE: ISO 11615:2012, 3.1.59, modified]

3.33
prescribing
process of creating a prescription

3.34
prescription
direction created by an authorized healthcare person, to instruct a dispensing agent regarding the preparation and use of a medicinal product or medicinal appliance to be taken or used by a subject of care

Note 1 to entry: The term "prescription" alone is best avoided as it is colloquially used at random for the following terms: new prescription message, prescription set and prescription item. Further, it is also used to describe a prescription form. The use of the terms prescription set, prescription item and new prescription message where appropriate is recommended.

3.35
prescription product
abstract level of a medicinal product that contains the elements for prescribing a medicine at a generic level, which are necessary to dispense the appropriate medicine

EXAMPLE Salbutamol aerosol 100 µg/dose 200 doses volumatic. The addition 'volumatic' is not included in the pharmaceutical product, but is necessary in the description of the prescribed medicine to express that the product with the 'volumatic' (and not e.g. the autohaler) is meant.

Note 1 to entry: The level of abstraction needed for generic prescription can vary between the healthcare settings

3.36
quality
degree to which all the properties and characteristics of a product, process or service satisfy the requirements which ensue from the purpose for which that product, process or service is to be used

[SOURCE: ISO 9000:2015, 3.6.2, modified]

3.37
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 1 to entry: The reference strength refers to the strengths of the base, in case the strength of the substance is expressed as the salt or water for hydration.

[SOURCE: ISO 11616:2012, 3.1.26]

3.38
route of administration
path by which the pharmaceutical product is taken into or makes contact with the body

EXAMPLE Oral, intravenous, oromucosal, ocular.

[SOURCE: ISO 11615:2012, 3.1.73]

3.39
safety
freedom from unacceptable risk of harm

[SOURCE: ISO/IEC Guide 51, 3.14, modified]

3.40
strength
quantitative composition
amount of substance or specified substance expressed quantitatively per dosage unit, per unit of mass or volume, according to the dosage form

Note 1 to entry: 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 to entry: 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.

[SOURCE: ISO 11616:2012, 3.1.29]

3.41
substance
any matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical

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

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

[SOURCE: ISO 11238:2012, 2.1.58]

3.42
term
designation of a defined concept in a special language by a linguistic expression

[SOURCE: ISO 1087-1:2000, 3.4.3, modified]

3.43
terminological system
ordered collection of concepts, in which each concept is expressed by terms, words or expressions

[SOURCE: ISO/IEC 11179-1:2015, 3.2.25, modified]

3.44
unit of measurement
real scalar quantity, defined and adopted by convention, with which any other quantity of the same kind can be compared in order to express the ratio of the two quantities as a number

Note 1 to entry: Depending on the nature of the reference scale, the unit of measurement expression may stand either for a physical unit of measurement that is related to a system of quantities (e.g. SI units) or for an arbitrarily defined unit of measurement, which might refer to a certain reference material, a standard measurement procedure, a material measure or even to a combination of those.

[SOURCE: ISO 11239:2012, 3.1.27]

3.45
unit of presentation
discrete countable entity in which a pharmaceutical product or manufactured item is presented, in cases where strength or quantity is expressed referring to one instance of this countable entity

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

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

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

[SOURCE: ISO 11239:2012, 3.1.28, modified]

4 Abbreviated terms

For the purposes of this document, the following abbreviations apply.

ADR	adverse drug reaction
CDSS	clinical decision support system
CEN	Comité Européenne de Normalisation
EHR	Electronic Health Record
EHR-S FM	Electronic Health Record — System Functional Model
HL7	Health Level Seven
ICSR	individual case safety report
IDMP	identification of medicinal products
ISO	International Organization for Standardization
SPC	summary of product characteristics

5 Boundary between MPD-systems and IDMP, ancillary information to build an MPD-system and local implementation

5.1 Boundary between MPD-systems and IDMP

IDMP Standards guide the regulation processes for medicines in specified jurisdictions, and contain a maximum of detail. It is not required to cover every detail in an MPD-system which the ISO IDMP Standards specify. Concepts or elements from IDMP that do not support the use cases in this Technical Specification are not included. Further, the MPD-system can add locally required concepts, characteristics and data fields, for instance a historic identifier, necessary for a medication history for a patient, or to facilitate ongoing trends analysis. See Clause 6 for further description of the relationship between the MPD-system and IDMP.

5.2 Boundary between MPD-systems and ancillary information to build an MPD-system

Furthermore this Technical Specification addresses the MPD-system as it is offered by the MPD maintenance organization to hospitals, pharmacies, software vendors or other parties. To maintain the MPD-system, ancillary information may be needed, like the list of substances, dose forms and routes of administration from the databases which are specified in the implementation guides for the ISO IDMP Standards. These lists are not part of the MPD-system themselves, but can be used to deploy the concepts in the MPD-system.

5.3 Boundary between MPD-systems and local implementation

The MPD-system needs to be implemented in some way in health, clinical and/or pharmacy information systems, which creates a local implementation of the MPD-system. Such a local implementation can contain parts of the MPD-system, depending on the use case(s) that is/are supported. A local implementation can be considered as an implementation of the MPD-system functional requirements,

as long as the subset used is exactly the same as the MPD-system itself, and hence from the ISO IDMP standards. A local implementation can use the MPD-system in the following way:

— It can use a certain subset of the medicines included in the MPD-system.

— It can use a certain part of the structure (e.g. only the pharmaceutical or medicinal product part but not the packaged medicinal products).

— If for a certain use case a different set of elements is needed apart from what is defined in the MPD-system, it should be possible that the local implementation can use the separate elements to build its own view of a particular set of elements as needed for the particular use case.

5.4 Content of the MPD-systems in terms of product coverage

In terms of product coverage, the scope of the MPD-system includes all authorized medicinal products and may include medicinal products without authorization (including extemporaneous preparations). The implementations of the MPD-systems should describe more precisely which kind of products are included in the MPD-system and to what extent it is exhaustive. Concerning the authorized medicinal products, ISO IDMP Standards will be consistently adopted internationally to facilitate further harmonization and possible establishment of a common reference source for all regulated medicinal products. The reference source may be maintained and governed through a consortium of affected stakeholders such as authorizing bodies, bio/pharmaceutical manufacturers, and other IDMP terminology maintenance organizations. Further it is assumed that all concepts, characteristics, relationships, data model, data fields and data content as described in the IDMP standards are also available for the MPD-system. In case the ISO IDMP Standards are not yet fully implemented, the missing data cannot be present in the MPD-system based on the IDMP implementation, but may be added by the maintainer of the MPD-system.

Concerning the authorized medicinal products, the assumption is that the identifiers based on the ISO IDMP Standards are available. The identifiers used in the MPD-system shall be the identifiers of IDMP for the products that are covered by IDMP. It is not desirable to create new identifiers for concepts existing in IDMP. Concerning the products that are not covered by IDMP but need to be included in the MPD-system, the elements of the IDMP should be used as the model to create the information for these products. In case of products that are not covered by IDMP, it can be necessary to create new identifiers for the product (e.g. package ID), especially if the identifying characteristics or concepts do not exist in the underlying IDMP standards.

5.5 Definition of Medicinal Product Dictionary MPD-systems

An MPD-system establishes a consistent representation of medication concepts (set of identifiers) at various levels of detail and with meaningful relationships between the concepts, in order to support use cases in healthcare in which medication plays a role.

5.6 Benefits of the Technical Specification

The potential benefits of the Technical Specification for MPD-systems is that the functional requirements to which such systems should adhere are made explicit and organized into core and supporting sections, and that the relationships between MPD-systems with other health information systems are specified. Hence it becomes possible to determine to what extent MPD-systems meet requirements, and facilitate their (continued) development, maintenance and selection.

5.7 Target users for the Technical Specification

The target users of the Technical Specification for MPD-systems include:

- system developers,
- system maintainers,

- healthcare professionals with responsibilities for their practice ICT systems, such as for selection, application governance,
- those responsible for health informatics systems in their environment.

