DELIVERABLE 2.3 openMedicine final identifying and descriptive attributes

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Revision History, Status, Abstract, Keywords, Statement of Originality

Revision History

Revision	Date	Author	Organisation	Description
0.1	2016-02-17	William Goossen	NEN	First draft framework
0.2	2016-05-01	William Goossen	NEN	Building upon D 1.3 and other openMedicine content
0.3	2016-06-14	William Goossen	NEN	Adding various chapters content based on D 1.3 review, ISO meeting and Madrid workshop.
0.4	2016-0708	William Goossen	NEN	Handled review Comments from Isabel Lazaro, Kevin Horan, and Gerard Freriks (external review of the DCM only for use in ISO 13606-3).
0.5	20160708	William Goossen	NEN	Prefinal, copy of 0.4 without revision markings visible.
0.6	20160722	William Goossen	NEN	Version including revisions to handle the external review comments.
0.7	20160725	William Goossen	NEN	Version after handling the external review comments. Revison markings visible
0.8	20160726	William Goossen	NEN	Prefinal version. No revisions visible. Separate document explaining handling of external reviewer comments
0.85	20160728	Giorgio Cangioli Marcello Melgara	HL7 International LISPA	Document review and adding the table on correspondence between currently implemented eP/eD and PS and ISO IDMP
0.90	20160729	William Goossen	NEN	All final revisions handled.

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Abstract (for dissemination)	This deliverable's goal is to present the final list of identifying and descriptive attributes of medicinal products and will give implementation recommendations based on the materials developed in D1.1, D 1.3, D2.1, D2.2, D3.1, and 4.1 of openMedicine. D2.3 will be a relevant input to D3.2, which will extend the attribute lists to special products.
Keywords	Unambiguous identification of medicinal products, standards framework, standards identified, identifying and descriptive attributes

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise, in particular through references to earlier work, in particular also to other openMedicine deliverables.

Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Table of Content

Executive Summary D 2.3

The task of this deliverable D 2.3 is to specify the final identifying and descriptive attributes of medicinal products as they are depicted in the tables from D 2.2[1] and modelled in the Detailed Clinical Model of D 1.3[2]. Outputs from D4.1[3] and D3.1[4] are considered as inputs to this deliverable. On the other side, D2.3 is taken by WP3 to assess and, if needed extend, the attribute list, for special products (D3.2[5]). In order to achieve D 2.3 and openMedicine's goals, a close collaboration with European Medicines Regulatory Network (EMRN) and European Medicines Agency (EMA) is ongoing. The methods applied include mainly review the specific data elements in table format and through the Detailed Clinical Model that has been updated for three use cases. However, based on the selected clinical use cases ePrescription, eDispense and record keeping it has become clear that not all data elements from ISO IDMP and EMA's article 57 database for medicines regulations are relevant for use in the clinical systems and cross border exchange.

The tables included here therefore only include those data elements, their data types and where possible the **required** controlled terminologies and value sets. However, derived from this work, the tables do include the final Identifying & Descriptive Attributes, in particular the final Identifying Data Elements and the final Descriptive Attributes as they can be represented by data elements. These have informed an updated version of the Detailed Clinical Model for the Medicinal Product, for which a full walkthrough and its background information is presented.

Terminologies, Codes and OIDs form an important next step for the developments. These are not yet available for all required data elements, value sets and controlled terminologies and OIDs. An example of ongoing work was presented for EDQM and finally, the position of EMA as broker for all required terminologies is discussed.

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1 openMedicine D2.2: Comprehensive set of openMedicine identifying and descriptive attributes of medicinal products and the available standards

2 openMedicine D1.3: Initial openMedicineinfostructure

3 openMedicine D4.1: Reverse identification, cluster prescriptions and other special cases

4 openMedicine D3.1: Assess the WP2 solution for special products

5 openMedicine D3.2: Identification and description of special products

1 Aim and Scope of the Document

The purpose of openMedicine is to give practical solutions for the cross border exchange of data relevant for the prescription and dispense of medicinal products. The project is closely following the ISO IDMP series of standards, which consists of both a set of five guiding principles for the regulation process of medicinal products and a (draft) set of accompanying implementation guides. In Europe, both European Medicines Agency (EMA) and the national medicine evaluation boards through the European Medicines Regulatory Network (EMRN) are responsible for the implementation of IDMP.

However, the IDMP is not aimed at clinical processes. ISO IDMP is accompanied at ISO level with a set of more clinical standards, such as for prescription, medicinal product dictionary and dispense. Nevertheless, these more clinical standards are drawn up in accordance with ISO IDMP. In Europe and internationally, there have been projects in the past, such as epSOS, and there are ongoing projects e.g. eStandards and openMedicine that focus on implementation of patient summaries and ePrescription. openMedicine is carefully following up on the epSOS experiences and is closely working with EMA and EMRN. In the ongoing dialogue within the project and with various stakeholders it was decided that both the IDMP identifiers and descriptive attributes are required to properly identify a medicinal product.

D 1.1 determined that identifying data elements of medicinal products and contextual factors are important. From D 1.2 only the use cases of ePrescription, eDispense and its record keeping in Electronic Health Records (EHR) and pharmacy systems are selected, since each use case will have its own requirements, and these three are relevant for the cross border exchange for a patient. From D 1.3 the Detailed Clinical Model (DCM) is taken that shows the relevant data classes for the three identified use cases. This work informs ongoing work at the European Medicines Agency (EMA), and EMA is currently updating its article 57 data base to meet the IDMP set of standards. From this exchange of ideas, D 2.1 and D 2.2 identified the single data elements in the article 57 database, and specified the kind of data types and controlled terminologies required to implement this. Also, at the EU level these organisations currently work on the controlled vocabularies. Outputs from D3.1[6] and D4.1[7] are considered as inputs to this deliverable. On the other side, D2.3 is taken by WP3 to assess and, if needed extend, the attribute list, for special products (D3.2[8]).

The current task of D 2.3 is to specify the final identifying and descriptive attributes of medicinal products as they are depicted in the tables from D 2.2 and modelled in the DCM of D 1.3. In order to achieve D 2.3 and openMedicine's goals, a close collaboration with CEN/ISO and EMA is imperative. The IDMP standards are enormous and only a subset of attributes from the standards and the EMA's article 57 database are relevant for use in the clinical systems and cross border exchange. Hence, the purpose of this D 2.3 work is as follows:

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6 openMedicine D3.1: Assess the WP2 solution for special products

7 openMedicine D4.1: Reverse identification, cluster prescriptions and other special cases

8 openMedicine D3.2: Identification and description of special products

1. To identify from the D 2.2 tables and the D 1.3 DCM class model, the IDMP and the article 57 data elements that are further selected and specified as the final versions.

2. For each selected IDMP and article 57 data element an appropriate representation must be included in the final DCM.

3. Each class in the DCM representing a specific data element must be identified by a unique code from a code set. Available code systems and codes will be selected, if and when available.

4. Several data elements/ classes have data type CD (concept descriptor). This implies that the values to include in the cross-border exchange or store in an EHR depend on an identified value set with unique codes per value.

5. Those terminology and/or code systems that have already been selected by EMA, EMRN, EDQM, or national medicines evaluation boards and that specify data elements, classes and terminologies will be listed.

6. In the collaboration with EMA, the appropriate OIDs will be selected, or even generated, to facilitate cross Europe, and hence cross-border, use and exchange. One practical issue arises that is that the deadline for D 2.3 is July 2016, where phase one of the parallel work on identifiers, controlled vocabularies and OID determination at EMA level only starts in September 2016 and will offer the first results ends December 2016. So for the specifications of OIDs (object identifier), controlled terminologies and value sets, this deliverable cannot be complete.

2 References

Various documents publications were taken into consideration while preparing this document. References in this document come from the below mentioned sources:

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- EN ISO 11238, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances.
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3 Terms and Definitions

In the document the following terms and definitions were included.

