This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No. 875299

Project acronym: UNICOM
Project full title: Up-scaling the global univocal identification of medicines in the context of Digital Single Market strategy
Call identifier: H2020-SC1-DTH-2019

WP5 – IDMP adoption by eHealth Services
D5.4: Semantic Specifications

Version:	1.0
Status:	Final
Dissemination Level[1]:	PU
Due date of deliverable:	28.02.2022
Actual submission date:	16.05.2022 (ready on 28.02.2022)
Work Package:	WP5: IDMP adoption by eHealth Services
Lead partner for this deliverable:	ARIA
Partner(s) contributing:	SPMS, DWIZ, IEDOH, ELGA, GNOMON, HL7, HZZO, IDIKA, INDRA, IHE, KELA, ARIA, SEMPA, AGES, REGLOMB, SAS
Deliverable type[2]:	R

Main author(s):

WP5 members	Various

DELAY REQUESTED in January 2021 from M21 (31.08.2021) to M27 (28.02.2022). Delay discussed and agreed with PO Syzmon BIELECKI.

Deliverable is ready in M27 on time for submission.

As EMP is currently in the amendment process, with the requested deliverable delays, we awaited feedback from PO on when to submit the ready deliverables. PO proposed to submit deliverable when ready, thereby we submit deliverables ready in M27 and M28 on 16.05.2022, before the amendment and official change in deliverable due date on the EC portal.

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1 Dissemination level: PU: Public; CO: Confidential, only for members of the consortium (including the Commission Services); EU-RES: Classified Information: RESTREINT UE (Commission Decision 2005/444/EC); EU-CON: Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC); EU-SEC Classified Information: SECRET UE (Commission Decision 2005/444/EC)

2 Type of the deliverable: R: Document, report; DEM: Demonstrator, pilot, prototype; DEC: Websites, patent fillings, videos, etc.; OTHER; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot

Revision history

Version	Date	Changes made	Author(s)
0.1	20.02.2022	First version of the document	All authors
1.0	28.02.2022	Final version of the document	AC, VM, CW, LW, JT

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Deliverable abstract

This document presents the semantic components that shall be considered to adopt the International Organization for Standardisation Identification of Medicinal Products (ISO IDMP) standards among the national and cross-border systems, in order to ensure the semantic interoperability of eP/eD & PS in the different Member States. Data definitions and terminologies from both sides - IDMP/SPOR and eHDSI – are used in a clinical document such as ePrescription (eP), eDispensation (eD), Patient Summary (PS) to ensure the univocal identification of national medicinal products.

Information provided helps to understand the relationships of the different semantic assets required to implement the ISO IDMP on the eHDSI infrastructure and supports the Member States to prepare their own systems to enrich their current eHealth services.

Keywords: Semantic, eHDSI, IDMP, guideline, interoperability, cross-border, eHealth

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List of abbreviations

Abbreviation	Complete form
ATC	Anatomical Therapeutic Chemical Code
CBeHIS	Cross-Border eHealth Information Services
CDA	Clinical Document Architecture
CEF	Connecting Europe Facility
DDD	Defined Daily Dose
EC	European Commission
eD	eDispensation
EDQM	European Directorate for the Quality of Medicines
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHealth Member States Experts Group Semantic
EMA	European Medicines Agency
EMA IG V2	EMA Implementation Guide V2
eP	ePrescription
FHIR	Fast Healthcare Interoperability Resources
ICD	International Classification of Diseases
IDMP	Identification of Medicinal Products
ISO	International Organization for Standardization
MPD	Medicinal Product Dictionary
MTC	Master Translation/Transcoding Catalogue
MVC	Master Value Catalogue
NCA	National Competent Authority
NCPeH	National Contact Point for eHealth
OID	Object Identifier
PCID	Packaged Medicinal Product Identifier
PhPID	Pharmaceutical Product Identifier
PS	Patient Summary
SDO	Standards Developing Organisations
SMS	Substance Management Service
SPOR	Substance, Product, Organisation and Referential
STF	Semantic Task Force
UCUM	Unified Code for Units of Measure

1 Executive summary

Semantic interoperability is the ability of different systems to understand and exchange data in a similar way with unambiguous, shared meaning. The overarching objective of eHDSI services is to support the delivery of semantic interoperability, working collaboratively with Member States to define:

- guidelines to create the eP/eD & PS and
- specifications on cross-border document checking, to verify the coherence between countries and between the eDispensation and the original ePrescription based on the eHDSI CDA document specifications and using the UNICOM Art-Decor Instance (HL7, IHE).

The Art-Decor based CEF eHDSI CDA Implementation Guides of eP/eD and PS are used by Member States to implement the HL7 CDA documents and by the CEF eHDSI Solution Provider to build the test tools to scrutinise the exchanged documents.

UNICOM has 3 main enablers: the IDMP standards and the applicable implementation specifications – eHDSI and Substance, Product, Organisation and Referential (SPOR).

- **IDMP** standards define the meaning of the concepts and data elements required to identify and fully describe a medicinal product.
- **eHDSI** specifications for cross-border eHealth services (eP/eD & PS), on minimal data sets and value sets
- **SPOR** specifications add to the IDMP specifications by providing some master value sets to be used in some of those data elements for a shared vocabulary.

This document presents the semantic components that shall be considered to adopt the International Organization for Standardisation Identification of Medicinal Products (ISO IDMP) standards among the national and cross-border systems, in order to ensure the semantic interoperability of eP/eD & PS in the different Member States. Data definitions and terminologies from both sides − IDMP/SPOR and eHDSI – are used in a clinical document such as ePrescription (eP), eDispensation (eD), Patient Summary (PS) to ensure the univocal identification of national medicinal products.

Information provided helps to understand the relationships of the different semantic assets required to implement the ISO IDMP on the eHDSI infrastructure and supports the Member States to prepare their own systems to enrich their current eHealth services.

2 Introduction and Background

2.1 Background

Information in healthcare is enormously complex, covering many different types of data. This information needs to be aggregated and shared across different healthcare settings to deliver citizen centric healthcare. The absence of clear and concise identification of medicines may have a negative impact on the safe delivery of cross-border healthcare.

In this regard, the **eHealth Digital Service Infrastructure (eHDSI)** was set up to manage the initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF). In response, eHDSI sets up and starts deploying the core and generic services, as defined in the CEF, for **Patient Summary and ePrescription**. The generic services are the necessary implementation of data exchange at country level, the core services at EU level. These together enable the provision of Cross-Border eHealth Information Services (CBeHIS).

Building on this, another EU initiative is the development of the UNICOM project. This work aims to support the implementation of several use cases including the introduction of IDMP standards to enable a global and univocal identification of medicines in cross-border ePrescription and eDispensation.

The **Identification of Medicinal Products (IDMP**) is a set of five different International Organization for Standardisation (ISO) standard specifications (Figure 1) used to identify medicinal products. It defines the data elements and structures for the unique identification and exchange of medicinal products information. This approach to medicine identification aims to ensure better safety to the patients at national or cross-border levels.

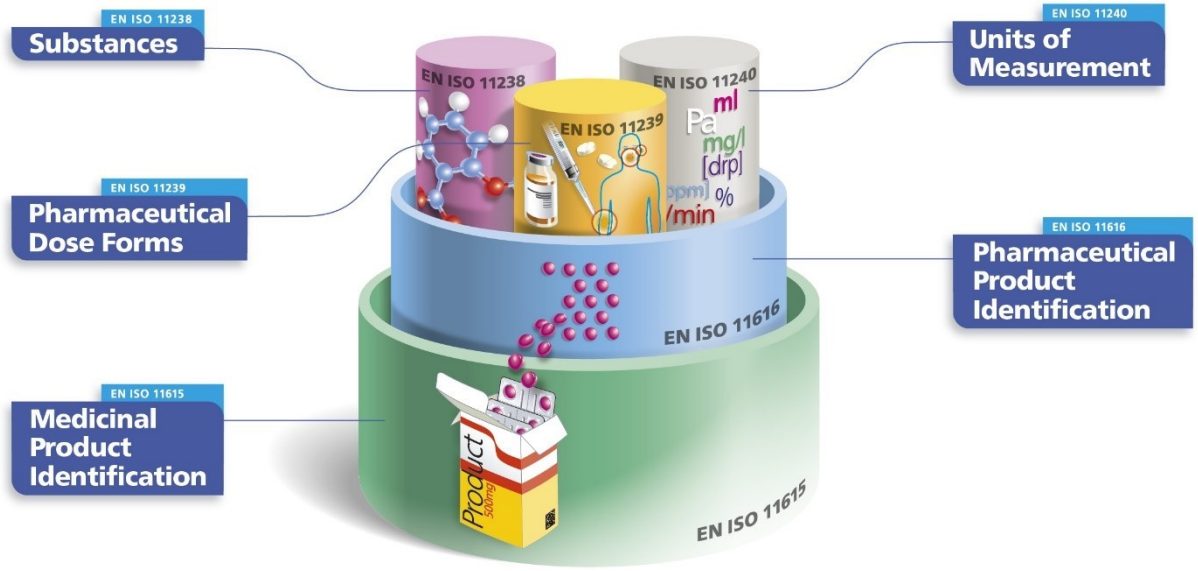


Figure 1: The 5 ISO standards used to identify medicinal products

To support the delivery of IDMP, the UNICOM project involves a number of Work Packages, each relating to different aspects of interoperability, business data and technology implementations.

Specifically, **Work Package 5** is tasked with the IDMP adoption in Member States eHealth services by coordinating the adoption of these standards at both national and cross-border levels. The focus in on ePrescription (eP) / eDispensation (eD) and Patient Summary (PS) cross-border topics. Implementing National eP systems for general practice Electronic Health Records and for Community Pharmacies within the same country will be a preparatory step to cross-border eP, without disregarding other scenarios on prescribing (e.g. hospital prescriptions) and making reference to medicinal products (e.g. medication plans, continuity of care documents, hospital discharge letters etc). These elements will be defined as reusable building blocks for medicinal product identification.

