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WP5 – IDMP adoption by eHealth Services

D5.7: Common minimum data set for implementation in the national NCA and eHealth solutions

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Deliverable abstract

To further improve the implementation of IDMP, it is also necessary to define a minimum dataset to ensure the implementation of the ISO IDMP data for eHealth proposes, set the ground for a basic understanding of the data, and allow enrichment of the current clinical documents.

The availability of a common minimum dataset recognises that each country or region may have a complex set of codes and attributes required to support local healthcare activities regarding the identification of medicinal products. By identification the 'minimum' dataset for cross-border exchange of healthcare information it is possible to provide a basic common set of information that will support the medicinal production data exchange for the different services associated with them.

This document presents a common minimum data set that needs to be implemented in the national NCA and eHealth provider to further support and facilitate the integration of IDMP into National systems.

Keywords:

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List of abbreviations

Abbreviation	Complete form
Ag	Agency
ATC	Anatomical Therapeutic Chemical Classification
CBeHIS	Cross-Border eHealth Information Services
CDA	Clinical Document Architecture
CEF	Connecting Europe Facility
CoE	Community of Expertise
CP	Change Proposal
D	Deliverable
DDD	Defined Daily Dose
eD	Electronic Dispensation
EDQM	European Directorate for the Quality of Medicines
eHDSI	eHealth Digital Service Infrastructure
eHN	eHealth Network
eHOMB	eHealth Operational management Board
EMA	European Medicines Agency
EMA IG	European Medicines Agency - Implementation Guide
eP	Electronic Prescription
EU	European Union
EUTCT	European Union Telematics Controlled Terms
FHIR	Fast Health Interoperability Resources
IDMP	Identification of Medicinal Products
ISO	International Organisation for Standardization
MALeH	Minimum Attributes List for eHealth
MoH	Ministry of Health
MPID	Medicinal product identifier
MVC	Master Value Set Catalogue
NCA	National Competent Authority
NCPeH	National Contact Point eHealth
OID	standard Object Identifier

OMS	Organisation Management Services
PCID	Packaged Medicinal Product Identifier
PhPID	Pharmaceutical Product Identifier
PMS	Product Management Services
PPL	Pilot Product List
PPT	Pre-Production Test
PS	Patient Summary
RMS	Referentials Management Services
RoA	Rout of Administration
SMS	Substance Management Services
SPOR	Substance, Product, Organisation and Referential
UFIS	UNICOM FHIR IDMP Server
UML	Unified Modelling Language
URL	Uniform Resource Locator
VMPP	Virtual Medicinal Packaged Product
WP	Work Package

Executive summary

The work previously completed on the WP5 deliverables has defined the guidelines and semantic specifications for the adoption of ISO IDMP in the eHealth services at national level, and their connections to the Medicinal Products databases both from National Competent Authorities (NCAs) and private providers. To further improve the implementation of IDMP, it is also necessary to define a minimum dataset to ensure the implementation of the ISO IDMP data for eHealth proposes, set the ground for a basic understanding of the data, and allow enrichment of the current clinical documents.

The availability of a common minimum dataset recognises that each country or region may have a complex set of codes and attributes required to support local healthcare activities regarding the identification of medicinal products. These datasets may be standardised through a national medicinal product dictionary, or they may be present across various drug files supporting local use cases. However, by identifying the 'minimum' dataset for cross-border exchange of healthcare information it is possible to provide a basic common set of information that will support the medicinal production data exchange for the different services associated with them.

In that sense, this document has defined a minimum dataset for the adoption of ISO IDMP in the eHealth services at national and cross-border levels. Also, presents a common minimum data set that needs to be implemented in the national NCA and eHealth provider to further support and facilitate the integration of IDMP into National systems. Guidelines targeted at NCA's, and eHealth agencies will also be designed in order to support this implementation.

1 Introduction and Background

1.1 Background

The UNICOM project intends to facilitate the overall implementation of the ISO IDMP (Identification of Medicinal Products) standards that provide the basis for the global identification of medicinal products. ISO IDMP is comprised by five ISO (International Organisation for Standardization) standards, which together, describe a standard data model for the proper identification and description of medicinal products and related concepts (Figure 1). Currently the Medicinal/Pharmaceutical products are described in a wide variety of forms and records among countries. By this project, the proposed work intends to support and facilitate the further development of ISO IDMP standards, its adaptation to the various (new) requirements which have or will arise, as well as to promote the successful implementation of ISO IDMP standards across countries, to allow the univocal identification of medicinal products across the European Union and globally.