3.1 Terms/Acronyms

API	Active Pharmaceutical Ingredient
CEM	Clinical Element Model
CIMI	Clinical Information Modeling Initiative
DCM	Detailed Clinical Model. ISO TS 13972
EC	European Commission
EHR	Electronic Health Record
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
epSOS	Smart Open Services for European Patients - Open eHealth Initiative for European Large Scale Pilot of Patient Summary and Electronic Prescription
EU	European Union
FHIR	Fast Health Interoperable Resources
GS1	Name of a standards developing organisation.
HL7	Health Level 7 standards developing organization
ICD	International Classification of Diseases
ICPC	International Classification of Primary Care
ISO IDMP	International Organization for Standardization – Identification of Medicinal Products
MPID	Medicinal Product Identifier
OID	Object Identifier
PCID	Package Identifier
PhPID	Pharmaceutical Product Identifier
RDF	Resource Description Framework
SDO's	standards developing organizations
SmPC	Summary of product characteristics
UML	Unified Modeling Language
WHO	World Health Organisation.
XML	eXtensible Markup Language

3.2 Use of Terms and Definitions

Active Pharmaceutical Ingredient Any substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings

[Reference: WHO]

ePrescription a medicinal prescription, as defined by Article 1(19) of Directive 2001/3/EC, issued and transmitted electronically

[Reference: openMedicine Dictionary]

Health Care Encounter Report (HCER) a synthetic document, based on the Patient Summary, generated after an encounter abroad, returned to the country of affiliation, which contains findings and the Medication Summary of medicinal products prescribed while abroad

[Reference: epSOS]

Medication Related Overview a subset of the Patient Summary including information a pharmacist might need, to safely dispense a medicinal product (e.g. Medication Summary, allergies,…), not having access to the full Patient Summary

[Reference: epSOS]

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

[Reference: ISO 11615:2012]

Patient Summary a dataset of essential and understandable health information that is made available at the point of care to deliver safe patient care during unscheduled care and planned care with its maximal impact in the unscheduled care

[Reference: epSOS]

Pharmaceutical product a qualitative and quantitative composition of a medicinal product in the dose form approved for administration in line with the regulated product information

[Reference: ISO 11615:2012]

4 Methods

The baseline for this deliverable comes from D 2.2 in which all the article 57 data elements were listed, and from the tables in D 1.3 where all data elements from the ISO IDMP series were listed and reviewed for clinical usefulness.

The Detailed Clinical Model (DCM) for the medicinal product, which started in D 1.3, has been further developed using discussions with experts in the openMedicine consortium, and also dialogues with groups as the HL7 pharmacy group, ISO TC 215 WG 6 pharmacy, NEN TC 303006 WG6 pharmacy, and individual experts. The DCM Medicinal Product was created in the Enterprise Architect software of Sparx©, with the Detailed Clinical Model ISO TS 13972 template to achieve the proper stereotyping of the DCM in UML, and with the DCM Model Creator which validates the models and facilitates its export into XML variants.

The completion of the identifying data elements and the DCM for medicinal products include PCID, MPID, PhPID and SubstanceID, to have the definitional standards available to populate both the structural components and to populate each descriptive component with unambiguous identifications derived from controlled terminology and code systems. From the EN ISO IDMP series, the core components are taken to create the base on the DCM medicinal product. In particular the substance and substance identifiers come from EN ISO 11238. The Pharmaceutical Product Identifier (PhPID) and Pharmaceutical concept name come from EN ISO 11616. The Medicinal Product Identifier (MPID) and Pharmaceutical concept name come from EN ISO 11615. The package identifier or PCID comes from EN ISO 11615 and TS 16791. These form the core identifiers on the four levels of substance, pharmaceutical product, medicinal product and package identifier. Some additional data elements also come from these standards, e.g. in particular where they define additional descriptive characteristics of a medicinal product. Two core characteristics include the Dose Forms and the Routes of Administration, which are specified in EN ISO 11239. In addition, some input from other openMedicine deliverables has been taken into account, such as from 4.1 about additional regulation data, as study number, not described in ISO IDMP.

The EMA's article 57 database, which is supposed to contain core data for all products registered in the EU (it is believed to contain ca 90% of all the products as of the date of writing of this document) holds the data that the pharmaceutical industry must submit in order to obtain a marketing authorization within the European Union, as it is expressed in detail in openMedicine D 2.2, is the core additional resource. This is done for the obvious reason that it is focusing on implementation in the EU context. The clinical usefulness is based on the applicability of a data element about the medicinal product as it would be used in an ePrescription, an eDispense or in an EHR or pharmacy system. These are further specified in the existing tables from D 1.3 and D 2.2. This is further accompanied by reference sets of data elements, data types, unique code bindings to for instance EDQM and value set specifications.

5 Key background materials

5.1 Use cases for Cross-border product identification

openMedicine works use case driven in order to achieve meaningful, desirable and achievable results. D1.1 and D 1.2 extensively described use cases where a Medicinal Product description would be applied. D1.1 described the basic Use Cases to be considered: ePrescription issued in Country A and dispensed in Country B. D1.2 assessed Complementary uses cases. D 1.3 used that set of use cases for the linkage to the various standards in the framework and the Initial openMedicine infostructure. Given that all possible use cases have already been identified, we suffice here to focus on the main use case for cross border e-Prescription. This is Use Case 1: Prescription is issued in one country (Country A), must be dispensed in another country (Country B). This use case cannot be fulfilled without eDispense and recording.

5.2 Clinical modelling within openMedicine

Technical or physical representations have their limitations for exchange of semantics, in particular for cross-border purposes, where one country uses technology A, and another technology B. Hence, one part of D 1.3, the infostructure, identified the Reference Model – Open Distributed Processing (RM-ODP) approach as potential helpful. That approach starts with use cases that represent the business and its goals and cover the conceptual level of modelling. Next, to bridge the conceptual view and the technical representation, a logical model is helpful. For openMedicine a Detailed Clinical Model (DCM) was created for the Medicinal Product according ISO TS 13972 which covers the core logics of the medicinal product data elements, their relationships and their code and valueset bindings if and where available.

DCMs are logical models of clinical concepts useful for defining and structuring clinical information. A well-formed DCM includes meta-data, versioning, medical content and medical contexts, specification of data elements, relationships, code bindings to medical terminologies and attributes. DCMs offer maximal detail and precision, without specifying these details in a specific computer programming language such as archetype definition language (ADL) or eXtended Markup Language (XML). The goal is to have a point of reference, independent of one specific technical implementation format, in contrast to HL7 or 13606.

Given that the eHealth architectures in the European member states all can choose their own technologies, the DCM functions as a generic translator on conceptual and logical level via mapping data elements and terminologies. It is relatively simple to use the DCM as a point of reference to map local technical solutions e.g. from an ISO 13606 archetype approach to an epSOS CDA approach to an HL7 v3 pharmacy messaging approach to an HL7 FHIR approach, thus facilitating semantic interoperability.

6 Final Identifying & Descriptive Attributes

This chapter will present the final identifying data elements for medicinal products and in addition the final descriptive attributes. These are based on the IDMP following the tables in D 1.3 and the analysis of the article 57 database from EMA following the tables in D 2.2. All the attributes in the EMA article 57 data elements are either already ISO IDMP attributes, or they will all be ISO IDMP soon. Few additional items are derived from D 4.1.

6.1 Final Identifying Data Elements

D 1.3 presented the draft core data elements for identification of medicinal products. This table is included here but with the status of final identifying data elements for medicinal products. These identifiers will serve in principle all use cases as depicted in D 1.2, so clinical, logistical, payment related and regulation related. These are carried over from the IDMP that address the pharmaceutical industry and the approval processes to the clinical use cases as ePrescription, eDispensation, EHR documentation and more.

The following tables connects the source (e.g. international standards) and each data element, with its presence in the EMA Article 57 database, the fact that data element might be useful for cross-border use cases, and its coverage by the Detailed Clinical Model (DCM).

Table 1. Core identifying data elements from IDMP for all use cases for all domains.

Source	Data element	(Plan for) EMA article 57 database	Use case Xborder ePrescription / Dispense / Record keeping	Include/ exclude in DCM	Motivation
ISO 11238	Substance ID	Include	Include	include	Every substance will be identified by this mandatory ID.
ISO 11616	Pharmaceutical Product Identifier PhPID	Include	Include	include	Every pharmaceutical product will be identified by this mandatory ID.
ISO 11615	Medicinal Product Identifier MPID	Include	Include	include	Every (regulated) medicinal product will be identified by this mandatory ID.
ISO 11615	Medicinal Product Package Identifier (PCID)	Not in art.57 but planned for product iteration 1	Include	include	Every packaged product will be identified by this mandatory ID. Packaged Medicinal Product Identifier. The PCID should use a common segment pattern related to a package of a Medicinal Product, which when each segment is valued, should define a specific PCID concept. The pattern is: MPID for the Medicinal Product plus Package description code segment, which refers to a

					unique identifier for each package type and size.