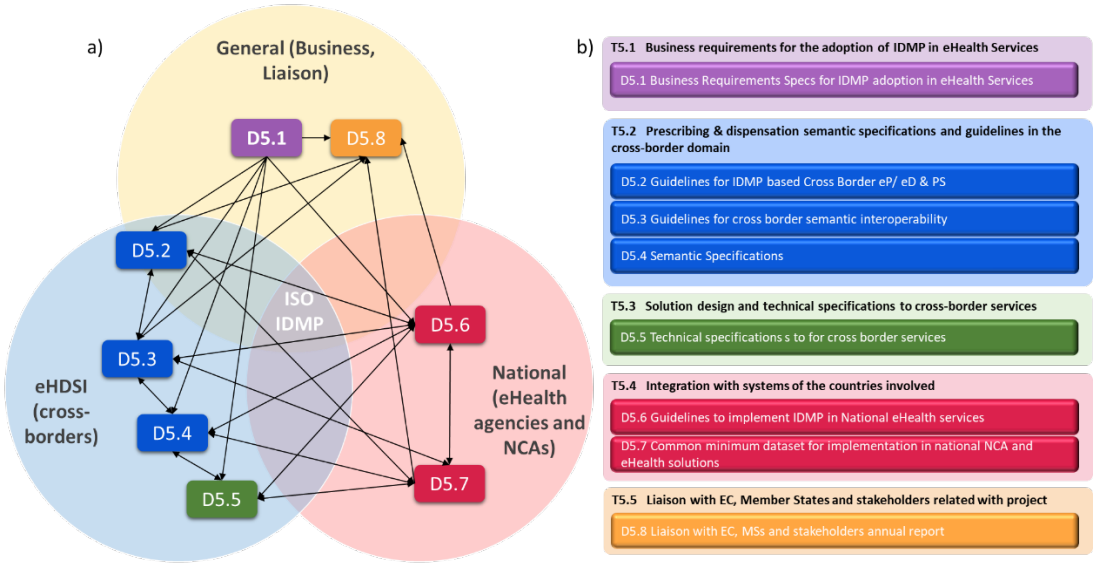


Figure 2: The WP5 deliverables relationship.
In a) the relationship between the different WP5 deliverables. b) the list of tasks and deliverables from WP5

The outputs of previous deliverables (Figure 2) provide the basis for D5.4 Semantic Specifications. This task will define the guidelines advising Member States on how to use the new IDMP mechanisms in combination with other relevant and currently implemented eP contents.

2.2 Introduction to D5.4

Semantic interoperability is the ability of computer systems to exchange data with unambiguous, shared meaning. Semantic interoperability in the context of exchanging data between two different countries, is a requirement to enable machine computable logic, inferencing, knowledge discovery, and data federation between information systems. It is not just concerned with the packaging of data (syntax), but the meaning of the data (semantics).

The meaning of the data can be shared:

- explicitly with the data itself, in one self-describing "information package" that is independent of any information system, in a shared vocabulary, and its associated links to an ontology, which provides the foundation and capability of machine interpretation, inference, and logic.
- Implicitly, by the systems adhering to a same convention of meaning.

In any case, the shared vocabulary must always exist for systems to be semantically interoperable.

eP/eD and PS semantic interoperability is an important feature for the eHDSI services. By establishing a common set of concepts and constraints, it helps ensure the correct identification of medicinal products, and addresses common issues associated with the usage of different terminologies and vocabularies between the different countries / regions.

This task defines the semantic specifications for creating the eP/eD & PS, including specifications on cross-border document checking, verifying the coherence between countries and also between the eDispensation and the original ePrescription. Any Value Sets and CDA document specifications created will be managed using the established tools, namely deposited in the UNICOM Art-Décor Instance (shared by HL7, IHE).

Art-Décor is a tool that hosts computable specifications − i.e., specifications that can be processed by computers, which has several advantages – besides objectivity, it enables computers to assess the

specification assertions – like what elements are mandatory, what values are permissible, etc. This allows a computable assertion and checking of this aimed semantic compatibility.

Testing semantic interoperability is essential to the successful use of eP/eD and PS. Art Décor contains the CEF eHDSI CDA Implementation Guides of eP/eD and PS (reference specifications) and is used by Member States to implement the HL7 CDA documents. Art Décor is also used by the CEF eHDSI Solution Provider to build the test tools to scrutinise the exchanged documents. These computable reference descriptions will be adopted. Feedback from the implementation phase may result in revisions to functional specifications and value sets of the Master Value Catalogue (MVC).

There are 3 key enablers to semantic interoperability which are provided by UNICOM:

- **IDMP** standards and the applicable implementation specifications – **IDMP** specifications define the meaning of the concepts and data elements required to identify and fully describe a medicinal product. An IDMP compliant attribute is an attribute that is compliant with IDMP specifications, i.e. it follows the IDMP definition and context (because IDMP specification establishes definition).

- The **Substance, Product, Organisation and Referential (SPOR)** specifications and master/reference data. **SPOR** specifications add to the IDMP specifications by providing some master value sets to be used in some of those data elements for a shared vocabulary. A SPOR compliant attribute is an attribute that is compliant with SPOR specification − i.e. it uses the value sets defined by SPOR (because SPOR does not specify element definitions but the values that can be used).

- **eHDSI.** eHDSI specifications define the data elements and their meaning for ePrescription, eDispensation, and the Master Value Set Catalogue (a collection of authorised values to be used in some data elements) allowing the introduction of important concepts like compliance of attributes (i.e. data elements in a model, specifically the descriptive elements of the medicinal product in eP/eD and PS).

In addition to identifying such specifications, this document introduces additional data definitions, gaps in existing specifications and guidelines required for adoption in different contexts to ensure a sustainable implementation.

2.3 Scope of the document

This document intends to present the semantic components that should be considered to adopt the ISO IDMP standards among the national and cross-border systems, and to ensure the semantic interoperability of eP/eD & PS in the different Member States.

The schema below identifies the data definitions and terminologies from both IDMP/SPOR and eHDSI perspectives and are used in a clinical documentation such as ePrescription (eP), eDispensation (eD), Patient Summary (PS).

- IDMP defines data elements, some have coded information while others are textual or other formats. IDMP does not address terminologies, however, SPOR specifications do provide some data elements for a shared vocabulary.
- eHDSI defines the data elements and assigns “Value Sets” from the Master Value Set Catalogue.

UNICOM strives to ensure that all elements that describe the medicinal products implemented by the National Competent Authority’s (NCA) and the focus is on those elements that are used ePrescription / eDispensation / Patient Summary across borders.

UNICOM, via SPOR terminologies, supports semantic alignment with IDMP using:

1) definition of a minimal (semantic) data set for the identification of national medicinal products.

2) determine the terminology systems and value sets for each element in the minimal data set, in order to align with the Master Value Set Catalogue for cross-border migration of ePrescriptions, eDispensations, and Patient Summaries in eHDSI.

3) Mapping of national medicinal products to the IDMP codes of the minimal data set, so that they can be truly interoperable across borders (Figure 3).

This determines the scope and intent of this document: documenting the specifications for semantic interoperability, by evaluating the IDMP+SPOR semantics and reference values, and the eHDSI+MVC semantics and reference values.

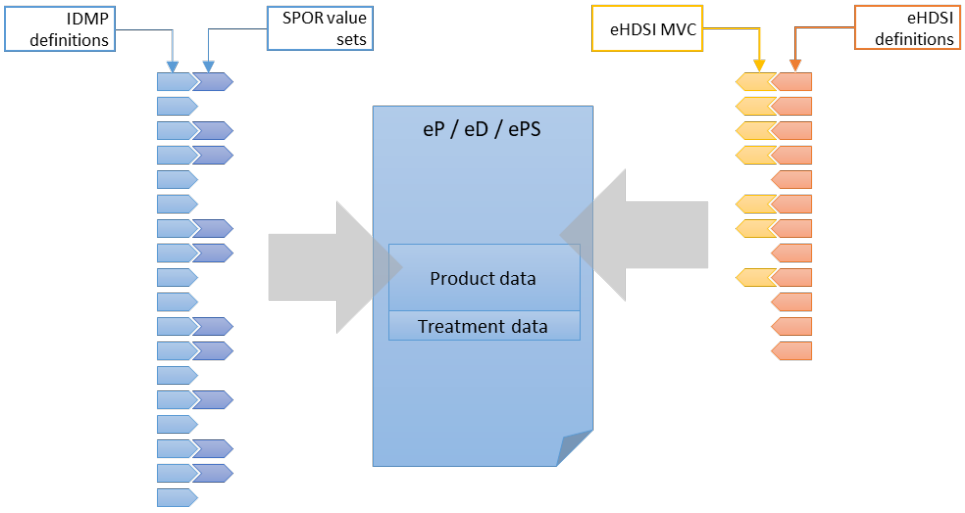


Figure 3: Common data attribute specifications between IDMP and eHDSI.

This work will result in an IDMP-based, CEF eHDSI-compatible data set, including the definitions and terminologies and the initial process is identifying the data elements in eHDSI and the corresponding value sets in the MVC.

3 CEF eHDSI Master Value Set Catalogue (MVC)

3.1 Current Status

The **CEF eHDSI Master Value Set Catalogue (MVC)** is "a collection of terms, used within certain parts of the eHDSI pivot documents (either parts describing the patient demographics or the clinical problems, for example), based on standardised code systems such as ICD-10, SNOMED CT, ATC Classification, EDQM Standard Terms, or UCUM"[3]. The **MVC** is the foundation for countries to use for the deployment of their Open NCP Patient Summary (PS) and ePrescription (eP) Use Cases. The value sets that are used, are combined in the MVC and should be used in the deployment of each Member State Open NCP in order to ensure semantic interoperability in the exchange of information between countries.