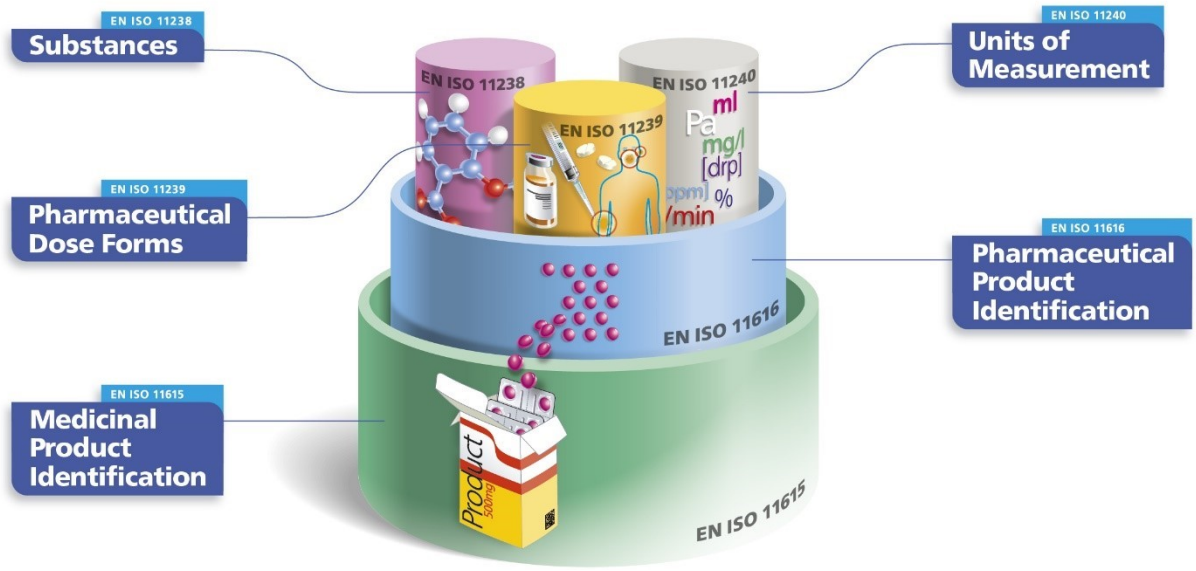

Figure 1: The 5 ISO standards used to identify medicinal products

There are many significant predictable benefits to the application of ISO IDMP that will invariably impact many domains, particularly through improved and safe semantic interoperability across language and other aspects related to data and information, such as the regulatory field, the clinical context and pharmacovigilance applications. Also, the ISO IDMP implementation will impact the commercial / non-commercial entities regarding their global competitive advantage. Therefore, the application of ISO IDMP is fundamental to contribute to the safe prescription and dispensation of medicines, in all its evolving environment.

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 and deliver better patient outcomes. The absence of clear and concise identification of medicines may have a negative impact on the safe delivery of cross-border healthcare.

In response, 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 this regard, eHDSI has started deploying the core and generic services, as defined in the CEF, for Patient Summary (PS) and ePrescription/eDispensation (eP/eD). The generic

services are the necessary implementation of data exchange at country level, and 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 development of IDMP as a global standard for the univocal identification of medicines for cross-border ePrescription and eDispensation.

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

Specifically, WP 5 (Figure 2) is tasked with the IDMP adoption in Member State eHealth services by coordinating the adoption of these standards at both national and cross-border levels. This WP5 concerns the overall orchestration to adopt ISO IDMP in eHealth Services, at national and cross-border levels, with a focus on cross-border on ePrescription (eP) and Patient Summary (PS) use cases at cross-border level, without disregarding other scenarios on prescribing (e.g., hospital prescriptions) and referring to medicinal products (e.g., medication plans, continuity of care documents, hospital discharge letters etc). It will be also driven by the state of IDMP adoption in EU eHealth services, including the significant challenges to be faced, current rates of adoption, public policy status and principal adoption methods. Medicinal product dictionaries provide a reference for the consistent naming of medicines within a particular region or country and enable interoperability and accurate identification of medicines across the healthcare service. These elements will be defined as reusable building blocks for medicinal product identification.

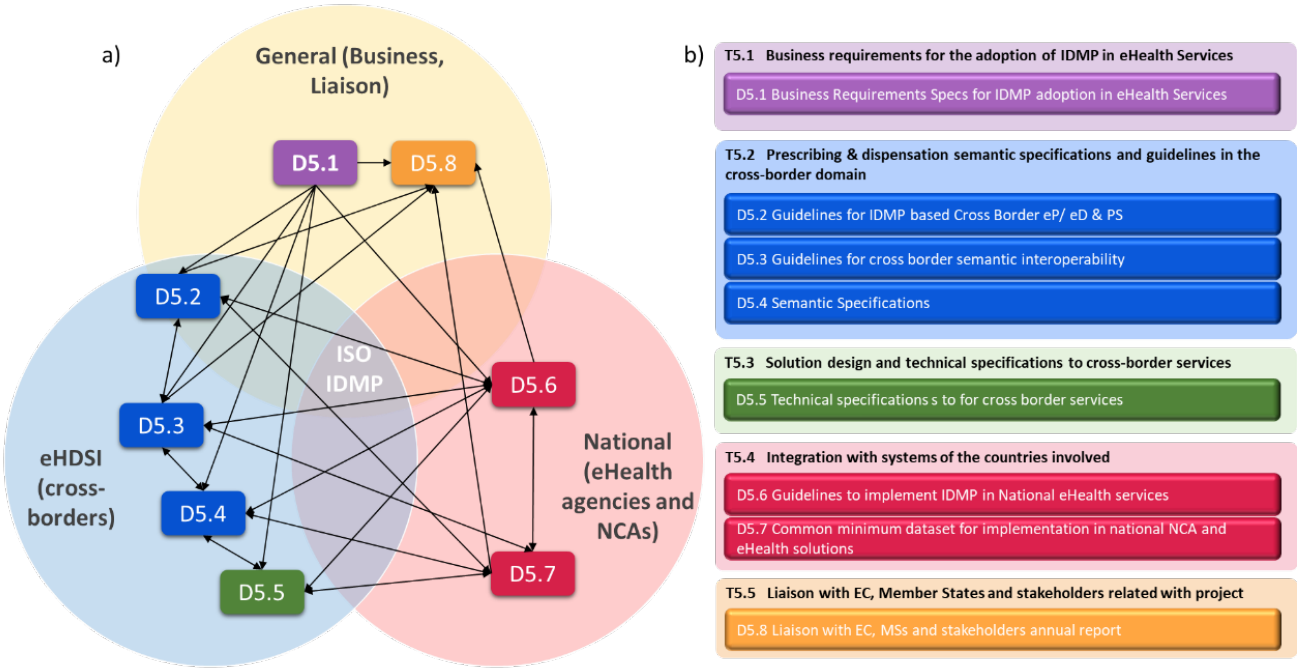

Figure 2: The WP5 deliverables relationship.