Which identifier or code set will be deployed, or most likely the mix of identifiers and code sets, must be determined. This will be firstly for the various identifiers for organizations as EMA and FDA that will assign unique numbers for medicinal products (PCID, MPID, PhPID and SubstanceID). EMA will be an example of such organizations. Secondly, it will be the code system(s) to identify the classes in the DCM. Unlike HL7 RIM, these will not get class names, but to overcome language barriers, unique codes that will represent the exact same concept in any language, allowing mapping or translation into each member state language(s). Thirdly, each controlled terminology, for those classes in the DCM where these are applicable, the unique id such as Unique Object Identifier (OID) must be available for implementation.

Currently the DCM specifies for PCID, MPID and PhPID an instance identifier and for the Substance a CD, concept descriptor. The latter is based on the discussions with EMA about the various systems in use and in development that deliver a unique code for each substance. At this stage no final conclusion can be given if all should be CD or instance identifier or that it can differ per identifying data element.

6.2 Final Descriptive Attributes

Those systems that have already been selected by EMA or national medicines evaluation boards that specify data elements, classes and terminologies will be listed in the table pointing out what they are, what they entail, what their use is, and the OID, and if relevant their version, and start-stop dates. This is followed up from D 1.3, D 2.1 and 2.2, and from D3.1 and D4.1.

EN ISO 11238 Substances holds various data elements that will not be used in clinical practice / e-prescription. A selection is made which elements can be of use in cross border exchange. ISO TS 19844 is the implementation guide for 11238 and holds implementation specifications, in particular in HL7 v3 format (CPM) of the data elements in 11238. A selection is made which elements can be of use in cross border exchange (Table 2). Several are included as optional. Where in the following tables EMA article 57 database is mentioned, this will become product iteration 1 in 2017 with a phased approach to capturing the pharmaceutical product. The roles of ingredients are identified specifically in article 57 database and include active ingredient, excipients and adjuvants (Table 3).

From Deliverable 4.1 various concepts about the Medicinal Products have been explored and included. Some of them are considered relevant in a cross-border setting, such as the procedure ID or procedure number and procedure type. All the concepts in Deliverable 4.1. are positioned at the Medicinal Product level. According D 4.1, doctors will not know what the procedure type is but with the procedure type in regulation procedures and the procedure ID, national systems should be able to identify the products that have the same dossier, assessment report, same SmPC (Summary of product characteristics), same Package leaflet, same label. In addition, the reference Medicinal Product (definition from EU Directive 83/2001) will help in the generic substitution and the legal basis too. However, these are not

in ISO. Hence, in table 6 additional items are suggested to cover for procedure identifier/ number and related topics. These are included as optional and will occasionally be used in eDispense in a Cross Border situation, not in ePrescription. These are optional data for identification numbers assigned by a Medicines Regulatory Agencies in relation to a specific medicines regulatory process. The procedure type is also listed but excluded since it is not used in ePrescription. Tables 4, 5 and 6 follow with the other IDMP standards.

Table 2 Data elements from the substance standard EN ISO 11238 and implementation guide ISO TS 19844

Source ISO IDMP	IDMP data elements	IDMP: Mandatory Should Conditional Optional	(Plan for) EMA article 57 database	Xborder use case	DCM include/ exclude	Motivation
ISO TS 19844	Ingredient	M	included	include	include	Core concept for the ingredient level of data elements. A substance is any matter that has a discrete existence, irrespective of origin, which may be biological or chemical.
ISO TS 19844	4.1. Specified_Substance	M	included	include	include optional	This one is normally not used in clinical practice, and hence not yet included in the DCM. However, included optional based on expert input.
ISO TS 19844	4.1. Specified_SubstanceGroup	M	included	include	exclude	Valueset 4 categories. Normally not used in clinical practice, could be considered for an extension later.
ISO TS 19844	4.2. Substance_ID	M	included	include	include	Every substance will be identified by an ID. Once a substance has been defined, a unique identifier that is permanently associated with that substance will be assigned.
ISO TS 19844	4.2.1 Substance type	M	included	include	include	To distinguish specific substances from each other.
ISO TS 19844	4.3. Substance_Name	M	Included, but not unique in art 57, new substance system (global substance registry system G-SRS) in 2017 will provide a defined common substance database	include	include	Name for the core concept. A substance is any matter that has a discrete existence, irrespective of origin, which may be biological or chemical.

			for Europe.			
ISO TS 19844	Substance name alternatives	M	Include. Currently based on a terminology list extracted from art 57 data, will be replaced by G-SRS	include	include optional	Names that come from official, authoritative sources, so which can be official names that are typically non-proprietary names used in a given jurisdiction and domain to refer to a specific substance. Can be described in various systems or formats such as official and systematic.

Table 3. Data elements from EN ISO 11616 Pharmaceutical product and for few data elements a draft ISO DTS 20451 implementation guide of 20150315 for EN ISO 11616

Source ISO IDMP	**IDMP data elements**	**IDMP:** Mandatory Should Conditional Optional	**(Plan for) EMA article 57 database**	**Xborder use case**	**DCM include/ exclude**	**Motivation**
EN ISO 11616	3.1.22 PhPID identifier	M	Not in art 57 will be generated when product iteration 1 becomes available in 2017 and published	include	include	Unique identifier for the pharmaceutical product, mandatory using the relevant pharmaceutical product identifiers. This provides a uniform representation of the pharmaceutical product using the active substance(s)/specified substance(s), their (reference) strength(s), the administrable dose form and, where applicable, the integral device and adjuvant.
EN ISO 11616 / TS 20451	Active substance	M	included	include	include	It needs to be known what the active ingredient is. PhPIDs shall be represented within two strata (active substance stratum and specified substance stratum), both of which contain four PhPID identification levels, for each pharmaceutical product contained in a medicinal product.
EN ISO 11616	3.1.1. Specified Substance	M	included	include	include	As described in ISO 11238, specified substance(s) shall capture detailed characteristics of single substances or the composition of material that contains multiple substances or multiple physical forms.

EN ISO 11616	3.1.58 PharmaceuticalProduct	M	included	include	include	Name for the pharmaceutical product. A pharmaceutical product shall be described in terms of its qualitative and quantitative composition and the pharmaceutical dose form authorized/approved for administration (administrable dose form) in line with the regulated product information.
EN ISO 11615	10.7 PharmaceuticalProduct	M	included	include	include	See above, checked for consistency in both standards
EN ISO 11616	3.1.24. Ingredient	M	included	include	include	There shall be one instance of the Ingredient class for each actual ingredient of either the manufactured item or pharmaceutical product, as appropriate.
ISO DTS 20451	4.2.1. Ingredient Role	M	included	include	include	The ingredient role of active substance, excipient or adjuvants or other roles. The ingredient roles are included in HL7 CPM file in the full upper case letters exactly as specified in the table in ISO DTS 20451 clause 4.2.1 Table 4.
EN ISO 11616	3.1.30. Substance	M	included	include	include	The active substance, if required as specified substance. A Substance can be specified for an ingredient in the role described.
EN ISO 11616	3.1.27 Specified substance	M	included	include	include	A specified substance can be specified for an ingredient in the role described. See above, checked for consistency in both standards
EN ISO 11616	3.1.29 Strength	M	included	include	include	The strength of the substance or specified substance shall be specified as a quantity of the substance/specified substance present in a given pharmaceutical product.
EN ISO 11616	4.2.6. Strength unit	M	included	include	include	A numerator value and its associated numerator unit as well as a denominator value and denominator unit shall be specified for all elements that have PQ data type. Not separate data element.
ISO DTS 20451	4.2.7. Strength Range (Presentation)	M	Not in art 57, not planned for product	include	include	The strength range (presentation) shall be specified.

			iteration 1			
ISO DTS 20451	4.2.8. Strength Range (Concentration)	O	Not in art 57, not planned for product iteration 1	include	include	The strength range (concentration) can be specified.
EN ISO 11616	5.7.2.4 Reference Strength	O	Not in art 57, not planned for product iteration 1	include	include	Even when a Reference Strength is not required, one may quantify the active moiety relationship to express the amount of active moiety.
EN ISO 11616	5.7.2.4.4 Reference Strength Range	M	Not in art 57, not planned for product iteration 1	include	include	The reference strength range shall be specified. A numerator value and numerator unit as well as a denominator value and denominator unit shall be specified.
EN ISO 11616	3.1.1. Administrable dose form	M	included	include	include	This shall describe the administrable dose form in accordance with the authorized/approved regulated product information.
EN ISO 11616	3.1.32. Unit of Presentation	M	included	include	include	The unit of presentation is a qualitative term describing the discrete unit in which a pharmaceutical product is presented to describe strength or quantity in cases where a quantitative unit of measurement is not appropriate.
ISO DTS 20451	5.1.5. Pharmaceutical Product Quantity	M	included	include	include	The quantity (or count number) of the pharmaceutical product shall be described. (INT)
ISO DTS 20451	5.1.6. Route of Administration	M	included	include	include	The route of administration is a concept that is used to describe the path by which the pharmaceutical product is taken into or makes contact with the body. The route of administration shall be specified using terms and a term identifiers as defined in ISO 11239, ISO TR 20440, and its resulting terminology.
ISO DTS 20451	5.1.10. Device (Pharmaceutical Product)	M	Not in art 57, planned for product iteration 1	include	include	A pharmaceutical product may refer to a drug that is associated with a medical device (e.g. drug/device, biologic/device). In this instance, the device term and term ID (unique device identifier) shall be displayed

						with the substance(s) and specified substance(s) terms for the product at PhPID level.
ISO DTS 20451	5.1.12. Adjuvants	M	In art 57 but not clearly defined included with excipients	include	include	A pharmaceutical product may refer to a drug that is associated with an adjuvant. In this instance, the adjuvant term and term ID (unique identifier) shall be displayed with the substance(s) and specified substance(s) terms for the product at all applicable PhPID levels.