The current version of MVC – MVC 5.1.0 (wave 5) – was released on 12th July, 2021[4], and the eHDSI Central Terminology Services plays an important role in managing the MVC content. As mentioned, the

[3] https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pageId=35208905 (eHDSI restricted access).

[4] The MVC 5.1.0 (wave 5) can be accessed through the following link: https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSI/MVC+5.1.0+%28Wave+5%29+-+Details (eHDSI restricted access)

MVC content is based on a number of different code systems, such as ATC Classification, European Directorate for the Quality of Medicines (EDQM) Standard Terms, International Classification of Diseases (ICD), HL7 Vocabulary, LOINC, SNOMED CT, Unified Code for Units of Measure (UCUM) Codes.

The value sets are selected based on the following criteria:

- Internationally Used
- In Use
- Existence of translation in Different Languages
- Has a well-defined Maintenance Process
- Existence of Transcoding Systems / Services
- Cost of licenses, implementation and maintenance
- The code system must be easily implementable

MVC maintenance

The MVC is a centrally maintained set of value sets: An index of the different value sets that are used in the different specifications.

eHealth Member States Experts Group (eHMSEG) and Semantic Task Force (STF) have provided rationale for the maintenance and evolution of semantic assets. Value sets that are "dynamically defined MUST be updated and extended at the time of MVC creation"[5]. Each concept is associated to a designation in English, which should derive primarily from the code system, if provided. Alternatively, the designation may also be added or modified by the author of the MVC. The maintenance circle recommendation is that the MVC should be updated once a year (Table 1).

Table 1: MVC maintenance lifetime

Maintenance circle	
Timeline (annual cycle)	**Milestones**
Until December 31st	• Elaboration / introduction of proposals.
December 31st	• Deadline for submission for the next cycle
January – February	• Processing of change proposal by the Semantic Community resulting in Change Proposals and dissemination. Clarifying incorporation of changes in underlying Code Systems.
March	• Adoption of proposals. • **Release of new version of the MVC**
April – June	• Checking Bugs of the MVC
September	• Release of minor changes to MVC (bug fixes) • Update Master Translation/Transcoding Catalogue (MTC), completed translation by Member States
March (of the following year)	• eH NCP-Implementation Member States • MVC is in Production

[5] eHealth Member States Experts Group Semantic Task Force. Semantic Assets rationale for Maintenance and Evolution under the eHDSI time frame 1 - Appendix 2: European MVC- maintenance procedure. V1.0, 2017

The final released MVC from the previous maintenance cycle is the starting point of each year's maintenance work. It is important that the maintenance process set up is understood and accepted by a majority of EU Member States, concurrently the work of maintaining and evolving the MVC is dependent on the collaboration of participating countries.

The guidelines for the final release of the MVC include:

- MVC must contain all Clinical content value sets that are references in the CDA IG. Requests for additional changes need to be justified and should be targeted for a release in September.

The terminology server operated by DG Santé contains all versions of the MVC (starting from version 2.2) and all available MTCs are uploaded and provided to the National Contact Point for eHealth (NCPeH). All changes in the content of the MVC will be synchronised with the national NCPeH.

The terminology server does not provide a collaboration platform for MVC maintenance activities. Member States are obligated to provide the technical infrastructure for semantic maintenance cooperation at the national and multinational levels. To support the work of the terminology experts, a set of terminological services (centralised or decentralised) is maintained.

Governance

The Semantic Task force (STF) Group is the acting body of MVC-maintenance work, comprised of European Commission (EC) representatives and nominated representatives of Member States. The Ministries of Health of each Member State nominate subject matter experts to contribute to the work and to liaise with specialists and institutions at the national level. These national representatives are also responsible for the national implementation of the content, national MTC and national mappings.

Changes to the MVC and new versions need approval by the eHMSEG. Once approved the EC published the changes by implementing them on the terminology server and communicating the changes through appropriate channels.

Members States are responsible for Standards Developing Organisations (SDOs) collaboration in the MVC creation. The EC is responsible for contracting SDOs at the European level, but agreements can be made centrally or at Member State level. Where the EC is responsible for contracting the SDOs, the following is included:

- codes into the MVC,
- translations in the MTC and
- exchange between the terminology server and the NCPeH and between the NCPeHs.

The EC identifies the contacting requirements for Member States and provides this information to the Country Terminology Responsible and contact point for MVC maintenance issues. If these catalogues or single codes are changed by the originally publishing institution during the maintenance process, the MVC must be updated with these changes.

Member States nominate responsible national institutions and persons that act as national experts for the maintenance process, working closely with the Semantic Task force Group.

The entities that can propose changes are:

- National responsible institutions for documentation or catalogue maintenance (if there is one) according to national maintenance rules, public health institutes, public health insurance institutions.
- Standardisation development organisations/SDOs, experts designated by the eHMSEG STF.

The change proposals from a national level are submitted to the national representative, who is responsible for a first verification before submitting to the Semantic Task Force. Similarly, SDOs inform the Semantic Task force regarding any changes, and this group then decides if these changes should be implemented into the MVC.

The proposals should be analysed by the other country representatives and validated by the respective national team of experts.

The final approval of the collected change proposal is taken by the eHMSEG and, if approved, is published by the EC and uploaded to the Central Terminology Server.

At the national level, the nominated person / institutions are responsible for providing a quality assured translation and mapping of the MVC (either translating the display name if the code system is the same or transcoding if the country is using a different code system). Thereafter, the MTC is implemented on the NCPeH and uploaded to the EU terminology server.

One important conclusion that emerged in the analysis of impact that gave origin to this document was that the MVC changes follow a (yearly) release cycle. As such, they are adequate for reference data, i.e. data that changes centrally and slowly. This release cycle may not be compatible with faster-changing master data, like packaged product identifiers which are defined as the product enters the market, and may even be centrally known, but are not managed by a centralised, yearly review cycle. See section 5.3 for a slightly more detailed evaluation of the difference between master data and reference data.

Regarding the coding systems:

- ATC Classification[6]: The WHO Collaborating group publishes a new issue of the complete ATC Index plus Defined Daily Dose (DDDs) every year. This groups meets twice a year, after which the new ATC Codes are published online in the next yearly update.
- EDQM Standard Terms[7]: The Standard terms are created in English after deliberation with the Standard Terms Working Party and, when appropriate, adoption by the European Pharmacopoeia Commission. Relevant national authorities produce translations on a regular basis.
- UCUM Codes[8]: UCUM does not have a release cycle. The maintenance work of UCUM is based on the submission of request and revision by the board members according to the internal procedure.

MVC and ISO IMDP

Table 2 shows all the value sets of the current MVC 5.1.0, that were analysed to identify those that would be impacted by ISO IDMP adoption.

Table 2: Main value sets of MVC 5.1.0, as respective analysis of those impacted by ISO IDMP adoption.

Entry	Value Set ID	Value Set Name	ISO IDMP Impact
1.	1.3.6.1.4.1.12559.11.10.1.3.1.42.47	eHDSIAbsentOrUnknownAllergy	N
2.	1.3.6.1.4.1.12559.11.10.1.3.1.42.48	eHDSIAbsentOrUnknownDevice	N
3.	1.3.6.1.4.1.12559.11.10.1.3.1.42.49	eHDSIAbsentOrUnknownMedication	N
4.	1.3.6.1.4.1.12559.11.10.1.3.1.42.50	eHDSIAbsentOrUnknownProblem	N
5.	1.3.6.1.4.1.12559.11.10.1.3.1.42.51	eHDSIAbsentOrUnknownProcedure	N
6.	**1.3.6.1.4.1.12559.11.10.1.3.1.42.24**	**eHDSIActiveIngredient**	**Y**
7.	1.3.6.1.4.1.12559.11.10.1.3.1.42.34	eHDSIAdministrativeGender	N
8.	1.3.6.1.4.1.12559.11.10.1.3.1.42.18	eHDSIAdverseEventType	N
9.	1.3.6.1.4.1.12559.11.10.1.3.1.42.19	eHDSIAllergenNoDrug	N
10.	1.3.6.1.4.1.12559.11.10.1.3.1.42.20	eHDSIBloodGroup	N
11.	1.3.6.1.4.1.12559.11.10.1.3.1.42.21	eHDSIBloodPressure	N
12.	1.3.6.1.4.1.12559.11.10.1.3.1.42.23	eHDSICodeProb	N
13.	1.3.6.1.4.1.12559.11.10.1.3.1.42.31	eHDSIConfidentiality	N
14.	1.3.6.1.4.1.12559.11.10.1.3.1.42.4	eHDSICountry	N
15.	1.3.6.1.4.1.12559.11.10.1.3.1.42.46	eHDSIDisplayLabel	N
16.	1.3.6.1.4.1.12559.11.10.1.3.1.42.32	eHDSIDocumentCode	N