6 Positioning of Medicinal Product Dictionary Systems for Healthcare

6.1 Base materials for MPD-systems

The MPD-system supports various functional requirements of the health and/or clinical systems where it is employed. The MPD-system will also have to support various requirements around the medicinal products themselves. The reference for the overall structure and hierarchy of clinical system functional requirements is taken from the Health Level 7 Electronic Health Record System Functional Model (EHR-S FM), and derived models and profiles. Further, the EHR-S FM serves as an inspiration for the expression of the functions the MPD-system supports. The functional requirements for the MPD-systems are organized similarly. To identify appropriate EHR-S FM sections, headers, functions and conformance criteria, the core functions of the MPD-systems shall be identified and organized against the health and clinical practice processes and clinical information systems. However, this work will not be part of this Technical Specification, except where the interactions are specified.

The MPD-system does not exist on its own; it is a component of a larger health, clinical, and/or pharmacy information system, related to CDSS, Medication Record, and Dose syntax instruction specifications. Therefore the distinction needs to be clear between the functions that the MPD-system fulfils and those that are handled in the health/clinical/pharmacy information system, CDSS, Dose instruction and Medication Records parts.

The relationships between the MPD-system, various health, clinical, and/or pharmacy systems, the IDMP normative specifications and the EHR-S FM are illustrated at a high level in Figure 1. Figure 1 is not intended to cover every detail, or variant of each component.

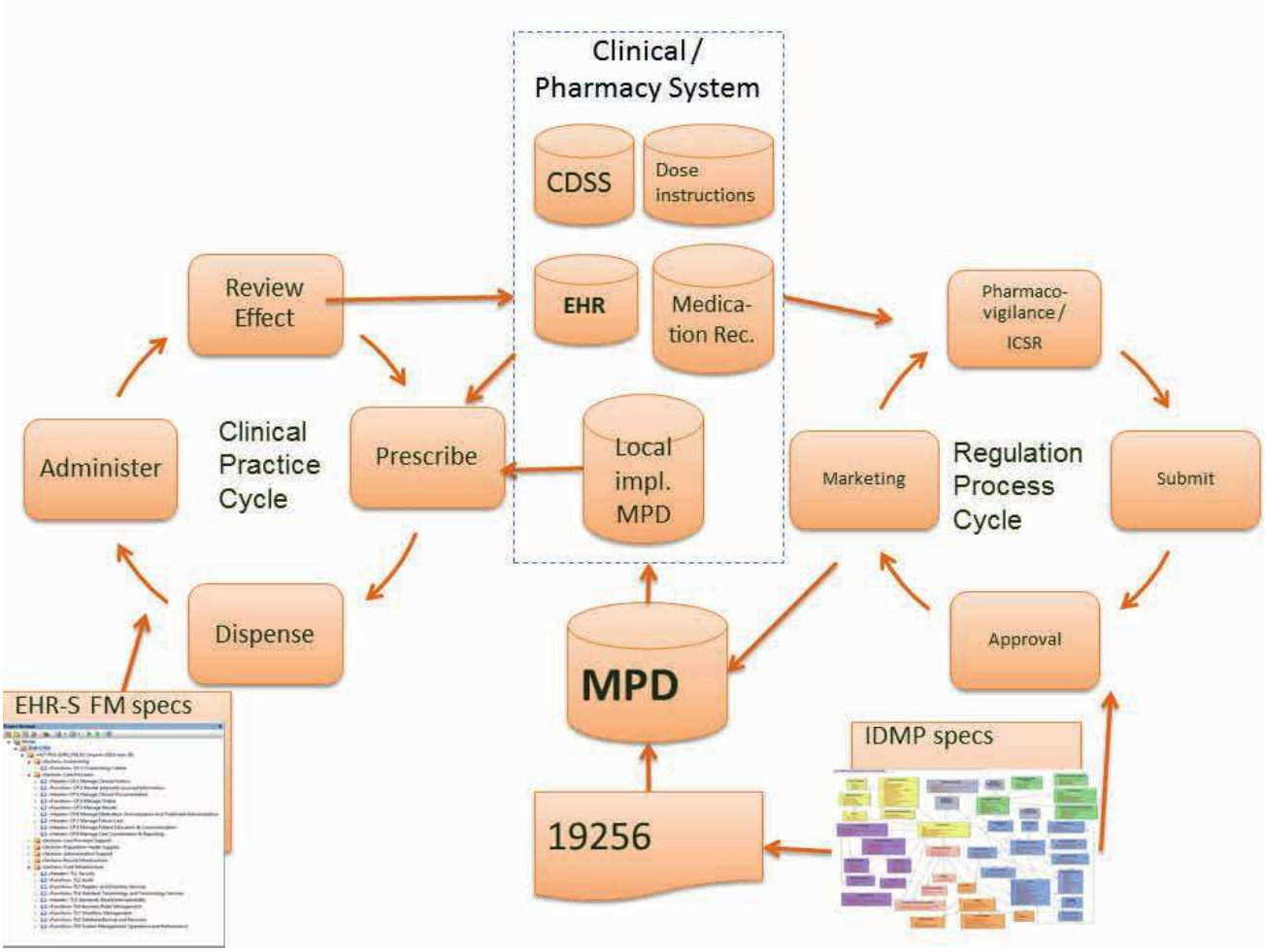

Figure 1 — The MPD-system and ISO/TS 19256 with relationships to health/clinical/pharmacy information systems, the clinical practice cycle, and the regulation process cycles

6.1.1 Relation with ISO IDMP standards

Medications around the world are becoming increasingly regulated. It is important to establish a consistent methodology (e.g. data elements, terminology and reference model) to facilitate consistent identification of medicinal products around the world. The IDMP standards are designed to cover a wide variety of medications and do not exclude identification of local, pharmacy prepared products which could be identified based upon the application of IDMP core concepts, relationships and data specifications.

The relationship between this Technical Specification for functional requirements for MPD-systems and the ISO IDMP Standards is as follows:

- This Technical Specification uses existing terminology, concepts and relationships as specified in the ISO IDMP Standards, in particular ISO 11615, ISO 11616 and ISO 11238.
- This Technical Specification assumes that the MPD is created and maintained in accordance with the IDMP series. In particular the following IDMP standards shall be used.
  - The substance referred to in an MPD shall be described in accordance with ISO 11238. Further, it should use the implementation specifications from ISO/TS 19844, and its resulting terminology. A term and a term identifier shall be used.

— The MPD shall specify the administrable dose form in accordance with ISO 11239. In addition, it should use the implementation specifications from ISO/TR 20440 and the resulting terminology. The term and the term identifier shall be specified.

— The MPD shall specify data elements and units of measurement according to ISO 11240.

— The MPD shall define the concepts required to associate Medicinal Products with an appropriate set of MPIDs in accordance with ISO 11615.

— The MPD shall define the concepts required to associate Pharmaceutical Products (authorized) with an appropriate set of PhPIDs in accordance with ISO 11616.

— The MPD shall support electronic prescription systems in accordance with ISO 17523.

— The MPD shall refer to machine readable coding of medicinal product package identifiers in accordance with ISO/TS 16791.

- This Technical Specification leverages and constrains the ISO IDMP terminology, concepts and relationships to support the clinical practice use cases for an MPD-system as included in this work. The subset of the ISO IDMP concepts, including the mapping to ISO IDMP identifiers is constrained to support the use cases described in this Technical Specification. This Technical Specification assumes that different users of MPD-systems can get different views on the included data, i.e. see less or more of the characteristics, depending on how granular they want to go to support their use case.

- It is anticipated that the entirety of IDMP standards, such as core concepts, characteristics, relationships, and data model be represented in an MPD-system to support as many use cases as possible. However, because the clinical practice use case does not require the level of specificity that IDMP covers, the MPD-system may only contain a subset of relevant concepts, characteristics and data elements from the core IDMP data model. For all MPD-system cases, whenever an IDMP concept, characteristic or data element is used, they shall be fully compatible and consistent with the applicable IDMP specification(s). For specific users even that might be too much, therefore it is suggested using different views on the data fields for different users.