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

1.2 Introduction to D5.7

The complexity of identifying medicinal products among Member States in their eP/eD & PS systems means it is essential to ensure the alignment of the elements and attributes to support the full implementation of the IDMP standards.

The work previously completed as part of deliverable '*D5.6 - Guidelines to implement IDMP in National eHealth Services defined the guidelines for the adoption of IDMP in all Member States*' has defined the guidelines for the adoption of ISO IDMP in the eHealth services at national level, and their connections to the Medicinal Products databases both from National Competent Authorities (NCAs) and private providers. To further improve the implementation of IDMP, it is also necessary to define a minimum dataset to ensure the implementation of the ISO IDMP data for eHealth proposes, set the ground for a basic understanding of the data and allow enrichment of the current clinical documents.

Some benefits of having a minimum dataset are that it concentrates on the essential elements (approximately 20 variables) of IDMP description of Medicinal product Packs, without going into the details of the full implementation of IDMP (approximately 100 variables). The full implementation is important for the full regulatory description with all the details of the packaging, which are out of scope of this project.

The availability of a common minimum dataset recognises that each country or region may have a complex set of codes and attributes required to support local healthcare activities. These datasets may be standardised through a national medicinal product dictionary, or they may be present across various drug files supporting local use cases. However, by identifying the 'minimum' dataset for cross-border exchange of healthcare information this package will:

- Support eHealth services in the identification of essential pre-requisite attributes
- Support eHealth services in the strategic prioritisation of IDMP pre-requisite attributes (i.e., provides attributes specific to eHealth operations rather than pharmacovigilance activities)
- Provides granularity of detail sufficient to identify which attributes are pre-requisite for specific eHealth services (eP, eD, PS)
- Provides transparency around common data sources for coding of identified attributes.

Therefore, this task will define a minimum dataset for the adoption of ISO IDMP in the eHealth services at national level. Importantly, the outputs of previous deliverables (Figure 2) will be used as the basis for D5.7 to build up meaningful and useful information for NCAs and eHealth agencies to adopt ISO IDMP in their respective systems. The final deliverables can be found on the UNICOM website[3] after the approbation of by the European commission.

1.3 Scope of the document

This document intends to present a common minimum data set that needs to be implemented in the national NCA and eHealth provider to further support and facilitate the integration of IDMP into National systems. Guidelines targeted at NCA's, and eHealth agencies will also be designed in order to support this implementation.

[3] https://unicom-project.eu/public-deliverables/

2 Overview of the state of play from NCAs and eHealth agencies

The eHealth Agencies play a central role on provision of the services such as eP, eD and PS. In alignment with eHDSI, each Member State has their governance model, in which generally, the Ministry of Health (MoH) regulates this activity or attributes this responsibility to a specific national agency, under the direction of the MoH.

To provide trusted information about the medicinal products on the eHealth services, the eHealth agencies require this information from the NCAs who are responsible for the regulatory process and provision of all medicinal product information in their respective country / region. This bridge between the eHealth agency and the NCA is fundamental to the success and correct provision of eHealth services.

Currently, eHealth services are available beyond the national boundary, through the eHDSI infrastructure that ensures the provision of the eP/eD and PS among the European Union (EU) Member States at the cross-border level. In this case, the exchange of clinical documents happens through the National Contact Point for eHealth (NCPeH), that 'transforms' the national document from Country A (Country of origin) into an interoperable format (at eHDSI), that will be read and 're-transformed' into a national format in Country B (country of treatment/dispensation). This process is required to ensure that all information in the original document from Country A will be issued and 'understood' in Country B, avoiding errors and misinterpretation.

Currently, the eHDSI infrastructure counts with several European countries that are onboarding in the cross-borders services. Many of these countries are also participating in the UNICOM project as can be seen in Table 1. The implementation and the operationalisation of these services follows the eHDSI Waves calendar, in which each wave represents a period of 1 year (from September to August of the following year).

The implementation of the ISO IDMP will provide a way to address the issues currently encountered in these services, such as the difficulty associated with the correct identification of medicines in a cross-border context. Furthermore, it will also improve medicines identification through the use of minimum attribute data, which can help to ensure a safer dispensation. Section 3 will provide more information regarding this minimum attribute data.

Importantly, the presence of 7 countries (Austria, Croatia, Estonia, Finland, Ireland, Portugal, and Sweden) where both eHealth agencies and NCAs are present in the UNICOM project, can speed up the process of IDMP implementation at the national/regional and eHDSI level. Moreover, this set of Member States can also support the piloting phase of UNICOM, where is intended to achieve at least 10.000 eP and 1.000 PS with IDMP data, from real eP/eD & PS. Currently, several countries are already in operation (Croatia, Estonia, Finland and Portugal), and these represent good candidates to participate in the UNICOM pilots. In addition, Table 1 shows the countries/regions, onboard on UNICOM, that plan to start operations for each service in line with the future eHDSI waves (6 to 8). UNICOM pilots are expected to start on wave 6 timeline, meaning four additional countries/regions are also potential pilot candidates.