[6] https://www.whocc.no/atc_ddd_methodology/who_international_working_group/

[7] https://www.edqm.eu/en/standard-terms-database

[8] https://ucum.org/trac

Entry	Value Set ID	Value Set Name	ISO IDMP Impact
17.	**1.3.6.1.4.1.12559.11.10.1.3.1.42.2**	**eHDSIDoseForm**	**Y**
18.	1.3.6.1.4.1.12559.11.10.1.3.1.42.5	eHDSIIllnessandDisorder	N
19.	1.3.6.1.4.1.12559.11.10.1.3.1.42.1	eHDSIHealthcareProfessionalRole	N
20.	1.3.6.1.4.1.12559.11.10.1.3.1.42.53	eHDSIHospitalDischargeReportType	N
21.	1.3.6.1.4.1.12559.11.10.1.3.1.42.52	eHDSILaboratoryReportType	N
22.	1.3.6.1.4.1.12559.11.10.1.3.1.42.6	eHDSILanguage	N
23.	1.3.6.1.4.1.12559.11.10.1.3.1.42.8	eHDSIMedicalDevice	N
24.	1.3.6.1.4.1.12559.11.10.1.3.1.42.55	eHDSIMedicalImagesType	N
25.	1.3.6.1.4.1.12559.11.10.1.3.1.42.54	eHDSIMedicalImagingReportType	N
26.	1.3.6.1.4.1.12559.11.10.1.3.1.42.37	eHDSINullFlavor	N
27.	**1.3.6.1.4.1.12559.11.10.1.3.1.42.3**	**eHDSIPackage**	**Y**
28.	1.3.6.1.4.1.12559.11.10.1.3.1.42.38	eHDSIPersonalRelationship	N
29.	1.3.6.1.4.1.12559.11.10.1.3.1.42.9	eHDSIPregnancyInformation	N
30.	1.3.6.1.4.1.12559.11.10.1.3.1.42.10	eHDSIProcedure	N
31.	1.3.6.1.4.1.12559.11.10.1.3.1.42.11	eHDSIReactionAllergy	N
32.	1.3.6.1.4.1.12559.11.10.1.3.1.42.30	eHDSIResolutionOutcome	N
33.	1.3.6.1.4.1.12559.11.10.1.3.1.42.39	eHDSIRoleClass	N
34.	**1.3.6.1.4.1.12559.11.10.1.3.1.42.12**	**eHDSIRouteofAdministration**	**Y**
35.	1.3.6.1.4.1.12559.11.10.1.3.1.42.26	eHDSISection	N
36.	1.3.6.1.4.1.12559.11.10.1.3.1.42.13	eHDSISeverity	N
37.	1.3.6.1.4.1.12559.11.10.1.3.1.42.14	eHDSISocialHistory	N
38.	1.3.6.1.4.1.12559.11.10.1.3.1.42.15	eHDSIStatusCode	N
39.	1.3.6.1.4.1.12559.11.10.1.3.1.42.7	eHDSISubstitutionCode	N
40.	1.3.6.1.4.1.12559.11.10.1.3.1.42.40	eHDSITelecomAddress	N
41.	**1.3.6.1.4.1.12559.11.10.1.3.1.42.41**	**eHDSITimingEvent**	N
42.	**1.3.6.1.4.1.12559.11.10.1.3.1.42.16**	**eHDSIUnit**	**Y**
43.	1.3.6.1.4.1.12559.11.10.1.3.1.42.28	eHDSIVaccine	Y[a)]

Abbreviations: **Y**: Yes, impacted to allow ISO IDMP adoption; **N**: No impact. **a)** Out of the initial scope of D5.4.

Note: Vaccine information is initially out of scope of this deliverable. This does not mean that vaccine information is deliberately excluded, but this deliverable concerns any medication, including vaccines, to the extent that vaccines have some common needs of identification. The inclusion of additional vaccine-specific content can be considered in later revision of the technical specifications or a later update to this document if required.

The main Value Sets that will be impacted by the adoption of ISO IDMP are extracted to Table 3.

Table 3: Main value sets impacted by ISO IDMP, with the respective value set ID, code system ID and version.

Value Set name	Value Set ID	Code system(s)	Code System(s) ID	Version
eHDSIActiveIngredient	**1.3.6.1.4.1.12559.11.10.1.3.1.42.24**	ATC Classification	2.16.840.1.113883.6.73	2021-01
eHDSIDoseForm	**1.3.6.1.4.1.12559.11.10.1.3.1.42.2**	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16
eHDSIPackage	**1.3.6.1.4.1.12559.11.10.1.3.1.42.3**	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16
eHDSIRouteofAdministration	**1.3.6.1.4.1.12559.11.10.1.3.1.42.12**	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16
eHDSIUnit	**1.3.6.1.4.1.12559.11.10.1.3.1.42.16**	Table of Example UCUM Codes for Electronic Messaging	2.16.840.1.113883.6.8	2021-04

As an example of the value set content (Table 3), please consider the following information:

- **eHDSIActiveIngredient**: contains 6439 different entries. For example,
  - Concept code: N02BE01
  - Description: paracetamol
- **eHDSIDoseForm**: contains 584 different entries. For example,
  - Concept code: 12150
  - Description: Prolonged-release capsule
- **eHDSIPackage**: contains 62 different entries. For example,
  - Concept code: 30050000
  - Description: Pre-filled pen
- **eHDSIRouteofAdministration**: contains 80 different entries. For example,
  - Concept code: 20035000
  - Description: Intramuscular use
- **eHDSIUnit**: contains 812 different entries. For example,
  - Concept code: mg/mL
  - Description: milligram per millilitre

These value sets address important attributes for the correct identification of medicinal products and are therefore impacted by ISO IDMP according to the defined specifications.

3.2 Summary of the Member State semantic compatibility (D5.6)

The details relating to the Member States specifications are presented in further detail in '*D5.6 – Guidelines to implement IDMP in National eHealth Services'*. All WP5 deliverables were developed with a focus on alignment between the different Work Package documents and the requirements to implement the IDMP at both the eHDSI infrastructure and national level. This document sets the semantic specifications in a way that they can be assessed for readiness/compatibility, and D5.6 will follow up on that.

3.3 IDMP compliant attributes and their MVC relation

This section describes how IDMP compliant attributes can be related to the corresponding value set in the MVC (Table 4) and highlights any gaps or outstanding requirements in this mapping process. A relation is defined as the specific MVC which contains the relevant data attribute that is to be mapped to an individual IDMP attribute.

The IDMP minimum attribute list is derived from Table 17**Erro! A origem da referência não foi encontrada.** in this document, and the MVC reference set is derived from Table 3 (above). Where multiple IDMP attributes are expected to be used from one MVC reference set, these have been merged in the table for easy reading.

As previously stated IDMP defines data elements, some of these elements have coded information, others are textual or another format. IDMP does not address terminologies, however, SPOR does for some data elements. The table below identifies IDMP relations that may be required from SPOR and also captures where it is expected that the IDMP relation may be more appropriate to be derived from SPOR. This means that a combination of SPOR and MVC attributes may be needed in order to achieve full semantic interoperability across borders.

Table 4: IDMP attributes mapping at eHDSI MVC

Essential Attributes for IDMP implementation	MVC relation
Active Ingredient: Pharmaceutical product ingredient	*See footnote*[9]
Active Ingredient: Packaged medicinal product ingredient	*See footnote*[10]
Active Ingredient: Pharmaceutical product substance	*See footnote*[10]
ATC Code	eHDSIActiveIngredient *(See footnote [10])*
Medicinal Product Code: MPID	*Will need to be defined dynamically in countries, may not qualify for a value set*
Medicinal Product Code: PCID	
Marketing Authorisation Holder (Organisation)	*Not directly available in MVC – master data available via SPOR*
Brand Name of the Medicinal Product: Full name	*Not directly available in MVC – master data available via SPOR; Will need to be defined dynamically in countries, may not qualify for a value set*
Medicinal Product Package: Package description	eHDSIPackage
Medicinal Product Package: Pack size	eHDSIUnit
Number of packages: Contained quantity	
Strength of the Medicinal Product: Strength (Presentation single value or low limit)	
Strength of the Medicinal Product: Strength (Concentration single value or low limit)	
Strength of the Medicinal Product: Reference Substance	
Strength of the Medicinal Product: Reference strength (Presentation single value or low limit)	
Pharmaceutical Dose Form: (Authorised) pharmaceutical form	eHDSIDoseForm as a master value set may provide a superset, but a subset should be derived for each of

[9] *Currently the ATC code represents the 'Pharmaceutical Product substance' in eHDSI, however there is no designated identification code directly available in MVC. It may be more appropriate to derive final ingredient list (across all three 'Active Ingredient' attributes) via SPOR Substance Management Service (SMS).*

[10] eHDSIActiveIngredient displays the ATC code but if the long-term use case is solely for classification rather than identification of active ingredients, an updated name is suggested (i.e. eHDSIClassification).

Essential Attributes for IDMP implementation	MVC relation
Pharmaceutical Dose Form: Administrable Dose Form	the elements. In addition, national implementations may further use local subsets
Pharmaceutical Dose Form: Manufactured dose form	
Route of Administration	eHDSIRouteofAdministration

4 CDA document specifications (Art-Decor)

4.1 Overview

This section describes how the model identified in *D5.3 (Guidelines for cross-border semantic interoperability)* can be mapped into the HL7 CDA R2 templates currently adopted by MyHealth@EU[11] to highlight possible gaps.

MyHealth@EU uses a document-based representation for the services currently supported: ePrescription / eDispensation and Patient Summary. HL7 CDA R2 standard is used for the physical representation of documents and HL7 Fast Healthcare Interoperability Resources (FHIR) may be considered in the future.

MyHealth@EU HL7 CDA R2 templates are formalised and published through the Art Decor tool:

- The on-development versions are published in https://art-decor.ehdsi.eu/art-decor/decor-templates--epsos-
- The release ones in https://art-decor.ehdsi.eu/html/publication/epSOS/

The classes of information that are required to define the eP/eD documents (as proposed in UNICOM *D5.3*[12]) are contained in the following figures (Figure 4,

Figure 5 : , Figure 6, and Figure 7). Also included is the Medication Summary section of Patient Summary.

[11] https://ec.europa.eu/health/other-pages/basic-page/myhealtheu-flyer-addressed-patients-and-health-professionals_pt

[12] At time of development of this deliverable, D5.3 was already submitted (30/11/2021) and is currently pending EC approval.