- This Technical Specification will identify how the IDMP concepts, characteristics, relationships and data elements are implemented in an MPD-system using classification terms such as: “Shall’ – For required concepts, “Should” - For concepts considered useful and important to the use case, “May” – For concepts that are considered optional. MPD-system providers shall not create additional identifiers that overlap with IDMP identifiers for the same products that IDMP covers. However, for products that are not covered by IDMP (e.g. extemporaneous preparations), the IDMP core concepts, characteristics and data elements should be used to generate identifiers for these medicinal products.

- There is a need to take into account that there are existing MPD-systems in various jurisdictions, which likely have to adhere to local requirements and the impact of practice implementations. For this situation the Technical Specification will specify a kind of migration strategy towards the full use of ISO IDMP regulations in the MPD-system. However, the Technical Specification will also allow space for local additional requirements and local medicinal product preparation, not covered by any regulation.

6.1.2 Relation with health/clinical/pharmacy information systems, decision support, EHR and dose instructions

An MPD-system or its local implementation is part of a health, clinical, and/or pharmacy information system. Such an information system includes various functions and types of information. From the viewpoint of the MPD-system the most important parts of a health, clinical, and/or pharmacy information system are - beside the MPD-system - the decision support information, the EHR and a system that provides the dose instructions. To prescribe or dispense the right medicine, the health/clinical/pharmacy information uses the MPD-system to identify the medicine to be described or dispensed, and it uses the decision support linked to the MPD-system, combined with the EHR of the patient, to check the safety and efficacy of the medicine for this specific patient. The dose instructions

are used in the health/clinical/pharmacy information system to express the dosage to be used by the patient and to check the dosage with the data in the decision support part.

6.1.3 Relation with EHR-S FM

The already mentioned work undertaken by Health Level 7 International on the Electronic Health Record System Functional Model (EHR-S FM), which describes in its 2nd Release seven main sections of functional requirements for EHRs, is used as guidance for this Technical Specification. These basic functionalities are presented in the figure below (Figure 2 EHR-S FM sections). Each section represented with a specific colour, includes headers, functions and conformance criteria.

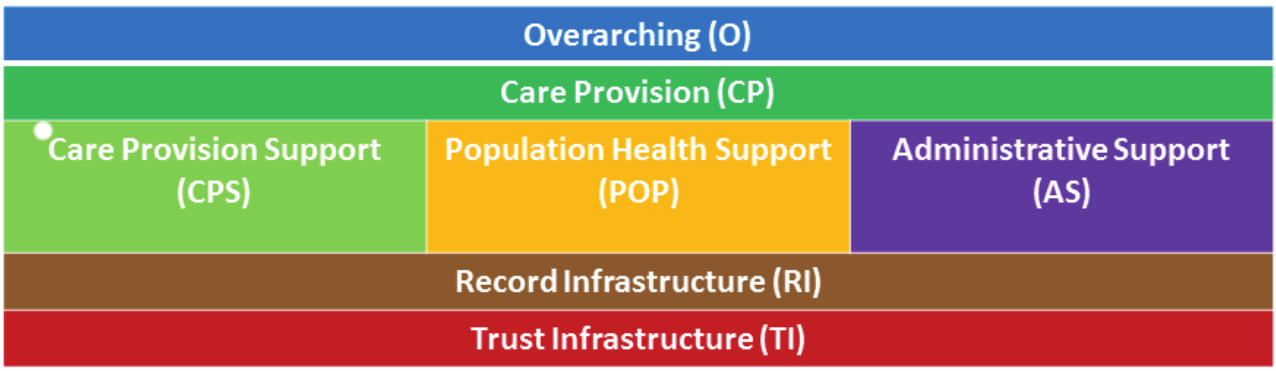

Figure 2 — Sections of the Electronic Health Record System Functional Model

The MPD-system functional requirements are presented following a similar approach as the EHR-S FM does.

6.2 Use cases for requirements for an MPD-system

Given the goal for this Technical Specification, the following use cases are identified and defined. The MPD-system aims at a minimum set of use cases that an MPD-system can enable or support, specifying the requirements for proper information content and structure:

- Prescribing
- Dispensing
- Administration
- Recording medication history
- Reconciling medication list
- Ordering and supply chain (logistics)
- Analytics / statistics around medicinal products, including pharmacoepidemiology
- Electronic data exchange of medicinal product information between healthcare systems and/or related systems
- Reimbursement against dispensed medicinal products
- Clinical research
- Tracking and tracing for patient and public safety purposes
- Pharmacovigilance

- Ensuring patient safety through linking personal data with the decision support system on medicinal products
- Migration

These use cases are further described in the following clauses.

6.2.1 Prescribing use case

The main contribution that an MPD-system shall provide to support the prescribing use case is to be able to describe medicinal product in sufficient detail that the next action in the process (either dispensing or administration) can identify the correct product to dispense/administer.

Depending on the domain of use, this might be to describe:

- a product *in full* – an actual manufactured product (brand named or not) and the relevant pack size;
- a product *in some degree of abstraction,* e.g. an abstraction level that contains elements like active substance, dose form and strength but no brand name.

In the latter above, the product may be described without reference to dose form, strength or unit of presentation. This may look very similar to a list of the product's active substances, but it is conceptually different. A patient cannot be administered "an amount of substance", they shall be administered a product formulated to contain the substance.

6.2.2 Dispensing use case

The main contribution that an MPD-system shall provide to support the dispensing use case is to be able to describe medicinal product in sufficient detail that the dispenser can correctly select the actual product to dispense.

Both the prescribing and dispensing use cases provide a requirement for the local implementation to have availability information in some way. A prescriber should not be given descriptions for products that are not available for dispensing; or if there is any restriction on availability that should be described. A dispenser should only select for dispensing those products that are available.

NOTE This requirement can be extended to include the provision of formulary information for prescribers and stock control information for dispensers – so that each has only a selected list of products from which to select.

6.2.3 Administration use case

The use case of administration deals with administering a (prescribed) medicinal product in a specified pharmaceutical dose to the patient, using an administration method, and via a defined route, and recording that the act has actually happened at a particular date and time.

6.2.4 Recording medication history use case

For several reasons it is useful to record the medicines that the patient has taken in the past, e.g. to know how long the patient has been taking the medicine or which medicines were tried but stopped for any reason.

6.2.5 Reconciling medication list use case

Where different healthcare providers provide a medication list for the same patient, it is necessary for these lists to be reconciled to know what the patient is actually taking for example in case of transfer of the patient. To facilitate the reconciliation, the medicines should be presented at the same level of granularity, or, when presented at a different level of granularity, should be able to be translated to a comparable level. This is needed to identify shared drugs or omissions in the medications list.

6.2.6 Ordering and supply chain (logistics) use case

This use case is about the ordering of medicinal products, transport, as well as the delivery and storage in a pharmacy. It is normal that such a process allows tracking and tracing during the various stages of the logistics process. To do this, a medicinal product needs for instance an identifier.

6.2.7 Analysis, statistics, and pharmacoepidemiology use case

Examples of analytics in the pharmacological domain could include retrospective analysis of data on medicinal product use. Pharmacoepidemiology is the study of the use of and the effects of drugs in large numbers of people. In order to gather data on drug use in large populations, information from many sources shall be pooled together. Therefore having a harmonious MPD-system with a structure or links to standard pharmacoepidemiology classification such as ATC would be useful.

6.2.8 Electronic data exchange of medicinal product information between healthcare systems and/or related systems, i.e. reporting use case

The MPD-system supports interoperability between systems, across care settings and across jurisdictions. Data that are exchanged will be based on the ISO IDMP Standards.

The MPD-system provides a framework for various health information technology applications and systems which deal with medications, prescription, dispensing, and administration information. For example, EHRs storing patient data, Clinical Decision Support system assisting with prescriptions, Drug Knowledge databases that hold knowledge on medications, relationships, interactions.