Table 4. Data elements from the EN ISO 11240 Units of Measurement standard

Source ISO IDMP	IDMP data elements	IDMP: Mandatory Should Conditional Optional	(Plan for) EMA Article 57 database	Xborder use case	DCM include/ exclude	Motivation
EN ISO 11240	Quantity Value	M	included	include	include	Shall be expressed as a unit of measurement of the quantity and its numerical value in that unit.
EN ISO 11240	Determined reference vocabulary	M	included	include	include	The reference vocabulary for quantities shall be the UCUM code system, as required for conformance with ISO 21090 and HL7 V3 data exchange standards. The OID for the UCUM code system is 2.16.840.1.113883.6.8.

Table 5. Data elements from the EN ISO 11239 Pharmaceutical Dose Forms Routes of Administration, Units of Presentation and Packaging and ISO TS 20440 Implementation guide for 11239

Source ISO IDMP	IDMP data elements	IDMP: Mandatory Should Conditional Optional	(Plan for) EMA Article 57 database	Xborder use case	DCM include/ exclude	Motivation
EN ISO 11239	Pharmaceutical dose form class	M	included	include	include	Shall be used to describe the pharmaceutical dose form as it is used in describing medicinal products, codedConcept (CD).
EN ISO 11239	Administrable dose form class	C	included	include	include	Used when a medicinal product consists of two manufactured items that need transformation to create the pharmaceutical product, e.g. dissolution.
EN ISO 11239	Unit of presentation class	M	included	include	include	Shall be used to specify the attributes that are needed to describe properly the unit of

						presentation concept (e.g drop, patch), if no quantitative unit is available. E.g. mg per tablet.
EN ISO 11239	Route of administration class	M	included	include	include	Shall be used to specify the attributes that are needed to define properly the route of administration concept.
EN ISO 11239	Packaging class	M	Not in art 57, probably planned for product iteration 1	include	include	Shall be used to specify the attributes that are needed to define properly the container, closure, or administration device concept. This has relevance for the dispense.

Table 6. Data elements from EN ISO 11615 Regulated Medicinal Product Information and DTS 20443 Implementation Guide standards

Source ISO IDMP	**IDMP data elements**	**IDMP:** Mandatory Should Conditional Optional	**(Plan for) EMA Article 57 database**	**Xborder use case**	**DCM include/ exclude**	**Motivation**
EN ISO 11615	8.2. MPID	M	Not in art 57, will be generated for product iteration 1	include	include	Medicinal Product Identifier. Each MPID should be generated with: Country code segment, Marketing Authorization Holder (Organization Identifier) code segment, and Medicinal Product code segment.
EN ISO 11615	10.1. Medicinal Product	M	Not in art 57, planned for product iteration 1	include	include	Used as a grouping mechanism in the model for the required data elements.
EN ISO 11615	10.2. Medicinal Product Name	M	included	include	include	The medicinal product name is one of the defining characteristics of a medicinal product and its MPID. There is only one medicinal product name for a medicinal product relative to a corresponding MPID from a jurisdiction.
EN ISO 11615	Association MPID & PhPID	M	Not in art 57, planned for product iteration 1	include	include	Association with Pharmaceutical Product Identifiers (PhPIDs).
EN ISO 11615	A.2.7 Product Classification	O	included	include	include	The medicinal product can be classified according to various classification systems, which may be jurisdictional or international. One or more of these various

						classifications of the product can be specified in this section. Example ATC
EN ISO 11615	A 2.8.2 Invented Name Part	C	included	include	include	The invented name (i.e. trade name) of the medicinal product without e.g. the trademark or any other descriptors reflected in the medicinal product name shall be specified as text, where applicable.
EN ISO 11615	A.2.8.3. Scientific Name Part	C	Not in art 57, planned for product iteration 1	include	include	The scientific or common (i.e. generic) name of the medicinal product without any other descriptors can be specified as text, where applicable.
EN ISO 11615	A.2.8.7 Intended Use Part	C	Not in art 57, planned for product iteration 1	include	include	The intended use, if reflected in the Medicinal Product Name, shall be specified as text, where applicable.
EN ISO 11615	A.2.8.8 Target Populatio n Part	C	Not in art 57, planned for product iteration 1	include	include	The target population, if reflected in the Medicinal Product Medicinal Product Name, shall be specified as text, where applicable.
EN ISO 11615	A.2.8.9 Container or Pack Part	C	Not in art 57, planned for product iteration 1	include	include	The container or pack, if reflected in the Medicinal Product Medicinal Product Name, shall be specified as text, where applicable.
EN ISO 11615	A.2.8.10 Device Name Part	C	Not in art 57, planned for product iteration 1	include	include	See in 11616 above. The device, if reflected in the Medicinal Product Name, shall be specified as text, where applicable.
EN ISO 11615	A.2.8.11 Trademar k or Company Name Part	C	Not in art 57, planned for product iteration 1	include	include	The trademark, if reflected in the Medicinal Product Name, should be specified as text, where applicable.
EN ISO 11615	B.2.1 Marketing Authorisat ion Number	M	included	include	include	The number as assigned to a Medicinal Product by the Regulatory Medicines Agency of a country shall be specified in text.
EN ISO 11615	10.8 Clinical Particular s	M	Not in art 57, not planned for product iteration 1, but is part of the	include	include	Specifies information about the clinical particulars of the medicinal product as described in line with the regulated product information This is included in Art 57 data as a document attached to the product information.

			smpc.			
EN ISO 11615	7.1.7 Packaged Medicinal Product	M	included	include	include	Specifies information about the packaging and container(s) of a medicinal product and any associated device(s), which are an integral part or provided in combination with a medicinal product, as supplied by the manufacturer for sale and distribution.
EN ISO 11615	C.3.2. Package Description	M	included	include	include	A textual description of the Packaged Medicinal Product shall be provided.
EN ISO 11615	F.2 Therapeutic Indication	O	Not in art 57, planned for product iteration 1, but is part of the SmPC	include	include	This class should be used to describe the authorized indication(s) for the Medicinal Product in accordance with the regulated product information.
EN ISO 11615	F.3 Contra-Indication	M	Not in art 57, not planned for product iteration 1, but is part of the SmPC	include	include	This class shall be used to describe the authorized contra-indication(s) for the Medicinal Product as described in the regulated product information
EN ISO 11615	Procedure number / identifier	M	included	Include see D 4.1	Include optional	Occasionally used in eDispense in Cross Border situation, not in ePrescription. Hence optional data for identification number assigned by a Medicines Regulatory Agency in relation to a specific medicines regulatory process
EN ISO 11615	Procedure type	O	included	Include see D 4.1	exclude	Not used in ePrescription: type of legal process applied to authorize or maintain a Medicinal Product marketing authorization
OM D4.1	Reference Medicinal product	O	unknown	exclude	exclude	The medicinal product to which the generic product refers.
EN ISO 11615	Legal status	M	included	Include for eDispense, ePrescription	Include	Data element that is relevant at eDispense to determine jurisdictional rule as to whether a Medicinal Product is subject to a medical prescription before it may be supplied to a patient or

						consumer
OM D4.1	Duplicate applica-tions	C	included	exclude	exclude	

The following table provides a mapping of the coverage of the Data Elements related to medications, present in the current implementation of the CEF eHealth DSI, cross border services for ePrescription, eDispensation and Patient Summary (derived from epSOS pilot and EXPAND specifications) and the attributes brought by the ISO IDMP. These CEF eHDSI Data Elements, the EC Guidelines and the CDA Implementation Guide should take into consideration such coverage and, very important, the one-to-many relationships among the ISO IDMP identifiers and their hierarchical structure.