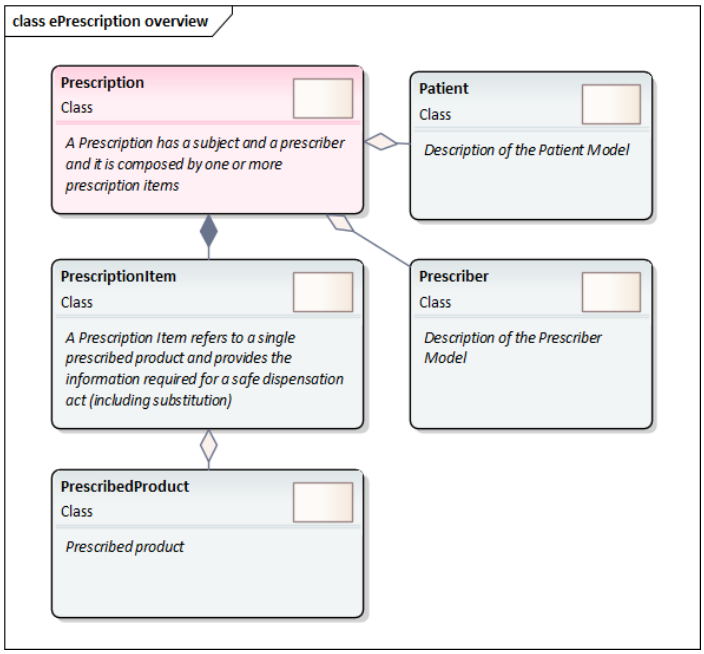


Figure 4: ePrescription overview (from UNICOM D5.3). The lines and arrows depict the types of relationships between the classes as specified according to the UML standard.

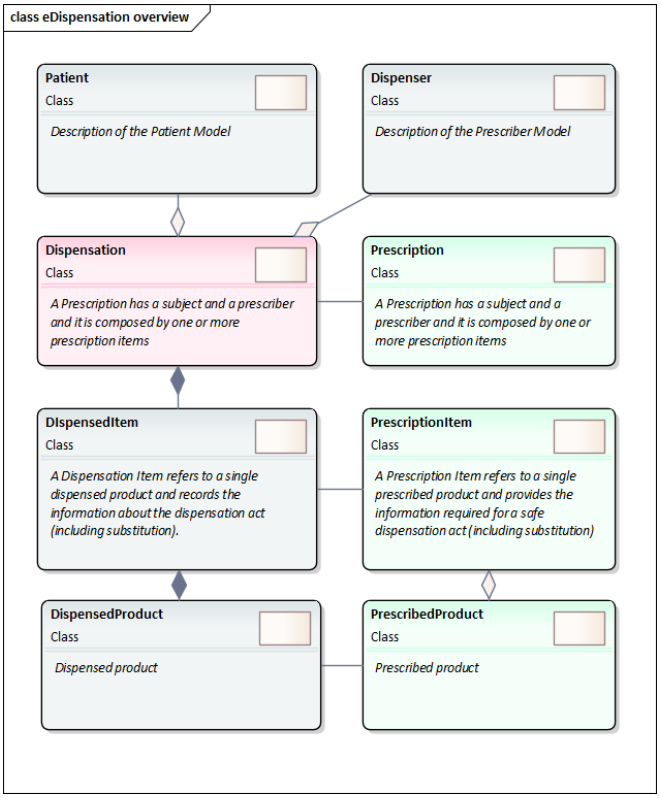


Figure 5 : eDispensation overview (from UNICOM D5.3)[13]. The lines and arrows depict the types of relationships between the classes as specified according to the UML standard.

[13] Suggested reorganisation of the information model; these suggestions have been designed in a way to ensure that these models stay in alignment with the current eHDSI CDA implementation.

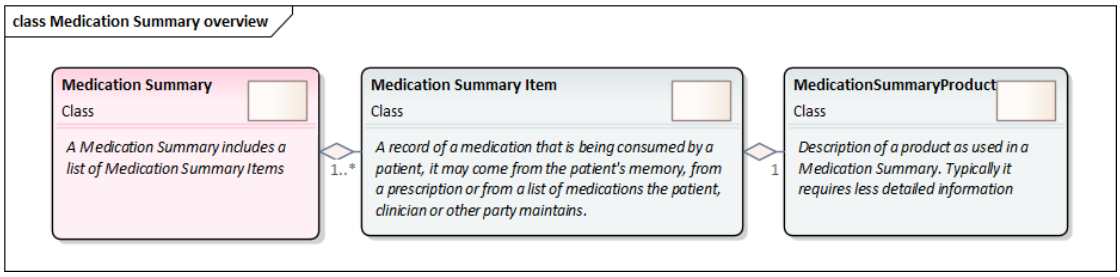


Figure 6: Medication Summary overview (from UNICOM D5.3)

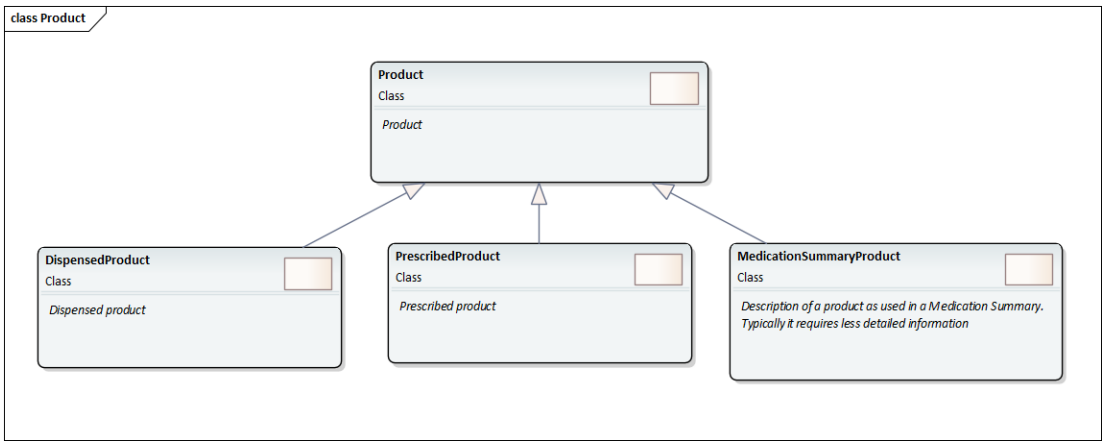


Figure 7: Suggested eHDSI Common Product Model

The way these classes are mapped into the existing MyHealth@EU HL7 CDA R2 templates is represented in Table 5. The template type (Document, Header, Section and entry level template) and the link to the currently adopted template is also provided.

Table 5: MyHealth@EU CDA Templates mapping (document, section)

Class	Type of template	Reference
Prescription	Document	https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20210621T103924/tmp-1.3.6.1.4.1.12559.11.10.1.3.1.1.1-2020-09-09T122247.html
Dispensation	Document	https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20210621T103924/tmp-1.3.6.1.4.1.12559.11.10.1.3.1.1.2-2020-09-09T120923.html
Medication Summary	Section	https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20210621T103924/tmp-1.3.6.1.4.1.12559.11.10.1.3.1.2.3-2020-09-07T095657.html

Table 6 provides the same information for the main actors.

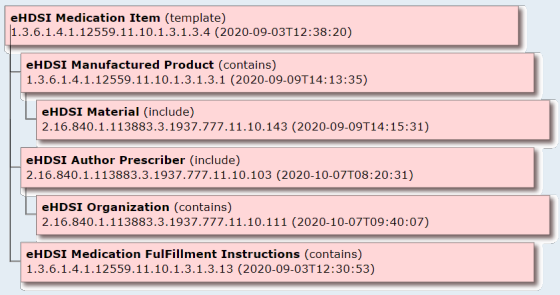
Table 6: MyHealth@EU CDA Templates mapping (main actors)

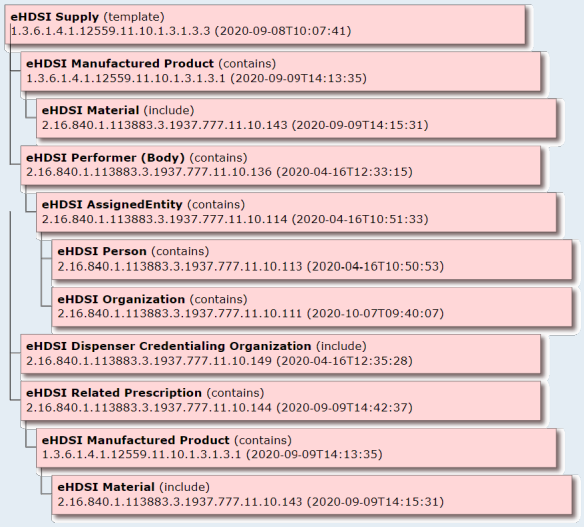
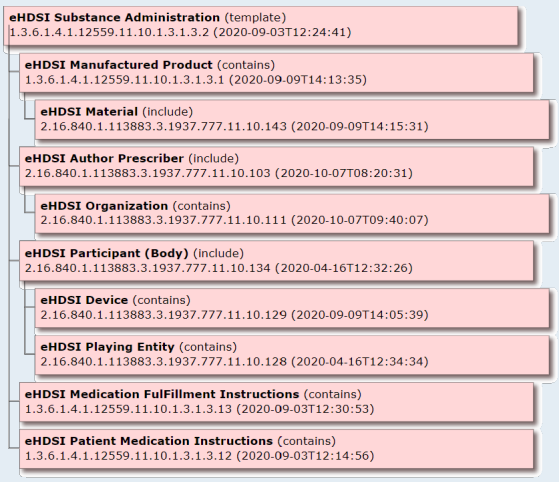
Class	Type of template	Reference
Patient	Header	https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20210621T103924/tmp-2.16.840.1.113883.3.1937.777.11.10.100-2020-10-02T140545.html
Prescriber	Header	https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20210621T103924/tmp-2.16.840.1.113883.3.1937.777.11.10.103-2020-10-07T082031.html
Dispenser	Entry	(supply.performer) https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20210621T103924/tmp-2.16.840.1.113883.3.1937.777.11.10.136-2020-04-16T123315.html

4.2 Product identification

Since product identification is the focus of the UNICOM project, a gap analysis has been performed by this WP (WP5) on the model classes and CDA templates that refer to this subject (Table 7).