Clinical Decision Support systems generate alerts about drug safety, improper medicine usage, medicines with supply shortages, etc. This knowledge can only be of practical value, if this is linked to an MPD-system that provides the data for the actual prescribed/dispensed medicine and the medication history of the patient. Besides that, an MPD-system provides the different levels of granularity that offer the possibility to maintain the link between the clinical decision support and the medicines efficiently and with the less risk of mistakes. This will be an important function for the reporting for pharmacovigilance.

6.2.9 Reimbursement use case

This use case is about the reimbursements received for dispensed medicinal products. An MPD-system should offer the required medicinal product information that supports a number of secondary uses such as transparency of pricing, and procurement (if appropriate linking exists).

6.2.10 Clinical research use case

Clinical research is research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects. This can involve medications for example in protocol driven clinical trials for which the identification of the investigational medicinal product can be supported for authorized medicinal products.

Types of clinical research may include:

Patient-oriented research – This type of research involves a particular person or group of people, or uses materials from humans. Where this type of research includes therapeutic interventions and in clinical trials, an MPD-system may be used to facilitate analysis.

Epidemiological and behavioural studies– These types of studies examine the distribution of disease, the factors that affect health, and how people make health-related decisions. Where this type of research includes medicinal product variables, an MPD-system may be used to facilitate analysis.

Outcomes and health services research– These studies seek to identify the most effective and most efficient interventions, treatments, and services. Where this type of research includes medicinal product variables, an MPD-system may be used to facilitate analysis.

The provision of accurate information about the medicinal products that a patient is using now and has used in the past is important for so called “secondary uses” of information – particularly for clinical research. Clinical research should therefore be able to contribute use cases to support requirements for an MPD-system.

For example: Subjects are selected as suitable for recruitment into a clinical trial based on eligibility criteria which are formally documented as part of the protocol for a study. Finding suitable subjects is known to be difficult and success in recruitment is variable. Various strategies are now being developed to support recruitment, including clinical trial recruitment support systems for protocol feasibility studies and patient recruitment. These use the content of prospective or actual eligibility criteria as queries against a clinical data warehouse to retrieve either numbers of likely to be eligible patients (for feasibility testing) or individual patients (for possible recruitment). Many eligibility criteria reference medication use, and therefore being able to accurately describe medications – preferably in the same way from a single MPD-system – in clinical care and clinical data warehouses and in the eligibility criteria used in clinical research which then become search queries – would greatly increase the likelihood of clinical trial recruitment support systems having success.

6.2.11 Tracking and tracing for patient and public safety use case

For regulatory tasks, for instance ICSR, the MPD-system should offer the required medicinal product information that supports traceability of medicines throughout the prescribe-ordering-dispense–supply-administration cycle. This might be established through a link. Another similar use would be reduction in fraudulent activities (such as false dispensing) and grey imports. For this use case also the post-dispense follow up is included:

- Parallel imports – Medicinal products licensed by a regulator for import, these products have no therapeutic difference from the equivalent products on the market within the same territory.
- Grey imports – Imported medicinal products without authorization.
- Specials – Medicinal products without authorization manufactured in a territory for use by individual patients in that territory.

6.2.12 Pharmacovigilance use case

Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

Pharmacovigilance usually focuses on adverse drug reactions, or ADRs, which include any response to a drug which is noxious and unintended, including lack of efficacy, but medication errors such as overdose, misuse and abuse of a drug, as well as drug exposure during pregnancy and breastfeeding, are also of interest because they may result in an ADR.

PV events may be reported by doctors, pharmacists, nurses and other healthcare professionals working with medicines or by patients as the users of medicines. The level of drug information available varies from partial, e.g. in spontaneous and patient reported events, to higher levels of detail in more controlled environments, e.g. hospitals and clinical trials.

PV events are analysed to determine ‘signals’ and to confirm the ‘suspect drug’ and cause of the event. An MPD-system could be used to provide information at different levels (e.g. active substances, dosage, dosage form, route of administration, product trade name, packaging/packaged product, administered product, manufacturer, batch) on the ‘suspect drug’ to identify the root cause of the events, e.g. a substance, a manufacturer, a batch.

6.2.13 Patient safety through linking personal data with the decision support system on medicinal products use case

Medicines are most likely to be effective if the patient gets the right medicine for his/her situation. Otherwise the medicine can be harmful or not effective. In order to prescribe the right medicine for the right patient, decision support information is needed that provides the knowledge about potential harmful or ineffective situations. Combined with the personal data from the EHR, this provides the information needed to prescribe the appropriate medicines.

The MPD-system can function as a framework to which the decision support information is linked. Decision support information can contain:

- information like drug-drug interactions, contraindications, duplicate therapy, dose checking, and patient label instructions, including the support of risk minimization activities, like pregnancy prevention program, educational programs and controlled access programs.
- Information that supports the choice of the right drug according to a formulary, which is based on therapeutic guidelines combined with the characteristics of the patient.

6.2.14 Migration use case

Migration is the difference between 'as is' and 'would be'. Two words often used to describe what currently is, and what should be in a foreseeable future. Around the world there are many MPD-systems in use. Some will adhere already to many or most of the functional requirements specified in this Technical Specification. However, some might just cover a few functions to meet a specific use case. It can be expected however that in the future the 'would be' situation will lead to increasing regulations and controlling if MPD-systems meet these requirements. It is of course not possible in practice to expect system to change immediately. The same is applicable to the usage of existing medicinal terminology. The mapping to terminologies that are already in use, as mentioned in 7.3.1.2, is intended to facilitate the migration from the usage of that terminology to the usage of the MPD-terminology.

This Technical Specification specifies the functions in the hope that existing MPD-systems will eventually meet all requirements. A reasonable timeframe would be the duration of this Technical Specification for those functions that are undisputed, or cause no implementation nor use issues. For those functions that would lead to issues in the upcoming years, a longer grace period might be required in order to upgrade this Technical Specification to a full International standard (IS) in some years.

The intention of this Technical Specification is to state these functions that should be met today already, or would not cause trouble are specified with the 'shall' statement. Others that would be allowed to implement later can have 'should' statements. The 'may' statement is for optional parts. Of course, this will not be a 100 % guarantee, because some statements might continue to have a 'should' statement, for instance for those functions for which the underlying data are not always present. In that case is to be interpreted as: it is OK to not use it, but if it is available or present, it should meet the criteria.

7 The Functional Requirements for MPD-systems

7.1 Introduction

This subclause describes functional requirements that shall, should or may be present in an MPD-system. Similar to the HL7 EHR-S FM, it will use sections, headers, functions and criteria. The criteria will be specified using the normative language shall (i.e. always present), should (to be included if it is available) or may (which is optional).

The concepts and its elements as defined in the ISO IDMP Standards are the building blocks for the MPD-system. The ISO IDMP concepts are also formally defined in terms of their relationships with other concepts; depending on the granularity of the concepts, different hierarchical layers of concepts can be formed. The ISO IDMP concepts and relationships are used as baseline for ordering into the various sections below.

The principle for this Technical Specification is that the global unique IDs shall be maintained in any MPD-system. That will be further explained in the various clauses further on.

7.2 Goal of an MPD system

The goal of the MPD System is to offer various parties in healthcare a complete overview of available medicinal products in such a way the (elements of the) concepts and the descriptions and identifiers can be used in a variety of other healthcare information systems. The MPD systems do depend on the ISO IDMP concepts that identify uniquely a certain set of characteristics of the medicinal products, which can differ in granularity and that can have (hierarchical) interrelations based on the identifying characteristics. In this way, the different use cases for the MPD system that require a different granularity can be met, while the interrelations between the layers and concepts support that all users 'understand' each other and can find the meaning of the concept that is used. The task of this Technical Specification is to specify those functions of the MPD-system that support this. This normative content for the MPD system is based on the data model from IDMP.