Table 1: Cross-border state of play of UNICOM onboard agencies

Country participating in UNICOM / eHDSI	NCA	eHealth Agency	eHDSI operation (Wave(s))[4]			
			eP/eD A	eP/eD B	PS A	PS B
Austria	AGES	ELGA	7	7	-	-
Belgium	AFMPS	-	-	-	7	7
Croatia*	HALMED	HZZO	2	1	3	2
Estonia*	EESAM	TEHIK	1	1	5	5
Finland*	FIMEA	KELA	1	1	6	7
Germany	BFARM	-	-	-	-	-
Greece	-	IDIKA	5	5	5	5
Ireland	HPRA	IEDoH	5	6	5	6
Region of Lombardia, Italy	-	ARIA / REGLOMB	6	6	6	6
Netherlands	-	NICTIZ	-	-	-	5
Norway	NOMA	-	7/8	7/8	7/8	7/8
Portugal*	INFARMED	SPMS	2	2	2	2
Spain*	AEMPS	SAS	6	6	5	5
Sweden	SE-MPA	SEHA	6	6	-	-

*In operation on eHDSI Cross-Borders.

2.1.1 Status of the IDMP implementation on NCAs

The Regulation (EU) No 520/2012[5] from the European Commission (Chapter IV - articles 25 and 26) states the use of the ISO IDMP on the different stakeholders related to the Medicinal Products identification, such as: Member States, European Medicines Agency (EMA), and marketing authorisation holders. From this, it is expected that the NCAs be the first national authority to implement the ISO IDMP to allow data consumption by the eHealth agencies, pharmacies, and other related stakeholders. The UNICOM project supports national stakeholders on this task by exchanging expertise between partners and supporting the national implementation.

To ensure the use of the ISO IDMP on the whole medicinal product chain, it is fundamental that NCAs which integrate this project are able to implement the IDMP on their systems, and gradually, update their data models with IDMP data. Currently the UNICOM consortium counts 11 NCAs that present different stages of IDMP implementation. The individual status of the implementation on each Member

[4] https://webgate.ec.europa.eu/fpfis/wikis/pages/viewpage.action?pageId=888405224
https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSIEHMSEG/MS+deployment+and+improvement+plans
Waves calendar: Wave 1: [2018-2019] / Wave 2: [2019-2020] / Wave 3: [2020-2021] / Wave 4: [2020-2021] / Wave 5: [2021-2022] / Wave 6: [2022-2023] / Wave 7 [2023-2024]

[5] https://eur-lex.europa.eu/eli/reg_impl/2012/520/oj .

State can be found on the following references: Austria[6], Belgium[7], Croatia[8], Estonia[9], Finland[10], Germany[11], Ireland[12], Norway[13], Portugal[14], Spain[15], Sweden[16],

Each NCA has presented their own strategy to implement the IDMP data in their database. Some NCAs have opted refactoring the current databases to be compliant with ISO IDMP, others have directed their efforts to build a new database and several NCAs have opted for cleansing and mapping their current database with the IDMP data. The common process between all NCAs is the use of the EMA Substance, Product, Organisation and Referential (SPOR) lists for referring the terminologies since it is already on IDMP format. Wherever the strategy, all NCAs are working towards implementing IDMP data (linked with SPOR) in their systems.

Currently, the 'Organisation Management Services' (OMS) and 'Referentials Management Services' (RMS) are already available on the SPOR website[17]. The 'Substance Management Services' (SMS) has released its lists through the European Union Telematics Controlled Terms (EUTCT)[18] or IRIS[19]; and, as of the publication of this document, the 'Product Management Services' (PMS) has not yet been released (please, see more details on section '3.2.1').

The deliverables referenced above provide more detailed information of the status of each NCA (footnotes 6 to 16). Nonetheless, in general, each NCA is advancing the mapping/refactoring of their medicinal products databases initially based on the SPOR-OMS and –RMS codes. The following steps include the work with SPOR-PMS and – SMS codes, which are expected to be released in the upcoming months.

For UNICOM, it is expected that the NCAs will provide, in the initial phase, a small set of IDMP attributes (see chapter Minimum Attributes List for eHealth (MALeH) to eP/eD & PS) for a subset of medicines defined on the UNICOM 'Pilot Product List' (PPL).

The PPL is a sample list of 35 substances 35 groups of substances with the role of precise active ingredient, sharing the same moiety, represented by 60 Pharmaceutical Products at level 1. (Annex 1 – Pilot Product List (PPL)). These substances represent frequently dispensed medicines, medicines targeted in the cross-border projects, and medicines with interesting implementation challenges for IDMP. After UNICOM eHealth pilots, NCAs will be encouraged to expand this initial list in order to have a full IDMP-compliant database aligning to their own roadmap.

The provision of standardised IDMP data by the NCAs will support interoperability between the IT systems and strengthen cross-border services by promoting the correct identification of medicinal products and consequently increase the safety and frequency of successful cross-border dispensations through a system that enables an unequivocal identification of the medicines.