Table 7: MyHealth@EU CDA Templates mapping (section entries)

Class	Type of template	Reference
Medication Summary Item	Entry	eHDSI Medication Item https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20210621T103924/tmp-1.3.6.1.4.1.12559.11.10.1.3.1.3.4-2020-09-03T123820.html  In scope for this deliverable: • eHDSI Manufactured Product • eHDSI Material

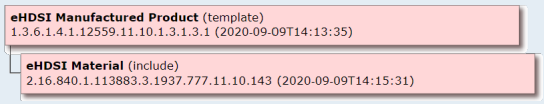
Class	Type of template	Reference
Dispensed Item	Entry	eHDSI Supply https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20210621T103924/tmp-1.3.6.1.4.1.12559.11.10.1.3.1.3.3-2020-09-08T100741.html  In scope for this deliverable: • eHDSI Manufactured Product • eHDSI Material
Prescribed Item	Entry	eHDSI Substance Administration https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20210621T103924/tmp-1.3.6.1.4.1.12559.11.10.1.3.1.3.2-2020-09-03T122441.html  In scope for this deliverable: • eHDSI Manufactured Product • eHDSI Material

Suggested changes

1. Medication Summary Item
   1.1. Align the profile to the IPS Medication Statement template[14], compliant with the UV Medication Statement template[15].
2. eHDSI Supply
   2.1. Align the profile to the UV Medication Dispense template[16].
3. eHDSI Substance Administration
   3.1. Align the profile to the UV Medication Order template[17].
4. eHDSI Manufactured Product and eHDSI Material
   4.1. Align with the UV Medication Information (detail)[18] template.

The adoption of these specialised templates will resolve some of the well-known inconsistencies[19] and shortages[20] of the currently used templates.

Table 8: MyHealth@EU CDA Templates mapping (product)

Class		Type of template	Reference
Product	Medication Summary Product	Entry	eHDSIManufacturedProduct https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20210621T103924/tmp-1.3.6.1.4.1.12559.11.10.1.3.1.3.1-2020-09-09T141335.html 
	Dispensed Product		
	Prescribed Product		

Suggested changes

5. Define a common model template − it can be a new version of the current eHDSI Manufactured Product, containing the attributes required in this analysis.
6. Create three specialised templates for prescribed, dispensed and medication summary products.

For each group of SPOR selected attributes reported in Figure 8, the results of the MyHealth@EU implementation analysis, are presented in the following subsections in tabular form.

[14] https://art-decor.org/art-decor/decor-templates--hl7ips-?section=templates&id=2.16.840.1.113883.10.22.4.4&effectiveDate=2021-09-02T12:17:54

[15] https://art-decor.org/art-decor/decor-templates--pharmcda-?section=templates&id=2.16.840.1.113883.10.21.4.7&effectiveDate=2021-08-04T14:09:15

[16] https://art-decor.org/art-decor/decor-templates--pharmcda-?section=templates&id=2.16.840.1.113883.10.21.4.15&effectiveDate=2021-08-04T16:35:09

[17] https://art-decor.org/art-decor/decor-templates--pharmcda-?section=templates&id=2.16.840.1.113883.10.21.4.1&effectiveDate=2021-08-04T17:03:38

[18] https://art-decor.org/art-decor/decor-templates--pharmcda-?section=templates&id=2.16.840.1.113883.10.21.4.11&effectiveDate=2021-08-04T12:39:04

[19] e.g. case of unknown administration period (first effectiveTime nullFlavored) wrong usage of the capacityQuantity element.

[20] e.g. the need of changing the template structure in dependence of the type of administration / product.

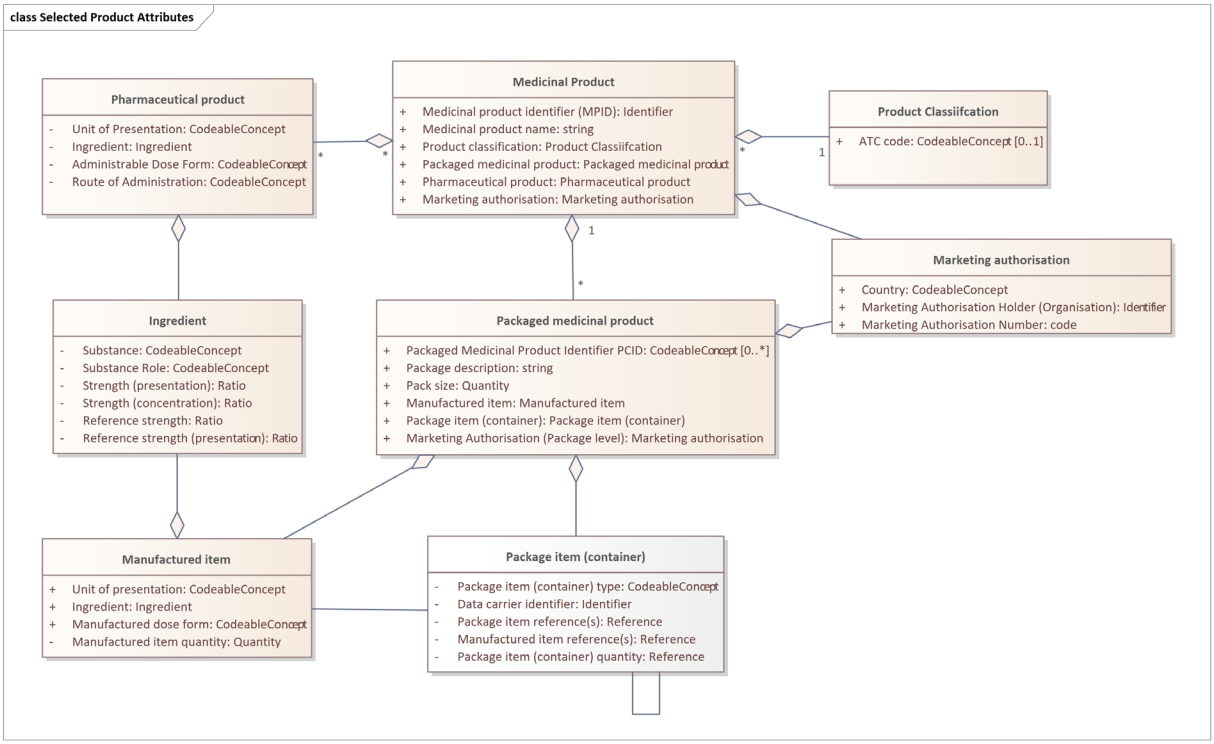


Figure 8: SPOR selected attributes (from UNICOM D5.3)

4.2.1 Medicinal Product

Table 9: General implementation notes for Medicinal Products

Attributes	Implementation Notes
Medicinal product identifier (MPID): Identifier	• Conveyed as `manufacturedMaterial*` code, the cardinality is 0..1 if more product codes have to be exchanged the translation element should be used. • Define the Object Identifier(s) (OID) to be used for the MPIDs
Medicinal product name: string	• Conveyed as `manufacturedMaterial` name. • No way to distinguish between different possible kinds of names
Product classification: Product Classification	• See 4.2.2 - Product Classification
Packaged medicinal product: Packaged medicinal product	• See 4.2.5 - Packaged medicinal product
Pharmaceutical product: Pharmaceutical product	• See 4.2.3 - Pharmaceutical product
Marketing authorisation: Marketing authorisation	• See 4.2.7 - Marketing authorisation

* `manufacturedMaterial` is the name of the CDA class, it does not necessarily represent a manufactured item (In general it provides details about any kind of product and is used in eHDSI).

4.2.2 Product Classification

Table 10: Implementation notes for Product Classification

Attributes	Implementation Notes
ATC code: CodeableConcept	• Conveyed through the `asSpecializedKind. generalizedMedicineClass.code` extension • Pharmaceutical Product Identifier (PhPID) sets and other classifications can be exchanged by using the same element, make this point clearer in the template

4.2.3 Pharmaceutical product

When PhPID will be made available, these identifiers will be represented in the HL7 CDA by using the `asSpecializedKind. generalizedMedicineClass.code` extension.