7.3 Normative content

7.3.1 Content of regulated medicinal products

7.3.1.1 The MPD-system provides identified content according the ISO IDMP Standards

The MPD-system shall, should or may provide the following content and functions to pharmacy information systems, to health and clinical systems and to pharmacovigilance systems:

- The local MPD-system shall contain the global unique medicinal products identifiers defined on the basis of the mandatory and defining elements of ISO IDMP as defined in ISO IDMP Standards, especially the ISO 11616 and ISO 11615. In case the MPD-system contains local, unauthorized medicines that do not have an IDMP identifier, the IDMP identifier shall be left out.
- The MPD-system shall provide a listing (inventory or catalogue) of medicinal products concepts for use in health, pharmacy and clinical applications.
- The MPD-system should provide both human understandable and machine readable identifications for the medicinal product concepts, according to ISO IDMP terminology and approved regulated products.
- The MPD-system may provide corresponding words/phrases in alternative languages, depending on target audience and localization.
- The MPD-system should offer synonyms for medicinal products.
- The MPD-system shall provide the separate characteristics of the concepts as separate discrete elements.

7.3.1.2 The MPD-system provides data specification according to the ISO IDMP Standards

The MPD-system shall, should or may include the following data according to the ISO IDMP Standards:

- The MPD-system shall distinguish between the following hierarchical layers of concepts, according to the ISO IDMP Standards, in particular ISO 11615:
    - Substances (as present in the medicinal products);
    - Pharmaceutical products;
    - Medicinal products;
    - Packaged medicinal products.

Concerning the substance (as present in the medicinal products):

- The MPD-system shall provide the Substance and it may provide data about the specified substance which contains more details about the substance;
- The MPD-system shall provide the confidentiality indicator;
- The MPD-system shall provide the Ingredient role;
- The MPD-system shall provide the reference to the identifier of substances as provided by the source that contains the ISO 11238 identifiers.

Concerning the pharmaceutical products:

- The MPD-system shall contain the pharmaceutical products and its characteristics based on ISO 11616. It shall contain the pharmaceutical products based on the 'substance' and it may contain the pharmaceutical products based on the 'specified substance'. It may provide the concentration range.
- The MPD-system shall provide the reference to the pharmaceutical product identifier as provided by the source that contains the ISO 11616 identifiers. In case a sublevel of the pharmaceutical product is used base on ISO 11616, the reference to the identifier of this sublevel shall be provided.
- The MPD-system may contain one or more classifications of the medicinal products. If the MPD contains a classification, it shall provide the classification system name. Examples are the classification ATC or a mapping to the medicinal terminology that is already in use in the country where the MPD will be used. The classification system name is not a defining element, but additional information concerning the pharmaceutical product. It is also applicable for the levels 'below' the pharmaceutical product like the medicinal product, the level where ISO 11615 places the classifications.

Concerning the Medicinal Products:

- The MPD-system provides the following information concerning the Medicinal Product Information:
    - The MPD-system may provide the Investigational Medicinal Product Identifier Cross Reference between the Medicinal Product Identifier of the authorized medicinal product and the related Investigational Medicinal Product Identifiers assigned during the development phase and clinical investigation of that medicinal product;
    - The MPD-system should provide the 'additional monitoring' indicator and the 'special measure indicator', unless this information is provided in a decision support system linked to the MPD-system;
    - The MPD-system shall provide (access to) the SPC and/or package insert of the regulated document, and its identifier;
    - The MPD-system shall provide the Medicinal Product Name;
    - The MPD-system shall provide the approved routes of administration; based on (inter)national guidelines it may contain off-label routes of administration, while it should be made clear whether a route of administration is approved or whether it is off-label;
    - In several instances it might be useful to include the medical indication associated with a medicinal product. The MPD may include attributes that specify the approved indications associated with a medicinal product.
    - In several instances it might be useful to include the colour of the medicinal product. The MPD may include attributes that specify the colour.
- The MPD-system provides the following information concerning the marketing authorization:
    - The MPD-system shall provide the marketing authorization number;

- The MPD-system shall provide the country in which the marketing authorization has been granted;
- The MPD-system shall provide the authorization status, status date;
- The MPD-system may provide the validity period of the authorization status;
- The MPD-system shall provide the marketing authorization holder;
- The MPD-system may provide the marketing status and date.

- The MPD-system shall provide information about the organizations that provide data for the MPD-system. This information shall be the name and may be other details as described in ISO 11615.
- The MPD-system provides the following information concerning the Manufacturer:
  - The MPD-system should provide information about the manufacturer of the medicinal product and the operation type (the kind of manufacturing: production of the product, re-labelling, re-packaging etc). The information about the manufacturer shall be the name and may be other details as described in ISO 11615.
- The MPD-system shall provide the reference to Medicinal Product Identifier as provided by the source that contains the ISO 11615 identifiers.

Concerning the packaged Medicinal Product:

- The MPD-system provides the following information concerning the Packaged Medicinal Product Information:
  - The MPD-system shall provide the package description;
  - The MPD-system shall provide the package item (container), the container type and container quantity; this includes the information of each of the parts of the package, including the outer and inner package, like the box and the blisters, as defined in each regional ISO IDMP implementation.
- The MPD-system provides the following information concerning the data carrier identifier:
  - The MPD-system shall provide the data carrier identifier code system and the data carrier identifier value.
- The MPD-system provides the following information concerning the package:
  - The MPD-system shall provide the component type and component material;
  - The MPD-system may provide the component alternate material.
- The MPD-system provides the following information concerning the shelf life/storage:
  - The MPD-system shall provide the shelf life type and time period;
  - The MPD-system shall provide the precautions for storage.
- The MPD-system provides the following information concerning the device:
  - The MPD-system shall provide the device type, device material and device quantity;
  - The MPD-system shall provide the device trade name;
  - The MPD-system may provide the device alternate material;

- The MPD-system shall provide the sterility indicator.

- The MPD-system provides the following information concerning the manufactured item:
  - The MPD-system shall provide the manufactured dose form;
  - The MPD-system shall provide the unit of presentation;
  - The MPD-system shall provide the manufactured item quantity.
- The MPD-system provides the following information concerning the physical characteristics:
  - The MPD-system may provide the, height, width and depth of the package.
- The MPD-system provides the following information concerning the marketing authorization:
  - The MPD-system shall provide the legal status of supply.
- The MPD-system provides the following information to support the recognition of falsified medicines:
  - The MPD-system may provide an indicator whether the package is serialized or not
  - The MPD-system may provide the information about the features of a package that the manufacturer added to discern between the original and the falsified version of a package.
- The MPD-system shall provide the reference to the Medicinal Product Package Identifier as provided by the source that contains the ISO 11615 identifiers.

Some characteristics used in the concepts represent a nomenclature of themselves, like the dosage form or route of administration.

7.3.1.3 The MPD-system provides data about relationships and cardinality of the ISO IDMP concepts

The MPD-system shall, should or may provide the following content and functions to pharmacy information systems, to health and clinical systems and to pharmacovigilance systems:

- The MPD-system shall support the concepts, characteristics, relationships between the concepts and elements from the IDMP data model that identify a medicinal product which are well laid out in ISO 11615, and in particular ISO 11238, as far as the items on which the relationships are built, are present in the MPD-system.
- The MPD-system shall make available all relevant elements (in particular the identifier) of the medicinal and pharmaceutical products, based on ISO 11615 and 11616.
- The MPD-system shall support views on subsets on these elements, as a grouping of shared elements of medicinal products. These views shall be supported in the following ways:
  - As a fixed grouping of identifiers, as described in 7.3.1.2;
  - To be created by the healthcare providers themselves, using the elements of the medicinal and pharmaceutical products as building blocks to create their own views and grouping of elements;
  - Views and groupings may have their own identifiers within the local implementation of the MPD-system, but for the exchange of information with others, these identifiers shall NOT be used;
  - For the exchange of data from the MPD-system to other systems the individual elements and their identifiers shall be used according IDMP.
- The MPD-system shall support the various cardinalities between concepts as are laid out in ISO 11616:2012 5.2 and 6.1, which explains the cardinality within the pharmaceutical products and

the cardinality between the pharmaceutical product and the medicinal product, for as far as these are included in the subset.

7.3.2 Prescription

This subclause describes how the MPD-system supports the use case of prescribing, as far as this is in scope of the MPD-system. This implies that identification of the right medicine is in scope, However, processes like decision support for instance to check for drug-drug interactions and processes of composing the dose instruction are NOT a function of the MPD-system and are therefore not described in this subclause.