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[6] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.1_Austria_Progress-report-on-implementation_20210201.pdf

[7] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.9_Afmps_Belgian-Progress-Report-_20210604.pdf

[8] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.10_Croatia-Progress-report-on-implementation_20210131.pdf

[9] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.2_Estonia-Progress-report-on-implementation_20210131.pdf

[10] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.3_Finland_Progress-report-on-implementation_20210131.pdf

[11] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.4-Germany-Progress-report-on-implementation_20210226.pdf

[12] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.5_Ireland_Progress_report-on-implementation_20210131.pdf

[13] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.6_Norway-Progress-report-on-implementation_20210226.pdf

[14] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.11_Portugal-Progress-report-on-implementation_20210226.pdf

[15] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.7_Spain-Progress-report-on-implementation_20210131.pdf

[16] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.8_Sweden-Progress-report-on-implementation_20210131.pdf

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

[18] http://eutct.ema.europa.eu/

[19] https://iris.ema.europa.eu/substances/

3 Minimum Attributes List for eHealth (MALeH) to eP/eD & PS

The description of each medicinal product can be done by using attributes that represent all the essential features of the medicinal product for their respective identification. Such attributes can be found on the EMA Implementation Guide (EMA IG) Version V2.1[20]. This EMA IG guideline presents a list of approximately 200 items, which are fundamental to represent all the attributes necessary to cover the lifecycle of a medicinal product. However, it is important to highlight that only a small set of attributes relate to the ISO IDMP specifications are required to issue clinical documents (eP/eD & PS). In that sense, this document will focus on the key attributes required to issue the clinical documents (eP/eD & PS).

In order to identify all attributes relevant to the ISO IDMP implementation from the EMA IG Version V2.1, the UNICOM FHIR IDMP Server (UFIS) working group has identified approx. 65 attributes. Based on the key elements for eP/eD and PS, this list of attributes was further reviewed and aligned to the current eHDSI data elements to achieve the critical minimum set of attributes necessary for the referred eHealth services at the cross-border level.

The first version of the Minimum Attribute List for eHealth (MALeH) was analysed and presented within '*D5.3 - Guidelines for cross-border semantic interoperability*', which was further refined and updated in '*D5.4 - Semantic Specifications*'. This list was subject to multiple rounds of discussion and alignment with UNICOM partners and other stakeholders (e.g., eHealth Network – eHN and eHDSI). One key outcome of this process was the co-creation of the Change Proposal-066 – '*Prepare eHDSI Requirements Catalogue for ISO IDMP'* (CP-066 - Annex 2 – CP-eHDSI-066: Prepare eHDSI Requirements Catalogue for ISO IDMPAnnex 1 – Pilot Product List (PPL)

The PPL contains 35 substances (PhPID L1) that have been selected for the UNICOM pilots and should be considered by NCAs and eHealth Agencies when planning the Pilots / data provision.

Table 8: Pilot Product List

#	Moiety	Salt/ester/modification (and notes, synonyms)
1	simvastatin	
2	enalapril	enalapril sodium
		enalapril maleate
		enalaprilat
3	omeprazole	omeprazole sodium
		omeprazole magnesium
4	diclofenac	diclofenac sodium
		diclofenac potassium
		diclofenac diethylamine (synonym: diclofenac diethylammonium)
		diclofenac epolamine
5	cefuroxime	cefuroxime sodium
		cefuroxime axetil

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

Due to the differences on the names and meaning of the EMA IG attributes, when compared with the eHDSI data elements, we would like to advise to consider the indicative numbers of EMA attributes and go deep on the EMA IG definitions to avoid misunderstood on the interpretation of the data.

#	Moiety	Salt/ester/modification (and notes, synonyms)
6	salbutamol	salbutamol sulfate
7	amoxicillin and clavulanic acid	amoxicillin (anhydrous, explicitly)
		amoxicillin (unspecified)
		clavulanic acid
		amoxicillin sodium
		amoxicillin trihydrate
		potassium clavulanate
8	insulin glargine	
9	teriparatide	
10	drospirenone and ethinylestradiol	drospirenone
		ethinylestradiol
11	atorvastatin, amlodipine and perindopril	
12	calcium + vitamin D	calcium carbonate
		ergocalciferol
13	paracetamol	
14	diazepam	
15	morphine	morphine hydrochloride
		morphine sulfate
		morphine tartrate
		morphine liposomal (sulfate)
16	enoxaparin	enoxaparin sodium
17	hydrocortisone	hydrocortisone sodium succinate
		hydrocortisone valerate
		hydrocortisone acetate
		hydrocortisone butyrate
		hydrocortisone aceponate
		hydrocortisone probutate (synonyms: butyrate propionate; buteprate)
		hydrocortisone cypionate
		hydrocortisone sodium phosphate
18	lidocaine	lidocaine hydrochloride
		also tosilate, hydrocarbonate, bicarbonate, maleate, carbonate - but not used in products?
19	trastuzumab	trastuzumab emtansine (synonym: ado-trastuzumab emtansine)
		trastuzumab deruxtecan
20	imatinib	imatinib mesilate
21	clomipramine	clomipramine hydrochloride
22	carbamazepine	
23	metformin	metformin hydrochloride
		metformin pamoate (synonym: metformin embonate)
24	amlodipine	(racemic)
		amlodipine besilate
		amlodipine benzoate
		amlodipine maleate

#	Moiety	Salt/ester/modification (and notes, synonyms)
25	perindopril	perindopril arginine
		perindopril erbumine (synonym: perindopril tert-butylamine)
		perindopril erbumine monohydrate
		perindopril tosilate
26	tramadol	(racemic)
		tramadol hydrochloride
27	ciclosporine	Synonym: ciclosporin A
28	itraconazole	itraconazole trihydrochloride
29	goserelin	goserelin acetate
30	glyceryl trinitrate	nitroglycerin
31	chloroquine	chloroquine phosphate
		chloroquine sulfate
		chloroquine hydrochloride
32	clotrimazole	
33	varenicline	
		varenicline tartrate
		varenicline dihydrochloride
34	ibuprofen	(racemic)
		ibuprofen sodium
		ibuprofen lysine
35	tafluprost	

Annex 2 –) that will impact wave 6 of eHDSI. Therefore, the MALeH presents the minimum data that meets the expectations of the project and cross-border services.