Table 11: Implementation notes for Pharmaceutical product

Attributes	Implementation Notes
Unit of Presentation: CodeableConcept	• From D5.3 "The unit of presentation is not captured for the time being as distinct information in the current model (Figure 14), more analysis is needed to understand if is valuable to include as separate element, or if it is used only as unit for the strength (presentation)."
Ingredient: Ingredient	• See § 4.2.4 - Ingredient
Administrable Dose Form: CodeableConcept	• In the current implementation a single dose form, independently on the kind of, is documented by mean of the `formCode` extension. This is close to the Authorised dose form concept. To be confirmed that for the purpose of myHealth@EU this is enough. • Review the **eHDSIDoseForm**[21]
Route of Administration: CodeableConcept	• In the current implementation it is recorded the Route of Administration, actual or intended, associated to the administration; rather than the attribute associated to the product (`substanceAdministration.routeCode` element). This information is not in fact recorded for the dispensation act. To be analysed if both should be recorded or not. • Review the **eHDSIRouteofAdministration**[22]

[21] https://art-decor.ehdsi.eu/art-decor/decor-valuesets--epsos-?id=1.3.6.1.4.1.12559.11.10.1.3.1.42.2
[22] https://art-decor.ehdsi.eu/art-decor/decor-valuesets--epsos-?id=1.3.6.1.4.1.12559.11.10.1.3.1.42.12

4.2.4 Ingredient

Table 12: Implementation notes for Ingredient

Attributes	Implementation Notes
Substance: CodeableConcept	**eHDSIActiveIngredient** Value set to be revised
Substance Role: CodeableConcept	Value Set to be specified and added. See 2.16.840.1.113883.1.11.10430 **RoleClassIngredientEntity**[23]
Strength (presentation): Ratio	Different kinds of strengths can be distinguished based on the substance roles and of the ratio unit of measure. To be analysed if it is worth to have more strengths in the product description.
Strength (concentration): Ratio	
Reference strength: Ratio	
Reference strength (presentation): Ratio	

4.2.5 Packaged medicinal product

Table 13: Implementation notes for Package Medicinal Product

Attributes	Implementation Notes
Packaged Medicinal Product Identifier PCID: CodeableConcept	• Supposed to be recorded in the `asContent.containerPackagedMedicine.code` extension. This element is not defined in the current myHealth@EU specification. • OID(s) for PCID to be identified
Package description: string	Provided as part of the Package name. To be analysed if this is enough.
Pack size: Quantity	• Wrongly implemented by using the `capacityQuantity` element, instead of using `asContent.quantity`. • The `asContent.quantity` provides the quantity of included package items.
Manufactured item: Manufactured item	See § 4.2.8 - Manufactured item
Package item (container): Package item (container)	The current implementation supports only one package level, allow for at least the inner, intermediate and outer packages. See also § 4.2.6 - Package item (container)
Marketing Authorisation (Package level): Marketing authorisation	See § 4.2.7 - Marketing authorisation

4.2.6 Package item (container)

Note that the current MyHealth@EU implementation supports only one package level, in practice only the most outer package.

[23] https://art-decor.org/art-decor/decor-valuesets--pharmcda-?id=2.16.840.1.113883.1.11.10430&effectiveDate=dynamic

Table 14: Implementation notes for Package Item

Attributes	Implementation Notes
Package item (container) type: CodeableConcept	• Documented by using the `formCode` element. (currently 1..1 R) • Verify if the 'double' binding with **eHDSIDoseForm** [24] or **eHDSIPackage**[25] is correct at this level • Review the above-mentioned value sets
Data carrier identifier: Identifier	• Not covered by the current specification
Package item reference(s): Reference	• Reference not implemented in the current specification, (`asContent` is 0..1 for the time being)
Manufactured item reference(s): Reference	• Reference not implemented for the time being. See also § 4.2.8 - Manufactured item
Package item (container) quantity: Reference	• Wrongly implemented by using the `capacityQuantity` element, instead of using `asContent.quantity`. The `asContent.quantity` provides the quantity of included package items.

4.2.7 Marketing authorisation

Table 15: Implementation notes for Marketing Authorisation

Attributes	Implementation Notes
Country: CodeableConcept	• No details about the Marketing authorization act are provided.
Marketing Authorisation Holder (Organisation): Identifier	• Conveyed by the `manufacturedProduct.marketingAuthorizationHolder.id` extension. The extension has to be revised in case details about the authorisation act should be provided.
Marketing Authorisation Number: code	• No details about the Marketing authorisation act are provided. • In some jurisdiction the Marketing Authorisation Number are used also as Product code

4.2.8 Manufactured item

Table 16: Implementation notes for Manufactured Item

Attributes	Implementation Notes
Unit of presentation: CodeableConcept	From D5.3 "Further assessments to evaluate the effective need of representing the manufactured item in the product model as distinct information are required, as well as for the mapping of
Ingredient: Ingredient	
Manufactured dose form: CodeableConcept	

[24] 1.3.6.1.4.1.12559.11.10.1.3.1.42.2
[25] 1.3.6.1.4.1.12559.11.10.1.3.1.42.3

Attributes	Implementation Notes
Manufactured item quantity: Quantity	manufactured item details as ingredient, unit of presentation and dose form.”

4.3 Value sets specifications

Details about the value sets to be reviewed are provided in the tables of section 4.2 Product identification.

Note: A detailed analysis should be performed by MyHealth@EU to evaluate whether the value sets specified by SPOR have to be adopted and when. The evaluation should include the use of the “SPOR-specific” code systems (such as SMS). Or, if international code systems have to be used for those concepts, relying on existing documented mapping within SPOR, where available. The latter is the preferrable solution.

5 Revised Functional specifications

From this analysis, and focusing on the necessary changes, requirements have been identified to support a successful, IDMP-based semantic interoperability, and its implementation of the syntactical specifications (like CDA technical specifications).

The overarching objective of semantic interoperability is that data semantics (meaning) are consistent across specifications, and the following requirements are immediately evident:

1. The meaning of data elements shall be clear, unambiguous, and shared between the parties.
2. When data is coded, the values and their meaning shall also be shared between the parties.

This brings additional requirements which are represented as functional specifications. The technical specifications that correspond to these functional requirements are developed in ‘*D5.5 - Technical specifications for cross-border services’*. D5.5 documents how those technical specifications are aligned with these functional requirements.

- Semantics of the ePrescription, eDispensation, Patient Summary data elements shall be clearly stated and mastered,
  - As a prerequisite, the “as is” specifications shall also be captured
  - Developing specifications (“to be”) shall be clearly stated, to evaluate the impact of the changes and inform future maintenance.
  - There needs to be a clear governance structure for managing release models, to ensure derived specifications can be anticipated and changes planned.
  - Governance of change proposals to eHDSI specifications can be leveraged to continually support these requirements. Specific feedback may be given in the technical specifications in UNICOM.
- The definitions that are used in eHDSI SHOULD be computable, i.e., consumable by computers that can assert and/or assess when definitions are updated.
- Semantics of the ePrescription, eDispensation, Patient Summary shall be compatible with IDMP, and this compatibility SHOULD be controlled and documented (in a computable way).
  - This can be facilitated with other deliverables, but an important step is the creation of the ISO IDMP Logical Model(s) foreseen in WP1.

- The list of data elements and the semantic alignment needs are presented in section '*3.3 - IDMP compliant attributes and their MVC relation'* of this document.
    - A computable model of those data elements should be created and maintained, as well as the correspondences and gaps to the current and planned eHDSI elements.

- If Member States are able to extend or partially constrain their interfaces with regards to the "standard" cross-border specification, they shall be able to do it in a confirmed compatible manner – in other words, if extensions or "dialects" are expected, they shall be confirmed as not introducing any compatibility issue.

- Context-appropriate value sets shall be defined. UNICOM work has demonstrated that while the comprehensive value sets (or rather supersets) are defined in MVC or SPOR, they need to be adequate for use.
    - For example, as per Table 17 in this document, "dose form" may be used in at least 2 value sets – administrable dose form (required for generate the PhPID) and manufactured dose form.
    - This also includes the inclusion of hierarchical value sets with the ontologies as deemed adequate.

- When the value sets are not "mastered" in the MVC (i.e., those value sets whose primary source is not the MVC), the master system of record shall be identified.

- Systems that consume and produce the MVC or other value sets shall have mechanisms in place for updating their value sets from the main source.
    - Terminology services shall be implemented and available supported by well-defined processes.
    - The rules for updates should also be well-defined − Systems that consume the MVC shall propagate the updates within an interval that may be variable, but that must be defined. For example, if a new dose form is added to a value set, the Member State systems may not need to update their applications immediately, but an update deadline shall be defined to ensure all applications are in sync.

- Master data quality controls should be put in place and corresponding rules defined.

- Some of the data may not be originating from a value set. This is the case for identifiers, like product identifiers (especially MPIDs, PCIDs), MAH /Organisation identifiers, etc. and:
    - There may be no strict need to produce and maintain such value sets.
    - Adequate quality controls shall be put in place, even if a master value set may not be attainable or desirable.

5.1 Dataset revision to allow IDMP adoption

This section describes the dataset required to support the IDMP adoption.

Currently, eHDSI has many value sets to specify the correct information in their infrastructure. However, until now, they do not provide a specific value set, and coding system, to represent 'substance'. At the moment, this identification is made through ATC, which is not considered the best-fit coding system for substance identification. One possible way to resolve this issue is the use of the Substance Management Service[26] (SMS), which primarily manages the EU substance referential and has the following advantages for cross-border services:

- SMS data is the "simplified" PUBLIC substance data
- supports selection in regulatory processes

[26] https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/spor-master-data/substance-product-data-management-services

- distinguish between two or more similar substances
- provides internal translation for all EU languages

As SMS is managed by SPOR[27], it is also aligned to the ISO IDMP implementation, facilitating further adoption processes at eHDSI and Member States.

D5.3[12] defined a list of the minimal attributes associated with the eHDSI data elements. In this deliverable the attributes are associated with the eHDSI value sets (Table 17). This list comes from the European Medicines Agency (EMA) Implementation Guide V2[28] (EMA IG V2).

To successfully adopt IDMP attributes, the granularity of attributes associated with the correspondence between the different Member States and eHDSI needs to be addressed. The diversity of similar attributes in EMA IG V2 and its use by different NCAs offers the eHDSI the opportunity to use as input, different attributes to represent the same element, e.g. to represent the eHDSI element 'Pharmaceutical dose form', the Member State should provide one of 3 options: authorised, administrable or manufactured dose form to the eHealth services.

It is important that Member States provide the 'administrable dose form' in order to generate the PhPID. In the medium-term, Member States should be able to use and provide the correct IDMP attributes to issue the eHealth services in a cross-border context.