Prescribing medicines can be done on an abstract, generic level, or on the level of the manufactured medicine. Legislation on how to prescribe medicines (generic or brand level) can vary per jurisdiction.

Therefore, it is difficult to describe a certain set of data and their characteristics that define the level that can be used for prescribing medicines, because of different needs in different jurisdictions. On the other hand, a kind of guidance should be provided, as a link to the decision support and to (the recording of) the dispensable package.

An MPD-system may have a concept that represents the level on which the prescriber can prescribe the drug on a generic level. Mostly this level is the pharmaceutical product or a level between the pharmaceutical product and the medicinal product:

- In case the MPD-system has a fixed prescription level, to support the prescribing use case the MPD-system shall offer descriptions of all the available medicinal products at various levels of abstraction from the most detailed form to the very generic, with appropriate relationships between these levels.
- In case the MPD-system does NOT have a fixed prescription level, it shall be possible to compose a prescription based on the identifiers of the different layers of concept.
- The various levels of concepts shall support the linkage to the decision support. In case the MPD-system supports the process of prescribing by using separate identifiers, the prescribed medicine based on the separate identifiers shall support the linkage to the decision support system.
- The MPD-system shall support the linkage to the medication record in such a way, that a prescribed medicine name, identifiers and other relevant concepts, can be saved in the medication record.
- The MPD-system may support the linkage to the dose instructions in such a way that choosing a medicine to describe leads to the applicable dose instructions to be used.
- To support the prescriber in searching for the medicinal product description that they require, an MPD-system may provide various additional concepts such as navigation or grouping concepts and/or search strategies (short keys, abbreviations etc.) and synonym terms to support implementation.

7.3.3 Dispensing

This subclause handles the interactions between the MPD-system and clinical systems that pharmacies use to keep record of dispensed medicinal product(s):

- To support the dispensing use case, the MPD-system shall offer descriptions of all the available medicinal products at various levels of abstraction from the most detailed form to the very generic, with appropriate relationships between these levels. This is needed in order to choose the right packaged medicinal product to dispense, in case a higher level of abstraction is prescribed.
- To aid the dispenser in selection of the correct actual product, an MPD-system may provide various additional concepts such as navigation or grouping concepts and/or search strategies (short keys, abbreviations etc.) and synonym terms to support implementation.
- To support the dispensing use case, the MPD-system may support the various local or national requirements around “dispensability” of a product (is this patient eligible to receive this product, is this product reimbursable or should an alternative be used).

- The various levels of concepts shall support the linkage to the decision support system.
- The MPD-system shall support the linkage to the medication record in such a way, that a dispensed medicine can be saved in the dispense record.
- The MPD-system may support the linkage to the dose instructions in such a way, that choosing a medicine to describes leads to the applicable dose instructions to be used.

7.3.4 Administration

This subclause handles the interactions between the MPD-system and clinical systems that are used to keep record of administered medicinal product(s). The MPD-system itself will likely not have functions to record the actual administered medications. That function is usually taken care of in an EHR, or medication record, or increasingly in personal health records and mobile applications. Therefore only the interactions of the MPD-system with such systems are described.

It is assumed that healthcare organizations carefully track and trace the administered medicinal products. In the future it might expand to patients carefully tracking their self-administered prescribed and over the counter medicinal products. This subclause is considered essential for proper handling of medicinal products in healthcare, but at this time cannot be complete in the light of the many developments going on with personal health records, devices and smartphone apps:

- To support the administration use case, the MPD-system shall offer descriptions of all the available medicinal products at various levels of abstraction from the most detailed form to the very generic, with appropriate relationships between these levels. This is needed in order to choose the right packaged medicinal product to administer, in case a higher level of abstraction is prescribed.
- To support the administration use case, the MPD-system shall offer the licensed route(s) of administration and may offer other accepted routes of administration of a specific medicinal product. This can include examples such as oral intake, inhalation or injection with by which the patient gets the product inside his/her body.

7.3.5 Recording and reconciliation

The MPD-system will play a role in the documentation of prescribed medications in the medication history section of electronic health records and/or personal health records. At times, it is important to reconcile all medications that a patient has been prescribed, and actually have been dispensed, and administered. The use case explained that different healthcare providers usually provide a separate medication list for the same patient. In several situations, these different lists need to be reconciled to know what the patient is actually taking, e.g. in case of transfer of the patient. The MPD-system will only offer the right naming, identifiers and other concepts from the IDMP standards to these other systems to facilitate the reconciliation:

- To support the recording and reconciliation use case the MPD-system shall offer descriptions of all the available medicinal products at various levels of abstraction from the most detailed form to the very generic, with appropriate relationships between these levels. This supports recording the medicines in the EHR as the actual dispensed package into an abstract level that can be used for grouping the medicines, representing them in an appropriate way for performing medication reviews or making an overview of the medicines used. The same is applicable for reconciliation: grouping of the medicines and insight into the actual dispensed packages in a standardized way supports the healthcare provider in reconciling different medication lists for the same patient.
- To record the medicines and to present to the user in a comprehensible way, an MPD-system may provide support to record the data on medication use and hence offers the possibility in the medication history section of an electronic health record to aggregate the data on the desired level.
- An MPD-system should present the medicinal product information in a standardized way to different medication record systems at different levels of presentation.

- To support the recording use case, the MPD-system should facilitate the linkage of stored data in electronic health records or personal health records about specific administered medicinal products for an individual to the IDMP identifying data, as they are offered by the MPD-system.
- To facilitate appropriate reconciliation of the medication list, the MPD-system should facilitate the presentation of medicinal products at the same level of granularity or if a different level of presentation is present, support the translation to comparable levels.

In other words, the MPD-system should facilitate in detection of the shared and missing medicinal products on the medication history:

- The MPD-system should offer the required medicinal product information that supports review or reconciliation of a profile of medication in an EHR, and for other applications and systems which deal with medications, prescription, dispensing, clinical decision support, drug knowledge databases, and administration information.
- To support medication reconciliation processes in healthcare, the MPD-system should facilitate the linkage of stored data in multiple electronic health records, personal health records and pharmacy systems with specific data about prescribed, dispensed and administered medicinal products to an individual.

7.3.6 Order and supply chain and logistics

When patients take medicinal products, these shall be readily available at the point of care. Hence the logistic process around medication is important. That process is fully dependent on the proper identification of the medicinal products, according the IDMP standard. The logistics include the production, the storage of supplies, the transport to the pharmacies, stock keeping and management, the timely ordering of new supplies, the actual physical hand over to the patient, and the secure removal of waste medications:

- The MPD-system should facilitate the various logistic processes around the storage, distribution, stock keeping and inventory, ordering and handing over medicinal products, and disposing of medicinal product waste. Especially the data about the packaged medicinal product are helpful for this.
- The MPD–system should facilitate in tracking and tracing during the various stages of the logistics process.
- The MPD-system should include machine readable barcode identifiers for any medicinal product for tracking and tracing throughout the logistics process.

7.3.7 Analysis, statistics, pharmacoepidemiology, and clinical research

There is a growing need for data analysis in healthcare, with a growing focus on observational data for research in addition to the traditional clinical trial data. In the context of the MPD-system for healthcare, this section will not try to describe all options, however, those data uses that will be augmented when IDMP medicinal product identifiers are applied. There are four key data uses defined: analysis, statistics, pharmacoepidemiology and clinical research. For ease of reading, analysis will be used in the normative statements, unless a very specific type of analysis is intended:

- To support the analysis use case, the MPD-system should allow linked stored personal medication administration data in electronic health records or personal health records with identified specific medicinal products from the MPD-system to be exchanged to for instance a clinical data ware house for further analysis.
- Various data aggregations, based on personal data on medicinal product administration and IDMP identification data should be facilitated, including continuity of care, ICSR, pharmacological usage research, and more.