As mentioned, from the initial UFIS list, MALeH is composed by attributes that were identified as essential and represent the minimum data required for eHealth services (Table 2). These attributes are IDMP-compliant and were aligned with eHDSI Master Value Set Catalogue (MVC)[21] and EMA IG V2.1.

The other attributes highlighted initially in the UFIS list are relevant for other areas of the medicinal product lifecycle, such as pharmacovigilance, and, thus, were not selected because they are out of the scope of eHealth services.

Considering the above, Table 2 presents the minimum dataset for eHealth services, their relationship with the eHDSI data elements, EMA IG and the recommended coding system to represent data when applicable. All the indicated preferred coding systems are international standards. The lines in the table with dark blue background bold indicate the main sections and subsections of attributes based on the organization of the EMA IG. Importantly, one medicinal product may have duplicate attributes, such as in cases of having two active ingredients or having two different units of presentation forms. The table below is a flat representation that allows to represent different levels of information, such as those mentioned above. The next subsection will provide an explanation and further detailed this table.

[21] For the coding system IDs of the MVC 6.1.0, please see Annex 3 – Code Systems in MVC 6.1.0.

Table 2: MALeH and their relationship with eHDSI data elements

EMA SPOR			eHDSI MVC 6.1.0[21]		
#	Attributes from EMA IG V2.1	EMA-SPOR database	Preferred coding system	eHDSI Data Elements[22]	Value Set name
1.	**Medicinal Product**				
1.1	Product Management Service Identifier (PMS ID)			Medicinal Product Code	
1.2	Medicinal Product Identifier (MPID)				
1.5	**Authorised Pharmaceutical Form***	RMS	EDQM	Pharmaceutical Dose Form	eHDSIDoseForm
1.13	Product classification				
1.13.3	**ATC code(s)***	RMS	WHO - ATC	ATC code	eHDSIActiveIngredient
1.14	Medicinal Product Name				
1.14.1	Full name			Brand Name of the Medicinal Product	
2.	**Marketing Authorisation Information**				
2.8	Marketing Authorisation Holder	OMS	SPOR-OMS	Marketing Authorisation Holder of the prescribed medicinal product	
4.	**Packaged Medicinal Product**				
4.1	Packaged medicinal product Identifier (PCID)			Medicinal Product Code	
4.3	Pack size**		EDQM	Medicinal Product Package	eHDSIQuantityUnit
4.7	Package item (container)**				
4.7.1	**Package item (container) type***	RMS	EDQM	Medicinal Product Package	eHDSIPackage
4.7.5	Package item (container) quantity				
4.10	Manufactured Item				
4.10.1	Unit of Presentation	RMS	EDQM		eHDSIQuantityUnit
4.10.2	**Manufactured Item Quantity***	RMS	UCUM	Package size	eHDSIUnit
4.10.3	Manufactured Dose Form	RMS	EDQM	Pharmaceutical Dose Form	eHDSIDoseForm
5	**Ingredient**				
5.1	Ingredient role	RMS	SPOR-RMS		
5.5	Substance				
5.5.1	Substance	SMS	SPOR-SMS	Active Ingredient	eHDSISubstance
5.5.2	Strength (quantitative composition)				
5.5.2.2.2	Strength (Presentation single value or low limit)	RMS	UCUM	Strength of the Medicinal Product	eHDSIUnit
5.5.2.3.2	Strength (Concentration single value or low limit)	RMS	UCUM		eHDSIUnit
5.5.3.	Reference Strength				
5.5.3.1	**Reference Substance***	SMS	SPOR-SMS	Active Ingredient	eHDSISubstance
5.5.3.3.2	**Reference Strength (Presentation single value or low limit)***	RMS	UCUM	Strength of the Medicinal Product	eHDSIUnit
5.5.3.4.2	**Reference Strength (Concentration single value or low limit)***	RMS	UCUM		eHDSIUnit
6.	**Pharmaceutical Product**				
-	Pharmaceutical Product identifier (PhPID)[23]			Medicinal Product Code	

[22] 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
For some eHDSI data elements there are more than one correspondence of EMA attributes. In those case, the eHDSI data elements are repeated in this column.

[23] Note: This version of the guidance does not report information on additional identifiers such as the Pharmaceutical Product Identifier (PhPID). Further details on the related definitions and defining elements will be available at later stage as it requires further discussions prior the implementation.

6.2	Administrable Dose Form	RMS	EDQM	Pharmaceutical Dose Form	eHDSIDoseForm
6.3	**Unit of Presentation***	RMS	EDQM	Foreseen to wave 6[24]	eHDSIQuantityUnit
6.6	**Route(s) of Administration***	RMS	EDQM	Route of Administration	eHDSIRouteof Administration

***** The attributes marked in **bolt should be preferred** over similar ones (e.g., dose forms and unit of presentation) and considered as highly recommended. The reader is advised to read the next section for further details.

******Pack size and Package item (container) should be considered optional for simple-type package medicines, but mandatory for complex packaging medicines (e.g., box containing 'tables + cream', or 'vial + syringe', etc.).