3 IDMP identifiers − PhPID, MPID and PCID − if represented in the minimal attribute list are not being provided in the short-term. There is a need for a European effort to address this nationally in order for the NCAs to generate and make available these identifiers. Considering the correspondence between the identifiers and the eHDSI elements, eHDSI could create a field to introduce the IDMP identifiers.

[27] https://spor.ema.europa.eu/sporwi/

[28] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso_en-0.pdf

Table 17: Minimal Attribute List[29]

Attributes from EMA IG Section V2.1 (2021-02)[28]			eHDSI data elements[30]	eHDSI MVC / Value set ID	
#	Class	Attribute			
6.4.	Medicinal Product	Ingredient	Active Ingredient / Active ingredient ID (code)	See footnote 10	When identifying a Substance, prepare the use of a new value set (SMS)
4.10.4.	Medicinal Product	Ingredient			
1.13.3.	Medicinal product	ATC Code(s)	ATC code	eHDSIActiveIngredient 1.3.6.1.4.1.12559.11.10.1.3.1.42.24	Add a new data element – Classification – and use the ATC value set
1.2.	Medicinal Product	Medicinal product identifier (MPID)	Medicinal Product Code	Not directly available in MVC – available via SPOR	SPOR to define the MPID name space for unambiguous use
4.1.	Medicinal Product	Packaged Medicinal Product Identifier (PCID)			SPOR to define the PCID name space for unambiguous use
2.8.	Medicinal Product	Marketing Authorisation Holder (Organisation)	Marketing Authorisation Holder of the prescribed medicinal product		SPOR to define the MAH name space for unambiguous use
1.14.1.	Medicinal Product	Full name	Brand Name of the Medicinal Product		SPOR to define the BrandName name space for unambiguous use
4.2.	Medicinal Product	Package description	Medicinal Product Package	eHDSIPackage 1.3.6.1.4.1.12559.11.10.1.3.1.42.3	Clarify that this is “PackageType”
4.3.	Medicinal Product	Pack size	Package size	eHDSIUnit 1.3.6.1.4.1.12559.11.10.1.3.1.42.16	Quantity – use eHDSIUnit
4.7.5.	Medicinal Product	Package item (container) quantity			
5.5.2.2.2.	Medicinal Product	Strength (Presentation single value or low limit)	Strength of the Medicinal Product		
5.5.2.3.2.	Medicinal Product	Strength (Concentration single value or low limit)*			
5.5.3.1.	Medicinal Product	Reference Substance			
5.5.3.3.2.	Medicinal Product	Reference strength (Presentation single value or low limit)*			
1.5.	Medicinal Product	(Authorised) pharmaceutical form	Pharmaceutical Dose Form	eHDSIDoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.42.2	Consider creation of dedicated value set for pharmaceutical dose form
6.2.	Medicinal Product	Administrable Dose Form*			Consider creation of dedicated value set for administrable dose form
4.10.3.	Medicinal Product	Manufactured dose form			Consider creation of dedicated value set for manufactured dose form
6.3	Medicinal Product	Unit of presentation	Not implemented yet		
6.6.	Medicinal Product	Route of Administration	Route of Administration	eHDSIRouteofAdministration 1.3.6.1.4.1.12559.11.10.1.3.1.42.12	

*Required to generate the PhPID – as such, it is important to define a well-bound value set to avoid ambiguity when creating the PhPID.

[29] For more details please see *UNICOM D5.3 - Guidelines for cross-border semantic interoperability.*

[30] The eHDSI data elements were evaluated from the eHDSI confluence page at (eHDSI restricted access):
https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/05.01.+Create+the+eHDSI+Patient+Summary+content
https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/06.01.+Create+the+eHDSI+ePrescription%28s%29+content
https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/07.01.+Create+the+eHDSI+eDispensation+content

5.2 Revised CDA specifications to allow IDMP adoption

This section sets out the recommendations required to implement and map the ISO IDMP data into the eHDSI infrastructure:

Suggested changes

1. Medication Summary Item
   1.1. Align the profile to the IPS Medication Statement template[31], compliant with the UV Medication Statement template[32].
2. eHDSI Supply
   2.1. Align the profile to the UV Medication Dispense template[33].
3. eHDSI Substance Administration
   3.1. Align the profile to the UV Medication Order template[34].
4. eHDSI Manufactured Product and eHDSI Material
   4.1. Align with the UV Medication Information (detail)[35] template.
5. Define a common model template, it can be a new version of the current eHDSI Manufactured Product
6. Create three specialised templates for prescribed, dispensed and medication summary products

5.3 Data Set management

The semantic specifications in scope (definitions, constraints and value sets) must be managed through the lifecycle. The specifications will evolve over time resulting in a number of upgrades. Therefore, any changes, additions, usage and monitoring should be managed carefully.

5.3.1 Reference Data and Master data

There are different requirements necessary depending on the type of data and it is necessary to elicit the most appropriate requirements as part of a managed process.

Master data is data whose formats and allowable values are managed by business rules and are not usually limited to pre-defined domain values. Reference data is data used to classify or categorise other data. From a UNICOM perspective, product information definitional data is considered master data and the terminologies are considered reference data.

While master data and reference data are similar, they differ in main 2 aspects, which are fundamental for the UNICOM work:

[31] https://art-decor.org/art-decor/decor-templates--hl7ips-?section=templates&id=2.16.840.1.113883.10.22.4.4&effectiveDate=2021-09-02T12:17:54

[32] https://art-decor.org/art-decor/decor-templates--pharmcda-?section=templates&id=2.16.840.1.113883.10.21.4.7&effectiveDate=2021-08-04T14:09:15

[33] https://art-decor.org/art-decor/decor-templates--pharmcda-?section=templates&id=2.16.840.1.113883.10.21.4.15&effectiveDate=2021-08-04T16:35:09

[34] https://art-decor.org/art-decor/decor-templates--pharmcda-?section=templates&id=2.16.840.1.113883.10.21.4.1&effectiveDate=2021-08-04T17:03:38

[35] https://art-decor.org/art-decor/decor-templates--pharmcda-?section=templates&id=2.16.840.1.113883.10.21.4.11&effectiveDate=2021-08-04T12:39:04

1. Whether or not they are managed centrally
2. Frequency of changes

On one hand country code, substance code, etc. are all reference data. This data type is relatively constant and usually managed centrally; any changes are done in a controlled manner.

On the other hand, product identifiers require frequent changes (e.g. a new PCID is generated when a package box is changed) which may not be compatible with the centrally managed value set like those in eHDSI.

Data in Prescriptions, Dispensations and Patient Summary uses is transactional data even though it uses master and reference data in its attributes and satisfies the requirements below:

There are a few common requirements for both master data and reference data specifically product attributes and their terminologies:

1. The Reference and Master Data Sources and Contributors should be identified – owners, contributors.
2. Governance processes should be defined – processes for updating and propagating those updates.
3. Content should be authentic and reliable, for example by ensuring versioning strategies, implementing data quality monitoring, etc.

The direct impact of this in the current specifications is:

- Reference data can be pointing to a value set that is defined, governed and shared. Knowing that the definition and governance processes are established, the key point for implementation is the sharing – ensuring that Member States and all interested parties have timely, managed access to the value set when required.
- Master data may not be in a common value set, but it should still be semantically sound and clear – when referring to a value, it is important to know what is the meaning behind the value. For example, MPID and PCID are different and it is important to know which one is being exchanged. This can be achieved by identifying the type or namespace in every data exchange.

5.3.2 Semantic documentation

Throughout this document, and previous documents in UNICOM, the semantic specifications are clarified, the “as is” and “to be” statuses are analysed, and this results in knowledge that is documented in these requirements. In similar analysis work, it is not uncommon, like in this document, to infer the semantics (meaning) of data element from their context, their technical specifications, or any other sources, including discussions or consultations with authoritative or informative sources.

Acknowledging that facilitating the adherence to UNICOM and IDMP by the Member States is also a requirement, this analysis confirms the need for a durable, managed, up-to-date semantic specification. One way to achieve this is to follow the recommendation in D1.2[36], using information or logical models that capture the information meaning, constraints and value sets.

Such documentation is advised important not only for editorial reasons (following up across UNICOM deliverables) but also, and especially, for the purposes of disseminating to Member States, and eventually assessing/validating the adherence of such Member States to the semantic specifications. In short, continuing to capture the semantic specifications, with tools such as Art Décor, will ensure that the UNICOM project persists its target solution, and especially that this can be consulted and assessed in the adoption phases.

[36] Deliverable 1.2: Requirements for a new ISO logical model [platform independent]. UNICOM. Available at: https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D1.2-Logical-Model_Final.pdf

5.3.1 Dissemination of data semantics and reference / master data

The dissemination of data semantics and reference / master data was briefly introduced in D5.3, where the need for sharing value sets along its flow.

Data sets have a lifecycle that can be seen as:

- They are created by one institution (e.g. EDQM Dose Forms)
- Curated, enriched, trimmed − for a given purpose, by another institution (e.g. an eventual, dedicated “administrable dose form” value set)
- Brokered by another institution (e.g. a central EMA terminology server, or federated terminology services)
- Consumed for use by other institutions (e.g. NCAs, etc)

All this will be done in iterations of versioned content.

These operations may be more or less time-sensitive. Downstream operations, such as brokerage & consumption, are typically asynchronous – each Member State may need to decide when to update their specifications and consequently adopt some of the value sets. This will of course impact interoperability, as systems running different versions of the reference data sets may present some interoperability issues.

These issues should be acknowledged and addressed in a master / reference data management and usage strategy, focused on operational needs. The mechanisms can be data quality controls, semantic alignment checks, real-time error-checking, etc. − their design is beyond the scope of this document, but after the analysis of the specifications in this document, it is recommended that such strategy is defined.