The first category of analysis in medicinal product data are simple kinds of analysis, often performed at the pharmacy for internal managerial purposes as stock keeping:

- The MPD system should facilitate any kind of analysis on medicinal products data from inside the MPD-system, or through linkage with a supply chain system, including, but not limited to: inventory, lead times, and usage patterns.

Statistics is of course a quite broad concept. In general for the use case around MPD-systems it is meant that baseline frequencies of use of particular medicinal products are calculated, and that tables and trends are created:

- To support statistical analysis of medicinal product data, the MPD-system should allow linked stored personal medication administration data in electronic health records or personal health records with identified specific medicinal products from IDMP to be exchanged to a clinical data warehouse for further statistical analysis.

- The results of the statistical analysis should be obtained from other applications than the MPD-system.

According to Strom[24] pharmacoepidemiology is the study of the uses and effects of drugs in well-defined populations:

- To support pharmacoepidemiology, the MPD-system should allow in electronic health records and/or personal health records the relevant linked data about the medicinal products, including descriptions of all the available medicinal products at various levels of abstraction from the most detailed form to the very generic, with appropriate relationships between these levels, to be stored and exchanged to a clinical data warehouse for further use in pharmacoepidemiological studies.

- The linked data for pharmacoepidemiology should include, but are not limited to, stored demographic data, detailed data about administered medicinal products including their IDMP identifiers, administration procedural data, symptoms and disease data, and both wanted and unwanted effects.

Clinical research determines the effectiveness, efficiency and safety of various treatments in healthcare to obtain the evidence that justifies application in practice. Medicinal products are one target of such research, usually taking several phases of research. The MPD-system can facilitate clinical research in each phase through facilitating the recording of precise medicinal product data into the electronic health record and/or clinical trial reporting system (such as clinical trial management system, electronic case report form or eCRF system and so on):

- To support clinical research, the MPD-system should allow in electronic health records and/or personal health records and various clinical trial reporting systems the relevant linked data about the medicinal products including descriptions of all the available medicinal products at various levels of abstraction from the most detailed form to the very generic, with appropriate relationships between these levels to be stored and exchanged to a clinical data warehouse for further use in pharmacoepidemiological studies.

- The linked data for clinical research should include, but are not limited to descriptions of all the available medicinal products at various levels of abstraction from the most detailed form to the very generic, with appropriate relationships between these levels, and link these to data stored in records including demographics, details about administered medicinal products including their IDMP identifiers, administration procedures applied, symptoms and disease, data defined for the trial purposes, and both wanted and unwanted effects.

7.3.8 Ensuring patient safety through linking personal data with the decision support system on medicinal products

The MPD-system can function as a framework to which the decision support information is linked with EHR data. Hence the MPD-system can contribute to effective use of medication and prevention of harm. Decision support information can contain:

- Information like drug-drug interactions, contraindications, duplicate therapy, dose checking, and patient label instructions, including the support of risk minimization activities, like pregnancy prevention program, educational programs and controlled access programs.
- Information that supports the choice of the right drug according to a formulary, which is based on therapeutic guidelines combined with the characteristics of the patient.

For safe usage of medicines, decision support during prescribing and before dispensing is important. Preferably a decision support system is linked to the MPD-system, in order to ensure that the information is available at the moment the medicine is prescribed or dispensed. Therefore, the MPD-system should provide the framework to which the decision support can be linked:

- To support the linkage of decision support to the MPD-system, the MPD-system shall offer descriptions of all the available medicinal products at various levels of abstraction from the most detailed form to the very generic, with appropriate relationships between these levels to the decision support system.
- This supports to link the decision support on a generic level in case an alert is applicable for all the medicines belonging to that generic level or to link the decision support to a very specific product in case it is applicable only for that specific product.
- The MPD-system may offer groupings of each of the characteristics, in order to facilitate the linkage of decision support to a specific grouping which is not one of the fixed hierarchical levels. Example: linkage of decision support to all ibuprofen products with route of administration ‘oral’ and ‘rectal’, which excludes the cutaneous products.
- The MPD-system shall relate medicinal product concepts together within the inventory or catalogue in such a way as to support some reasoning (even if very basic).

7.3.9 Interaction with reimbursement systems

Every country has reimbursement systems in place as part of their healthcare system. It is obvious that often quite expensive medicinal products fall under such a regime.

This use case is about the reimbursements received for dispensed medicinal products. An MPD-system should offer the required medicinal product information that supports a number of secondary uses such as transparency of pricing, procurement (if appropriate linking exists), and research:

- An MPD-system should be used to submit correct information at the level that is asked by the organization that reimburses the medicine. This can be different levels of granularity, therefore an MPD need to support several levels of granularity.
- An MPD-system should facilitate to include additional data than the IDMP based data fields, for submission to reimbursement systems, such for instance as price of the medicine, value added tax, whether the medicine is reimbursed or not and within which reimbursement class (by government, by insurance company, etc).

7.3.10 Interaction of MPD-systems with pharmacovigilance systems

Pharmacovigilance usually focuses on adverse drug reactions, or ADRs, which include any response to a medicinal product which is noxious and unintended, including lack of efficacy. On the other side,

medication errors such as overdose, misuse and abuse of a drug, as well as drug exposure during pregnancy and breastfeeding, are also of interest because they may result in an ADR:

- An MPD-system should be used to provide information at different levels (e.g. active substance, dosage, dosage form, route of administration, product trade name, packaging/packaged product, administered product, manufacturer, batch) on the 'suspect drug' to identify the root cause of the events, e.g. a substance, a manufacturer, a batch.
- An MPD-system can be used in the electronic interaction between various electronic health record systems, personal health record systems and pharmacy systems in order to support the proper specification of the administered medicinal products.

An MPD-system can be used by a pharmacovigilance reporting system to support the medicinal product identifier and information to be submitted to national or international reporting systems which allow healthcare professionals and others to report adverse drug reactions to the central agency according to ICSR.

7.3.11 Data exchange and technical functions

The MPD-system shall be useful both for human users, and for various health information systems. It serves both humans and machines. The interactions with humans are carried out through the human computer interface. The interaction with other computer systems takes place through technical interfaces. This section specifies functional requirements on both levels.

7.3.11.1 Human interface to the MPD-system: multiple views

The MPD-system will have to work for various users, including regulators that want to review its completeness, developers that want to keep the system current, physicians that want to use it when prescribing, pharmacists when dispensing, patients that want to know precisely what it is, quality managers that want to report adverse drug reactions, and many more. Each has a different view on the MPD-system's content. One wants a very generic view, where the other wants a very granular view, highlighting all the details.

This leads to the following criteria for MPD-systems:

- An MPD-system should provide a function which allows defining different views on the data fields inside, and a selective choice of what is presented to which target audience.
- An MPD-system should provide the option to change such views on demand.
- An MPD-system should have a role based access system to control the content. Minimum roles are based on the CRUDE matrix: Create, Read, Update, Deprecate and Exchange.
- The role based access to the MPD-system shall be defined at individual database field level, on record level and on view level.
- An MPD-system's Deprecate function shall not actually destroy the contents about medicinal products, but will define policies around a products end of life.
- An MPD-system should facilitate the creation of views, based on a flexible set of fields to be shown, however, taking into account the limits set.

7.3.11.2 Technical interfaces with various Health IT systems

Besides the various human beings in various roles, the MPD-system will have to interface with various healthcare information systems. It is beyond the scope of this Technical Specification to specify every

possible interface, however some core systems will briefly be mentioned as examples, following some generic criteria:

- An MPD-system should provide a function which allows defining different technical interfaces to other health information systems.
- An MPD-system should provide a function which allows deploying standards for electronic interchanges to other health information systems. An example can be a Health Level 7 interface.
- An MPD-system should provide a function which allows defining from the user interface / specific view what event should lead to what kind of electronic data interchange, a so called trigger event generator. (This can be a pull request from a physician to get the required data for a prescription and subsequently store these in the patients EHR).
- An MPD-system should provide a function which allows such a trigger event to automatically carry out the specified data exchange task(s).
- An MPD-system should provide a function which allows specifying various data exchange tasks, such as pulling out the appropriate data with various levels of generality or specificity from the database in which the medicinal products are stored, arranging them in a format that a receiving system can handle (or which a messaging system can take up and handle), and exchanging the data accordingly.
- An MPD-system may provide a function which allows application roles to be handled, such as tracking and tracing which data have been exported to which system (when and where) and automatically sending updated or warning information in the case new information comes available for a specific medicinal product.
- An MPD-system shall provide a function which allows exchanging data with electronic health record systems.
- An MPD-system shall provide a function which allows exchanging data with clinical decision support systems.
- An MPD-system shall provide a function which allows exchanging data with clinical data warehouse systems.
- An MPD-system shall provide a function which allows exchanging data with pharmacovigilance case reporting systems, i.e. ICSR based systems.
- An MPD-system shall provide a function which allows receiving data from national regulatory systems, distributing market authorization data and IDMP based data.
- An MPD-system shall deploy a technical interface that allows regular updates from the (inter) national IDMP database.