3.1 MALeH Attributes explanation and examples

The provision of the eP/eD and PS in a cross-border scenario requires the exchange of health data between different stakeholders. The medicinal product information is provided by the NCAs to the eHealth agencies that use this data to issue the clinical document and that can be consumed at national or cross-border levels (when applicable). At the cross-border level, the data from the clinical document is 'transformed' in an interoperable format at the NCPeH-A and exchanged through the eHDSI infrastructure to the NCPeH-B to complete the exchange and provide the service to the end-user.

To ensure that all stakeholders involved in the eHealth services can communicate in an interoperable way, the definition of a minimum attribute list is essential to support all the actors of project and the stakeholders so that they can use the same minimum information to issue the eHealth services -aligned to ISO IDMP standards.

In this section, you can find the justification of all required attributes based on their grouping. Note that some attributes intend to support the identification of complex package medication accordingly to the eHDSI CP-063 – '*Improve Medication Information Representation*' (Annex 4 – CP-eHDSI-063: Improve Medication Information Representation) and are not required for the representation of most medicinal products.

The following diagram (Figure 3) presents the relationship and differences between the different sets of attributes and their implementations.

[24] The eHDSI Wave 6 is scheduled to starts in September 2022 and finishes in August 2023. For more details see chapter '

Roadmap with the eHDSI implementation

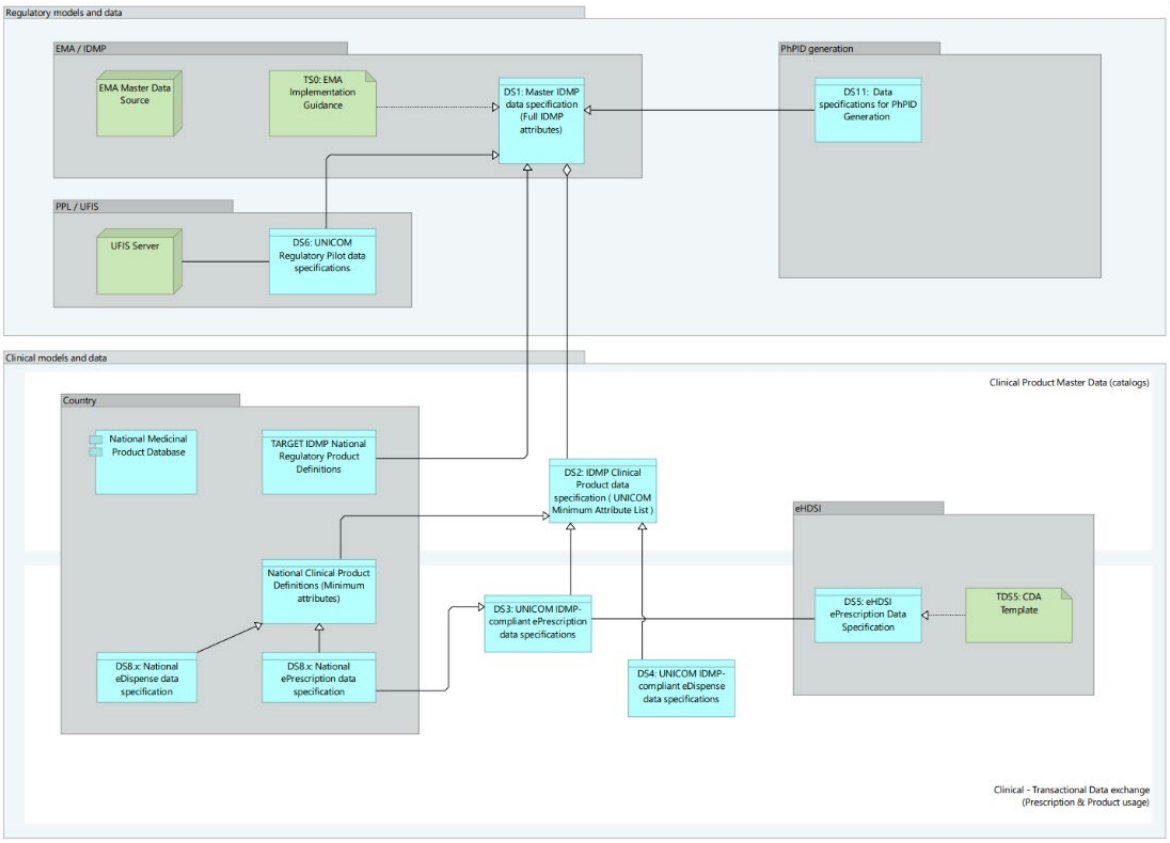

Figure 3: Relationship between different sets of attributes and actors

In summary,

- ISO IDMP defines all the attributes that can be used in identifying and describing a medicinal product.
- The EMA Implementation Guide is based on those attributes and defines a technical format for exchanging those attributes and provides any additional constraints – in other words the EMA Implementation Guide is a specialisation of the ISO IDMP attributes.
- UNICOM defined a standard set of product attributes for the regulatory space in the scope of the Pilot Product List (then implemented in the UFIS server).
- For clinical purposes, the smaller set of attributes (MALeH) is a subset or specialisation of the full attribute list – this means that the products are defined in the regulatory domain, and the clinical domain uses a subset of the attributes.

The MALeH, as is shown in the UNICOM WP5 deliverables, is derived from its “superset” (all IDMP attributes from EMA IG v2.1) - the IDMP attributes in the regulatory space. This ensures consistency, while allowing the clinical domain to advance with the critical data while expecting the regulatory data to be present at any present or future stage.