CEF eHDSI Data Element	***Cardinality*[9] *eP / eD / PS***	***Sub-stance ID***	***PhPID SUB_L 1***	***PhPID SUB_L 2***	***PhPID SUB_L 3***	***PhPID SUB_L 4***	***MPID***	***PCID***
Country A Cross-border/regional/national medicinal product code (National medicinal product code)[10]	O / NA / NA						√	√
Country B Cross-border/regional/national medicinal product code (National medicinal product code)	NA / O / NA						√	√
Brand name of the medicinal product prescribed in country A (Brand Name)	R / NA / O						√	√
Brand name of the medicinal product dispensed in country B (Brand Name)	NA / R / NA						√	√
Pharmaceutical Substance (ATC code)	RNFA / O/ RNFA [1..1]						√	√

[9] Legenda: R: Required, RNFA: Required, Null-Flavor Allowed; O: Optional; NA: Not Applicable

[10] The national medical product code can include different types of codes according to the Member State. It Is assumed it is a corresponding to the medicinal product registration number

CEF eHDSI Data Element	***Cardinality*[9] *eP / eD / PS***	***Sub-stance ID***	***PhPID SUB_L 1***	***PhPID SUB_L 2***	***PhPID SUB_L 3***	***PhPID SUB_L 4***	***MPID***	***PCID***
Pharmaceutical Substance (description)	O / O/ O [0..1]	√	√	√	√	√	√	√
Active ingredients list (code) (Active Ingredient)	RNFA / RFNA/ RFNA [1..*]	√	√	√	√	√	√	√
Active ingredients list (textual description) (Active Ingredient)	O / O/ O [0..*]	√	√	√	√	√	√	√
Strength of the medicinal product (as structured information) (Strength of the medicinal product)	RNFA / RNFA / RFNA [1..1]			√		√	√	√
Strength of the medicinal product (Description) (Strength of the medicinal product)	O / O / O [0..1]			√		√	√	√
Medicinal product package (Medicinal product package)	RNFA / RFNA / NA [1..1]							√
Pharmaceutical dose form (Pharmaceutical dose form)	R / R / O [0..1]				√	√	√	√
Route of Administration (Route of Administration)	O / O / O [0..1]				√[11]	√	√	√
Package Size (Package Size)	R / R / NA							√

[11] Route of administration is linked to the PhPID but it is not an identification attribute.

6.3 Detailed Clinical Model for the Medicinal Product

Figure 1 shows the draft DCM medicinal product logical UML model. The current version 0.82 supports all IDMP data elements, plus an additional openMedicine recommended item, that are relevant for the selected use cases. The data elements include the final openMedicine identifying data elements and the descriptive data elements. openMedicine decided to include not only the four pure identifiers (Substance ID, PhPID, MPID and PCID) but also "describing data elements" that enable – mostly combined with each other – to also identify a medicinal product. The national medicine product identifiers can be added to each part of the model (substance, pharmaceutical product, medicinal product and package) for implementations. Besides the classes that each represent a core data element, we need the comprehensive set of controlled terminologies and code systems. The integration of the data structures and the terminologies/codes takes place at the individual class level in the DCM.

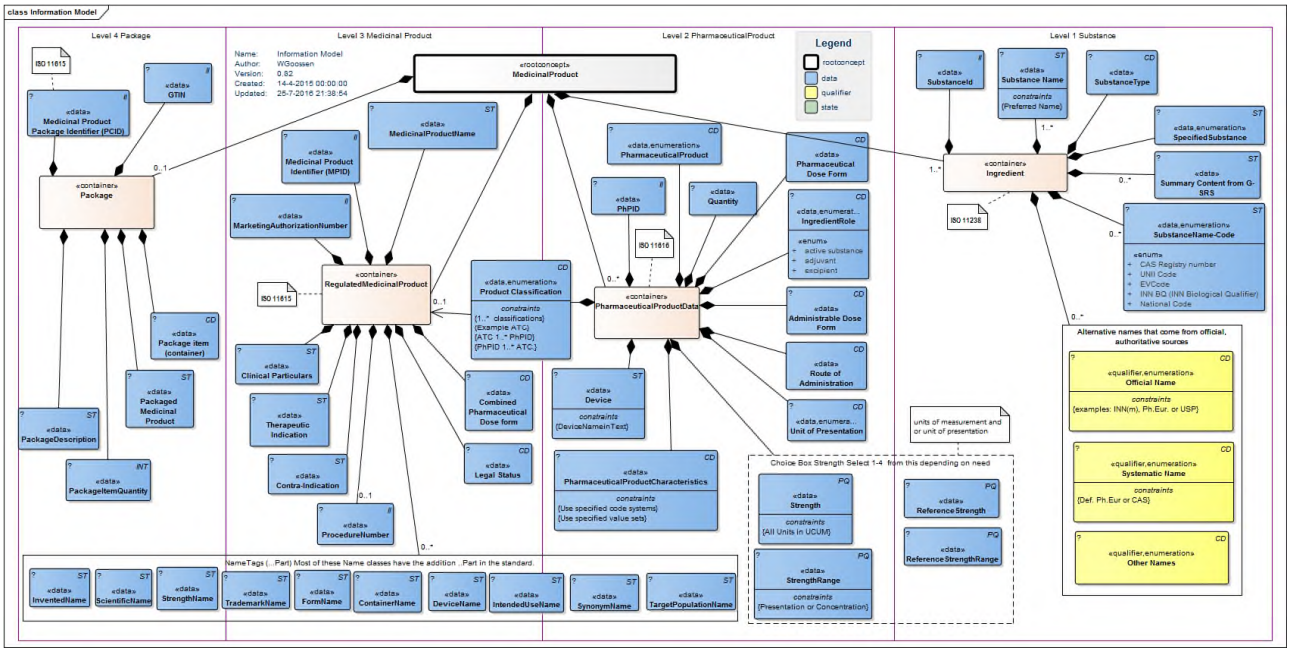

Figure 1. Detailed Clinical Model in UML for a Medicinal Product (draft 0.82).

For the 13606-2 the medicinal product DCM can be expressed in ADL to move from the logical model in UML to the implementation specification in ADL and for 13606-3 it is seen as one reference archetype. Collaboration with CEN TC 251 / ISO TC 215 WG 1 is currently leading towards a representation of this DCM in ADL format to facilitate implementation in archetype driven jurisdictions. Within the EHR standards, the DCM medicinal product can be seen as the core content specification for any medicinal product and would require a user interface representation, a storage representation, an operations representation and an exchange representation. The DCM can also be converted into HL7 v3 CPM and SPL. HL7 v3 is used for the IDMP implementation guides.

6.4 Walkthrough of the DCM

6.4.1 Concept

Medicinal product is defined as any substance or combination of substances which may be administered to human beings for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions (ISO 11238, 2012; ISO 11239, 2012; ISO 11240, 2012; ISO 11615, 2012; ISO 11616, 2012). A medicinal product may contain one or more manufactured items and one or more pharmaceutical products. In certain jurisdictions a medicinal product may also be defined as any substance or combination of substances which may be used to make a medical diagnosis.

6.4.2 Purpose

To record all data on the medicinal product, e.g. active substance(s) and excipients.

6.4.3 Patient Population

Applicable to every patient who is prescribed medications and for every pharmacy / pharmacist who provides medication.

6.4.4 Evidence Base

For patient safety it is necessary to reliably record and exchange both authorized and investigational medicinal product (further referred to as medicinal product) information in a robust and reliable manner. Therefore it is important to define and identify substances within authorized medicinal products or substances used for medicinal purposes. Substances or materials used in authorized medicinal products range from simple chemicals to gene-modified cells to animal tissues. Unique identifiers will support applications for which it is necessary to reliably identify and trace the use of medicinal products and the materials within medicinal products. The use of the identifier is essential for the description of substances in medicinal products on a global scale. A substance shall only have one unique identifier. The ISO standard states that if it is possible to represent a substance as a single substance or a mixture substance, the substance shall be represented as a single substance (ISO 11238, 2012; ISO 11615, 2012; ISO 11615).

Not only the definition and identification of substances is important when recording or exchanging authorized medicinal product information, but also the quantity values, routes of administration, and units of measurement are important.