7.4 Governance

The principles and processes that should be considered by developers of MPD-systems in support of proper application of international healthcare terminology standardization are outlined in ISO/TR 12309:2009 and should be respected. These principles relate to:

- Governance and due process;
- Openness and transparency;
- Impartiality and balance;
- Sustainability and responsiveness;
- Safety.

ISO/TR 14872 outlines the governance and maintenance considerations for the ISO IDMP Standards, and some of the principles mentioned in this document may be also applicable to the governance and maintenance models for the MPD-systems.

In addition similar principles would apply to the information models which represent the MPD-system. These need to have a governance and due process procedure, transparency, impartiality and balance, and need to be safe and sustainable. So although specified for other topics, this Technical Specification assumes similar approaches for the information model of MPD-systems.

An MPD-system should thus have a well-defined governance model to ensure the quality, consistency, maintenance, usability, security, and availability of information. The governance body should also coordinate development of the dictionary, e.g. by maintaining a business plan. The governance model should ensure that appropriate input is obtained from Subject Matter Experts (SMEs), Data Stewards and Dictionary Users as well as Management representatives. The governance model should also consider interaction or collaboration with governance organizations for related terminologies with dependencies or from which data are sourced, e.g. ISO IDMP Standards, to further promote consistency and interoperability and to reduce redundancy and duplication of effort.

- The governance mechanism for a body distributing an MPD-system should apply an established and proven governance model.

NOTE Examples would include the Plan Do Check Act process, or another example could be ISO 9001 based procedures.

- The governance mechanism for a body distributing an MPD-system should apply international input where appropriate, such as for medicinal product marketing authorization, identifiers, description at generic and specific level, and adverse reactions.
- The governance mechanism for a body distributing an MPD-system should apply clear lines of communication with regulators.
- The governance mechanism for a body distributing an MPD-system should apply safety procedures.
- The governance mechanism for a body distributing an MPD-system should apply links of communication to vendor communities both for medicinal products and for electronic healthcare systems.

7.5 Maintenance

Maintenance processes should be designed to meet the broad spectrum of use cases for the MPD-system, including data sharing and information exchange needs between stakeholders. The scope and content of regular maintenance includes the continued updating of the MPD. Such updates include new medications on the market, withdrawn medications should be removed from the active list, but remain available for lookup purposes, versioning needs to take place, among others. The maintenance of medicinal products registration and market authorization is handled through the IDMP standards, in particular through the IDMP identifier. Detailed maintenance processes may be unique to the maintenance organization, infrastructure, jurisdiction and data to be supported, and these may already exist for some established medicinal product dictionaries, but the following core principles should be considered when upgrading or developing new medicinal product dictionaries.

7.5.1 Regular maintenance processes of the MPD-system

- Maintenance processes should be fully documented, communicated and appropriately maintained, with approved Standard Operating Procedures (SOPs) and Service Level Agreements.
- Controlled terms, versions and whole vocabularies shall not be deleted, but instead should be designated as “retired” or “deprecated” and should be traceable at every time point.

- Requests for new terms, changes to terms or term retirement should be processed within an appropriate period based on the use cases, and the frequency and complexity of the maintenance activity.
- Decisions should be communicated, including publication of the new, modified or retired term, within the time frame specified in approved service level agreements.
- Requests for new terms, term changes or term retirement should be supported with appropriate levels of information, details of which should be specified in the approved service level agreements.
- Proportionate and appropriate procedures, with suitable security and quality control, should be in place for evaluation and approval of change requests by suitably qualified personnel. Independent audits may be considered.
- Electronic means for receiving, processing and communicating the outcome of change requests should be used where possible.
- There should be mechanisms in place to ensure that changes to elements and vocabularies that are mastered by another organization but used within the MPD-system are updated in a timely and appropriate manner within the MPD-system. Such elements and vocabularies shall not be amended within the MPD-system unless amended in the master source first. If changes to these elements and vocabularies are desired, requests for change should be made to the mastering organization.
- The MPD-system owner should deploy a strict and transparent versioning approach to guarantee up to date content to the various MPD-system users.
- Appropriate advanced notice and sufficient detail should be given to stakeholders for any major data or structural changes or releases of the MPD-system.

7.5.2 Interaction with regulatory information

This subclause consists of two main categories of regulation: the acceptance of new medicinal products and the withdrawal of medicinal products due to various reasons. Each category is placed under a different header.

7.5.2.1 New medicines

The interaction with regulatory authorities / pharmaceutical industry to submit new approved medications with all details that need to be included in the MPD-system.

- To support the availability of new medicines for the several use cases, the MPD-system shall synchronize regularly with regulatory master information services to obtain newly registered medications data.
- The usage of the identifiers for marketing status in the local MPD-system, support those new medicines can only be prescribed and dispensed if they are on the market (in the country or area where the MPD-system is applicable).

7.5.2.2 Withdrawn marketing authorization and discontinued medicinal products

This subclause describes the interactions of the MPD-system with regulatory authorities, and/or pharmaceutical industry databases in order to withdraw medications. This interaction should deal with all details that need to be removed from, 'inactivated' or made 'not available' in the MPD-system, or state that something cannot be distributed anymore, but still existed in past.

- The MPD-system shall synchronize regularly with regulation master databases to obtain data about withdrawn medicinal products that have lost their marketing authorization.
- In the implementation of the MPD-system it shall be made sure that the withdrawn medicinal products can be prescribed and dispensed as long as it is available from the marketing authorization

holder or the wholesaler if there is a legal transition period during which the product may be legally prescribed and sold..

- In the implementation of the MPD-system it shall be guaranteed that withdrawn medicinal products can be kept in the medication history of an individual.

7.6 Localization

In order to fit national or regional needs, an MPD-system would likely be adaptive to meet such needs.

- A local MPD-system shall specify exactly where it meets the requirements of this Technical Specification and where it differentiates.
- Any differentiation of a local MPD-system shall be made clear to the user populations and justified with appropriate documentation.
- If a localized MPD system is used, maintenance and governance principles laid out in 7.5 should be applied in a similar fashion.
- There may be a need to support foreign language translations in localized MPD-systems.

Annex A
(informative)

IDMP series in context, serving this Technical Specification

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Figure A.1 — Relationships between the ISO IDMP series of standards where this Technical Specification builds upon standards listed in this annex

- ISO 11615:2012, Health Informatics, Identification of Medicinal Products (IDMP) standard Data elements and structures for unique identification and exchange of regulated medicinal product information
- ISO 11616:2012, Health Informatics, Identification of Medicinal Products (IDMP) standard Data elements and structures for unique identification and exchange of regulated pharmaceutical product information

- ISO 11238:2012, Health Informatics, Identification of Medicinal Products (IDMP) standard Data elements and structures for unique identification and exchange of regulated information on substances
- ISO 11239:2012, Health Informatics, Identification of Medicinal Products (IDMP) standard Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
- ISO 11240:2012, Health Informatics, Identification of Medicinal Products (IDMP) standard Data elements and structures for unique identification and exchange of units of measurement.

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[6] ISO/TR 14872, *Health informatics – Identification of Medicinal Products – Core Principles for Maintenance of Identifiers and Terms*

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