6.4.5 Information Model description

The various classes of the DCM Medicinal Product are grouped around the root concepts in the DCM. The order is substance, pharmaceutical product, medicinal product and package. Within each area they will be presented clockwise. It starts with the top level entry of a Medicinal Product as rootconcept.

Concept	Definition and Code, Code system, Valueset , OID
MedicinalProduct *SnomedCT: 373873005* *Pharmaceutical / biologic*	The rootconcept of the information model that specifies the medicinal product. This serves as the top level entry to the full model.

product	

6.4.5.1. Substance Model Container and Classes (11238)

ContainerConcept	Definition and Code, Code system, Valueset , OID
Ingredient *Synonym code:* *SnomedCT: 127489000 Has active ingredient*	ISO 11238 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances. Geneva, ISO. This UML class container functions as model container concept and specifies the ingredients of the medicinal product through its representations as the manufactured item(s) and the pharmaceutical product(s), based on ISO11238, ISO11239 and ISO11240 and their resulting terminology (ISO 11615:2012).

Concept	Definition and Code, Code system, Valueset , OID
SubstanceId	Each substance and specified substance shall have only one permanently associated unique identifier that shall not indicate the order of submission to the system. The unique identifier shall be non-semantic, random and fixed length with an internal integrity check. The unique identifiers shall be publicly available and their use royalty free. A unique identifier shall be assigned to approved and investigational substances, excipients and impurities, solvents, ions, fragments and moieties.

Concept	Definition and Code, Code system, Valueset , OID	
Substance Name	**Names:** (EU) Preferred Name = G-SRS Preferred Name NOTE: name and id are 1=1 coupled with the EU-SRS Reference database. All underlying fields will be maintained by the G-SRS Reference database.	
Constraint	Preferred Name	

Concept	Definition and Code, Code system, Valueset , OID
SubstanceType	Substance Type (ISO 11238 3.6 Types of substances) . Substances shall be single substances, mixture substances or specified substances. If it is possible to represent a substance as a single substance or a mixture substance, the substance shall be represented as a single substance. examples (Stoichiometric/ Non-stoichiometric Chemical Substance; Peptide/ Protein Substance; Nucleic acid Substance; Polymer Substance; Structurally Diverse Substance, Herbal Substance/ Homeopathic Substance/ Plasma-derived Substance; Vaccin; Allergenic Substance; Multi-Substance material; Mixture Substance, Specified Substance Group 1)

Concept	Definition and Code, Code system, Valueset , OID
SpecifiedSubstance	group of elements that describe multiple substance materials and specify further information on substances and multi-substance materials relevant

	to the description of medicinal products (ISO 11616). Additional explanation: According to Herman Diederik a component is an intended constituent of a Specified Substance (Group1) material. A multi-substance material is defined as a group 1 **Specified Substance** and is a combination of its constituents which are substances in their own right. EXAMPLE: Dimethicone and silicon dioxide are components of simethicone. Human insulin protamine and zinc are the components in human insulin isophane. NOTE: Components are used to describe the substances and specified substances that form a multi-substance material ISO 11238:2012. As described in ISO 11238, specified substance(s) shall capture detailed characteristics of single substances or the composition of material that contains multiple substances or multiple physical forms. This can be according to Herman Diederik: + Specified substance group 1 name (as per G-SRS SSG1 Name), ST [1] + Constituent ID, II [1..*] + Constituent Name, ST [1..*] + SSG1_ID (as per EU-(G)-SRS), II [1] + SSG2_ID (as per EU-(G)-SRS), II [1] + SSG3_ID (as per EU-(G)-SRS), II [1..*]

Concept	Definition and Code, Code system, Valueset , OID
Summary content from G-SRS	This can hold a summary from the Global - Substance Registration System (G-SRS) documentation on substances which can be queried upon demand and added to substance data.

Concept	Definition and Code, Code system, Valueset , OID
SubstanceName-Code	Substance Name (ISO 11238 3.4 Naming of substances) At least one substance name or company code shall be associated with each substance. If the name is an official name, the naming authority, language and jurisdiction in which the name is used shall be identified. This International Standard shall be neutral with respect to any given systematic or official nomenclature. Examples for **Codes:** CAS Registry number; UNII-Code (= FDA-SRS-Code); EVCode (Old code from EMA). National Code (Used in Germany AKA-Code, Sweden internal code, NL internal Code).

CAS Registry number	+ CAS Registry number, ST [0..1] + UNII Code, ST [0..1] + EVCode, ST [0..1] + INN BQ (INN Biological Qualifier), ST [0..1] + National Code
UNII Code	
EVCode	
INN BQ (INN Biological Qualifier)	
National Code	

Choice box: from this model section one or more classes can be used optionally.

Concept	Definition and Code, Code system, Valueset , OID
Official Name	An official name in IDMP is a name that comes from an official, authoritative source and there can be several. **Official Names:** INN(m) , Definition (Systematic name) used in a Pharmacopeial monograph or in Martindale.
Constraint	examples: INN(m), Ph.Eur. or USP

Concept	Definition and Code, Code system, Valueset , OID	
Systematic Name	• **Systematic name:** CAS Registry Name (CAS = Chemical Abstract Service, facilitated by the STN Easy database, Karlsruhe).	
Constraint	Def. Ph.Eur or CAS	

Concept	Definition and Code, Code system, Valueset , OID
Other synonyms	Limited Acceptable Synonyms such as names sourced from companies.

6.4.5.2. Pharmaceutical Product Model Container and Classes

ContainerConcept	Definition and Code, Code system, Valueset , OID
PharmaceuticalProductData	Model class for as model container concept for data about the pharmaceutical product. Coming from ISO 11616 Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information.

Concept	Definition and Code, Code system, Valueset , OID
PhPID	Pharmaceutical Product Identification, PhPID. is a unique identifier for a pharmaceutical product.

Concept	Definition and Code, Code system, Valueset , OID
PharmaceuticalProduct	ISO 11616 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.

Concept	Definition and Code, Code system, Valueset , OID
Quantity	5.1.5. Pharmaceutical Product Quantity. The quantity (or count number) of the pharmaceutical product shall be described. (INT)

Concept	Definition and Code, Code system, Valueset , OID
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 (ISO, 11616, item 3.1.10). *EDQM:value set ID 1.3.6.1.4.1.12559.11.10.1.3.1.42.2* *valueset name epSOSDoseForm* *Code system EDQM 1.3.6.1.4.1.12559.11.10.1.3.1.44.1* *(OIDs from epSOS).*

Concept	Definition and Code, Code system, Valueset , OID
IngredientRole	**active substance** *SnomedCT: 55561003 | Active (qualifier value)* | **adjuvant** *SnomedCT:373846009 | Adjuvant - intent (qualifier value)* | **excipient**

Concept	Definition and Code, Code system, Valueset , OID
Administrable Dose Form	pharmaceutical dose form as administered to the patient, after any necessary transformation of the packaged pharmaceutical dose form has been carried out

Concept	Definition and Code, Code system, Valueset , OID
Route of Adminstration	path by which the pharmaceutical product is taken into or makes contact with the body (ISO 11239). EDQM are the source for the specifications, including a value set which is underway. Maps to *epSOS: 1.3.6.1.4.1.12559.11.10.1.3.1.42.12*

Concept	Definition and Code, Code system, Valueset , OID
Unit of Presentation	qualitative term describing the discrete countable entity in which a pharmaceutical product or manufactured item

	is presented, in cases where strength or quantity is expressed referring to one instance of this countable entity This is under development at EDQM. EXAMPLE 1 To describe strength: a puff, spray or tablet “contains 100 µg per spray” (unit of presentation = spray). EXAMPLE 2 To describe quantity: a bottle, box or vial “contains 100 ml per bottle” (unit of presentation = bottle). NOTE A unit of presentation can have the same name as another controlled vocabulary, such as a basic dose form or a container, but the two concepts are not equivalent, and each has a unique controlled vocabulary term identifier.

Choice Box Strength. From this model structure the following four classes can be selected optionally.

Concept	Definition and Code, Code system, Valueset , OID
Strength *LOINC: 18616-3 Administered medication, Strength*	The strength description shall be the content of the active substance/specified substance description expressed quantitatively (e.g. per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical form or unit of presentation) (ISO 11616:2012).
Constraint	All Units in UCUM

Concept	Definition and Code, Code system, Valueset , OID
ReferenceStrength	substance(s) and/or specified substance(s) used as a reference to form the basis of strength of an investigational or authorized medicinal product.

Concept	Definition and Code, Code system, Valueset , OID
ReferenceStrengthRange	The interval between the largest and smallest values of quantity of the substance/specified substance present in a given quantity of the pharmaceutical product.

Concept	Definition and Code, Code system, Valueset , OID
StrengthRange	The interval between the largest and smallest values of quantity of the substance/specified substance present in a given quantity of the pharmaceutical product.
Constraint	Presentation or Concentration

Concept	Definition and Code, Code system, Valueset , OID

PharmaceuticalProductCharacteristics	EN ISO 11616. 5.1.7. Pharmaceutical Product Characteristics. This class can be used to describe various characteristics of the Pharmaceutical Product, such as its onset of action. 5.1.8. Pharmaceutical Product Characteristics Code System. The code systems for 5.1.7. Note the implementation allows different code systems to be used here, and different valuesets. Specified as attribute of a class with reference to the code system. 5.1.9. Pharmaceutical Product Characteristics Value. The value sets for the code system for 5.1.7, specified in the class, with reference to the actual value set.
Constraint	Use specified code systems
Constraint	Use specified value sets

Concept	Definition and Code, Code system, Valueset , OID	
Device	**medical device** any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: — diagnosis, prevention, monitoring, treatment or alleviation of disease; — diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; — investigation, replacement or modification of the anatomy or of a physiological process; — control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means [EC Directive 2007/47 on Medical Devices] NOTE This definition is applicable for the purposes of this and related standards alone (ISO 11238, ISO 11239, ISO 11240, ISO 11615 and this International Standard).	
Constraint	DeviceNameinText	

Concept	Definition and Code, Code system, Valueset , OID	
Product Classification	categorization or grouping of Medicinal Products based on specific properties EXAMPLES Pharmacological classification, classification by therapeutic effect. *ATC::code displayName*	
Constraint	1..* classifications	
Constraint	Example ATC	
Constraint	ATC 1..* PhPID	
Constraint	PhPID 1..* ATC.	

6.4.5.3. Medicinal Product Model Container and Classes

ContainerConcept	Definition and Code, Code system, Valueset , OID
RegulatedMedicinalProduct	This class serves as a model container concept for 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

Concept	Definition and Code, Code system, Valueset , OID
Medicinal Product Identifier (MPID)	Medicinal Product Identifier (MPID) is a unique identifier allocated to a medicinal product supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction. NOTE: This is for indexing purposes and to contribute to improved patient safety by allowing for the unique identification of medicinal products worldwide ISO 11615:2012.

Concept	Definition and Code, Code system, Valueset , OID
MedicinalProductName	MedicinalProductName (Regulated). MedicinalProductName (Regulated) name as authorized by a Medicines Regulatory Agency.

Product classification is not repeated from PharmaceuticalProductData, but can have an 0..1 association with a medicinal product as well.

Concept	Definition and Code, Code system, Valueset , OID
Combined Pharmaceutical Dose form	The combined pharmaceutical dose form is a single term to describe two or more manufactured items that are intended to be combined in a specific way to produce a single pharmaceutical product; it includes information on the manufactured dose form of each manufactured item and the administrable dose form of the pharmaceutical product. If the Medicinal Product requires description of a combined pharmaceutical dose form, it can be specified here using a term and a term identifier as defined in ISO 11239 and the resulting terminology shall be specified.

Concept	Definition and Code, Code system, Valueset , OID
Legal Status	3.1.34 legal status of supply is the jurisdictional rule as to whether a Medicinal Product is subject to a medical prescription before it may be supplied to a patient or consumer

Concept	Definition and Code, Code system, Valueset , OID
Procedure Number	3.1.63 procedure number tracking or identification number assigned by a Medicines Regulatory Agency in relation to a specific medicines regulatory process

Concept	Definition and Code, Code system, Valueset , OID

Contra-Indication	ISO 11615. F.3 Contra-Indication. This class shall be used to describe the authorized contra-indication(s) for the Medicinal Product as described in the regulated product information.

Concept	Definition and Code, Code system, Valueset , OID
Therapeutic Indication	ISO 11615. F.2 Therapeutic Indication. This class should be used to describe the authorized indication(s) for the Medicinal Product in accordance with the regulated product information.

Concept	Definition and Code, Code system, Valueset , OID
Clinical Particulars	10.8 Clinical Particulars: specifies information about the clinical particulars of the medicinal product as described in line with the regulated product information.

Concept	Definition and Code, Code system, Valueset , OID
MarketingAuthorizationNumber	identifier assigned by a Medicines Regulatory Agency to a Medicinal Product

Choice Box Name Tags. From this model structure the following four classes can be selected optionally.

Concept	Definition and Code, Code system, Valueset , OID
InventedName	name for an innovative Medicinal Product as authorized by a Medicines Regulatory Agency in a jurisdiction

Concept	Definition and Code, Code system, Valueset , OID
ScientificName	The scientific or common (i.e. generic) name of the Medicinal Product without any other descriptors can be specified as text, where applicable.

Concept	Definition and Code, Code system, Valueset , OID
StrengthName	Strength reflected in the Medicinal Product Name, specified as text, where applicable.

Concept	Definition and Code, Code system, Valueset , OID
TrademarkName	Trademark reflected in the Medicinal Product Name

Concept	Definition and Code, Code system, Valueset , OID
FormName	pharmaceutical dose form reflected in the Medicinal Product Name

Concept	Definition and Code, Code system, Valueset , OID
ContainerName	The container or pack reflected in the Medicinal Product Name.

Concept	Definition and Code, Code system, Valueset , OID
DeviceNamePart	The device reflected in the Medicinal Product Name

Concept	Definition and Code, Code system, Valueset , OID
IntendedUseName	Intended Use reflected in the Medicinal Product Name

Concept	Definition and Code, Code system, Valueset , OID
SynonymName	Alternative name for the same Medicinal Product

Concept	Definition and Code, Code system, Valueset , OID
Target PopulationName	The target population reflected in the Medicinal Product Name

6.4.5.4. Package Container Concept and Model Classes

ContainerConcept	Definition and Code, Code system, Valueset , OID
Package	This class serves as a model container concept for package data that describe the container, box or other material in which medicinal products are put for distribution and sale.

Concept	Definition and Code, Code system, Valueset , OID
Packaged Medicinal Product Identifier (PCID)	Medicinal Product Package Identifier, PCID is a unique identifier allocated to a packaged medicinal product supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction. NOTE: This is for indexing purposes and to contribute to improving patient safety by allowing for the unique identification of medicinal products worldwide ISO 11615:2012.

Concept	Definition and Code, Code system, Valueset , OID
GTIN	GS1 GlobalTradeItemNumber, GTIN is a unique identifier of items that are traded (e.g. pharmaceuticals, medical devices) in the supply chain. NOTE: A GTIN is used to identify any item upon which there is a need to retrieve pre-defined information and that may be priced, ordered or invoiced at any point in any supply chain. GTINs may be 8, 12, 13 or 14 digits in length ISO 11615:2012.

Concept	Definition and Code, Code system, Valueset , OID
Package item (container)	individual, distinct item(s) contained in a Packaged Medicinal Product which act as containers for manufactured item(s) for sale or distribution ISO 11615: **5.3.5.4 Packaging class** The packaging class shall be used to specify the attributes that are needed to define properly the container, closure, or administration device concept. A packaging has one packaging category. EXAMPLE 1 For the container: ampoule, blister, bottle, tube, box, carton. See also Annex A (Table A.10) for controlled vocabulary examples, and Annex B for medicinal product examples. EXAMPLE 2 For the closure: cap, screw-cap, stopper. See also Annex A (Table A.10) for controlled vocabulary examples, and Annex B for medicinal product examples. EXAMPLE 3 For the administration device: needle, oral syringe. See also Annex A (Table A.10) for controlled vocabulary examples, and Annex B for medicinal product examples. The packaging class shall be described using a codedConcept.

Concept	Definition and Code, Code system, Valueset , OID
Packaged Medicinal Product	10.6 Packaged Medicinal Product. Specifies information about the packaging and container(s) of a medicinal product and any associated device(s), which are an integral part or provided in combination with a medicinal product, as supplied by the manufacturer for sale and distribution.

Concept	Definition and Code, Code system, Valueset , OID
PackageItemQuantity	Specification of the quantity (or count number) of the package item.

Concept	Definition and Code, Code system, Valueset , OID
PackageDescription	A textual description of the package, e.g. plastic bottle, 100 tablets.

It is obvious from this table that most data elements do not have a unique code to identify them, and no code system where this is maintained in as controlled terminology. Further, in case that the data element is of data type CD, the value set is under development and perhaps not ready yet in the CD required format. Also unique identifiers as OIDs are missing in many instances. However, many of these are under development at EMA and EDQM.

6.4.6 Instructions

The DCM Medicinal Product describes many details of Medicines that human beings can use. This DCM Medicinal Product is intended to be used in the following processes:

1. Prescription of medication by physician or other authorized prescriber.
2. Dispense of medication by a pharmacist.
3. Administration of medication by a health care professional.
4. Use of medication by the patient.
5. Individual Case Safety Reports about issues with use of medication.

All the medication regulation processes will not get sufficient detail from this DCM.

6.4.7 References for the DCM

Projects:

Netherlands, POEMA and GGG, Kempenheaghe (2015).

Literature:

- Anatomical Therapeutic Chemical (ATC). Obtained on April 23 2015, from http://www.atccode.com/
- G-Standaard. Obtained on April 23 2015, from https://www.z-index.nl/g-standaard

- ISO/TC 215/WG6, Pharmacy and medication (2012). ISO 11238 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances. Geneva, ISO.
- ISO/TC 215/WG6, Pharmacy and medication (2012). 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. Geneva, ISO.
- ISO/TC 215/WG6, Pharmacy and medication (2012). ISO 11240 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement. Geneva, ISO.
- ISO/TC 215/WG6, Pharmacy and medication (2012). ISO 11615 Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information. Geneva, ISO.
- ISO/TC 215/WG6, Pharmacy and medication (2012). ISO 11616 Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information. Geneva, ISO.

6.4.8 Deliberately Missing Content

In the original DCM several additional categories according ISO TS 13972 are completed, including meta-information. However for the purpose of this Deliverable are left out for readability. However, the full documentation is available and will be published by openMedicine in a later stage.

7 Terminologies, Codes and OIDs

As identified in the Detailed Clinical Model for the Medicinal Product, several of the data elements do need specific terminologies and codes. This will be discussed here in brief.

7.1 Required types of codes, terminologies and OIDs

The DCM identifies three kinds of requirements on the level of identifiers, controlled terminologies, codes and valuesets.

1. Each data element needs to be identifiable in systems, hence needs a unique code in order to overcome language barriers in class names in systems or tag names in ePrescription and eDispense messages. These are indicated with a question mark in the DCM class.

2. Those data elements that need a controlled terminology need this terminology uniquely identified. The common approach will be an OID, but alternatively a URI can be acceptable if long term stability is ensured. Some controlled terminologies have been identified, but others are not, and some controlled terminologies do have an OID, where others have not. See the EDQM example. Important is that controlled terminologies have unique codes for each concept in the system. And with respect to quality for clinical use should adhere to Cimino's (1998) desiderata for controlled clinical terminologies.

3. The data elements that have a CD (concept descriptor) as data type do require a specific value set. Such a valueset also needs an OID, so that it is internationally recognisable. Further the relevant values need to be entered, and each value also needs a unique code.

7.2 EMA Broker

EMA will become a broker for all terminologies used within the regulatory area for medicines, they will also become he European broker for substances and PhPIDs. The broker will consolidate all terminologies required by the EMRN and will act as single point of contact for all additions and change requests to the main supplier for the terminologies on behalf of the network.

Examples can be found on the following link:
http://eutct.ema.europa.eu/eutct/displayWelcome.do;jsessionid=VexvJOTx3wFvbfRN0QS4NoDmfxzLT2qtIKI6WZ6ldSFCHQu8s6MP!74800963

7.3 EDQM is final decided but has not an OID yet

For the ongoing work on this deliverable a search has been undertaken to find the appropriate OIDs, controlled terminologies and value sets. One that is required for dose forms is EDQM. However, this is not one controlled terminology, but a set of multiple terminologies, each populating one data element. From epSOS there is an availability of one OID for EDQM as a whole. Pharmaceutical Dose Form EDQM value set ID 1.3.6.1.4.1.12559.11.10.1.3.1.42.2 and value set name epSOSDoseForm, Code system EDQM 1.3.6.1.4.1.12559.11.10.1.3.1.44.1. However, this has been used as a pilot enabler

and cannot yet be seen as a final OID, but will continue to be relevant as a synonym code for this item. See below the mail exchange with the EDQM office about the need and the situation as of May 2016 (used with permission). EDQM and EMA are currently cooperating to obtain OIDs for the relevant term sets, making this search less relevant in the very near future. Nevertheless it is still not possible to finalize the DCM.

Q97104 EDQM Standard Terms Internal controlled vocabularies for pharmaceutical dose forms Version ...

11/05/2016 à 12h03 Treated

Question 1 (11/05/2016 à 12h03) :

Name: Goossen.
Firstname: William.
Organisation / Company: RESULTS4CARE.
Job title: director.
Address: De Stinse 15.
Postcode: 3823 VM.
Town: Amersfoort.
Country: Netherlands.
Phone: +31654614458.

Message:
For the openMedicine project, I am creating a deliverable which holds the infostructure. In order to implement all these materials, we are looking for unique identifiers. One specific identifier would be required for the EDQM Standard Terms Internal controlled vocabularies for pharmaceutical dose forms Version 1.0.0 – 14 November 2014.

Does this controlled vocabulary have a unique object identifier (OID), or can the weblink be seen as an never changing unique resource locator?

Thank you for any response.

dr. William Goossen
health information specialist.

Response 1 (12/05/2016 à 08h15) :

Good morning William,

At the moment there are no OIDs for EDQM Standard Terms, although this is a point that needs to be resolved. I can't guarantee that the web address would be a never-changing way to identify the resource, so other than using it as a temporary measure, I wouldn't recommend relying on that. I will endeavour to resolve the OID issues for EDQM Standard Terms as soon as possible. Are you working to a particular timeframe during which you need this to be resolved, and is it the same for all of the other IDMP controlled vocabularies?
If you wish, you may contact me directly at christopher.jarvis@edqm.eu for further discussions on this matter.
With best wishes,

Chris

Yours sincerely,
Dr Christopher Jarvis
Standard Terms
EDQM
Council of Europe
http://www.edqm.eu
http://www.edqm.eu/store

8 Discussion and Conclusion

The purpose of this deliverable 2.3 is to present the final identifying data elements and the final descriptive data elements for a medicinal product. This was accomplished using two tables that focus on such data elements. The first one is the full listing of the ISO IDMP series, from D 1.3. Only the selected data elements from that deliverable are included. The second one is the table with the IDMP attributes and the data elements from article 57 database from EMA which was included in Deliverable 2.2.

What is obvious is that for the use cases ePrescription, eDispense and recording in the EHR and pharmacy system, the set of data elements could be determined. This was possible because the specification of these data elements is ongoing in an international effort including key stakeholders on the regulation level. openMedicine decided to use these specifications as the baseline. This was motivated by both EMA being heavily involved in the IDMP developments, the ongoing work on IDMP implementation guides and the EMA strategy for making the article 57 database IDMP compliant.

Moving the article 57 database to an ISO IDMP compliant database will be carried out in a phased approach in collaboration with industry and regulators over the next number of years, with product iteration 1 being available in 2017. This target date is used in the tables to identify whether it is (soon) available in EMA, and hence can be decided to be final for openMedicine's final identifying and descriptive data elements for a medicinal product.

However, one consideration is that IDMP and all its implementation guides are mainly focusing on the regulation aspect of medicinal products, but do have relevance for ePrescription and eDispense as well. Nevertheless, IDMP is not intended for clinical practice, therefore the openMedicine use cases could not simply use all from IDMP. Nevertheless it has been the intention from the beginning to not create complete new materials for health care, but to keep specifications in accordance with IDPM. First examples of such congruence are the ISO standard for ePrescription and the TS for the Medicinal Product Dictionary. Both are written up in accordance with ISO IDMP. The same path has been followed for openMedicine and at ISO level for the ePrescription TS underway.

We therefore can conclude that openMedicine successfully specified the IDMP identifiers and defining characteristics data elements that are relevant for health care practice, in particular the core use cases of ePrescription, eDispense and record keeping in EHR and pharmacy systems. This is done in close collaboration with the European Medicines Regulatory Network (EMRN).

On the other hand we must conclude that at the international level, there is still ongoing work to establish unique code sets, codes value sets and object identifiers (OIDs) for many of the relevant data elements, and the associated and required controlled terminologies. A core recommendation is to speed up this work in the next year so that implementations will not be hampered by lack of identifiers, unique class codes or controlled terminologies. The fact that EMA has taken this up and will become the broker, consolidator and governance body for all terminologies used within the regulatory area for medicines, substances and PhPIDs, is encouraging.