The EMA IG and eHDSI sometimes presents similar names to describe the attributes, however with different meaning. In that sense is important for the reader to ensure to consult the correct reference to avoid misunderstanding. Below on the description of the attributes there are some examples regarding this issue.

From the Wave 6 (2022-2023), the eHDSI infrastructure will present in their system the fields for the IDMP identifiers (PhPID, MPID and PCID). However, as the IDMP identifiers are not yet available, the national identifiers shall continue be used on cross-border services, in the same way that this service is provided currently. Annex 3 – Code Systems in MVC 6.1.0

The Table 9 presents the coding systems and their identifiers codes used in the eHDSI MVC 6.1.0 for eHDSI wave 6 (2022-2023).

Table 9: Code Systems in MVC 6.1.0

Value Set name	Value Set ID	Code System(s)	Code System(s) ID	Version(s) of Code System used in MVC
eHDSIAbsentOrUnknownAllergy	1.3.6.1.4.1.12559.11.10.1.3.1.42.47	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	0.2.0
eHDSIAbsentOrUnknownDevice	1.3.6.1.4.1.12559.11.10.1.3.1.42.48	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	0.2.0
eHDSIAbsentOrUnknownMedication	1.3.6.1.4.1.12559.11.10.1.3.1.42.49	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	0.2.0
eHDSIAbsentOrUnknownProblem	1.3.6.1.4.1.12559.11.10.1.3.1.42.50	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	0.2.0
eHDSIAbsentOrUnknownProcedure	1.3.6.1.4.1.12559.11.10.1.3.1.42.51	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	0.2.0
eHDSIActiveIngredient	1.3.6.1.4.1.12559.11.10.1.3.1.42.24	ATC Classification	2.16.840.1.113883.6.73	2022-01
eHDSIAdministrativeGender	1.3.6.1.4.1.12559.11.10.1.3.1.42.34	HL7 v3 AdministrativeGender	2.16.840.1.113883.5.1	20210930
eHDSIAdverseEventType	1.3.6.1.4.1.12559.11.10.1.3.1.42.18	SNOMED CT	2.16.840.1.113883.6.96	44469
eHDSIAllergenNoDrug	1.3.6.1.4.1.12559.11.10.1.3.1.42.19	SNOMED CT	2.16.840.1.113883.6.96	43677 44469
eHDSIAllergyStatus	1.3.6.1.4.1.12559.11.10.1.3.1.42.59	FHIR Allergy Intolerance Clinical Status Codes	2.16.840.1.113883.4.642.4.1373	4.0.1
eHDSIBloodGroup	1.3.6.1.4.1.12559.11.10.1.3.1.42.20	SNOMED CT	2.16.840.1.113883.6.96	43677
eHDSIBloodPressure	1.3.6.1.4.1.12559.11.10.1.3.1.42.21	LOINC	2.16.840.1.113883.6.1	2.59
eHDSICertainty	1.3.6.1.4.1.12559.11.10.1.3.1.42.58	FHIR Allergy Intolerance Verification Status Codes	2.16.840.1.113883.4.642.4.1371	4.0.1
eHDSICodeProb	1.3.6.1.4.1.12559.11.10.1.3.1.42.23	SNOMED CT	2.16.840.1.113883.6.96	43677
eHDSIConfidentiality	1.3.6.1.4.1.12559.11.10.1.3.1.42.31	HL7 v3 Confidentiality	2.16.840.1.113883.5.25	913-20091020
eHDSICountry	1.3.6.1.4.1.12559.11.10.1.3.1.42.4	ISO 3166-1 Country codes (Alpha-2 code)	1.0.3166.1	Second Edition 2006
eHDSICriticality	1.3.6.1.4.1.12559.11.10.1.3.1.42.57	FHIR Allergy Intolerance Criticality	2.16.840.1.113883.4.642.4.130	4.0.1
eHDSICurrentPregnancyStatus	1.3.6.1.4.1.12559.11.10.1.3.1.42.60	SNOMED CT	2.16.840.1.113883.6.96	44469
eHDSIDisplayLabel	1.3.6.1.4.1.12559.11.10.1.3.1.42.46	epSOSDisplayLabel	1.3.6.1.4.1.12559.11.10.1.3.1.44.4	1.5

Value Set name	Value Set ID	Code System(s)	Code System(s) ID	Version(s) of Code System used in MVC
eHDSIDocumentCode	1.3.6.1.4.1.12559.11.10.1.3.1.42.32	LOINC	2.16.840.1.113883.6.1	2.59
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	44579
eHDSIHealthcareProfessionalRole	1.3.6.1.4.1.12559.11.10.1.3.1.42.1	ISCO-08	2.16.840.1.113883.2.9.6.2.7	2008
eHDSIHospitalDischargeReportType	1.3.6.1.4.1.12559.11.10.1.3.1.42.53	LOINC	2.16.840.1.113883.6.1	2.59
eHDSIIllnessandDisorder	1.3.6.1.4.1.12559.11.10.1.3.1.42.5	ICD-10 International Statistical Classification of Diseases and Related Health Problems 10th Revision	1.3.6.1.4.1.12559.11.10.1.3.1.44.2	2016
eHDSILaboratoryReportType	1.3.6.1.4.1.12559.11.10.1.3.1.42.52	LOINC	2.16.840.1.113883.6.1	2.59
eHDSILanguage	1.3.6.1.4.1.12559.11.10.1.3.1.42.6	ISO 639-1 + ISO 3166-1	1dd183a6-6d2b-4a9d-8f5d-be09d6bb5a6e	March 2017
eHDSIMedicalDevice	1.3.6.1.4.1.12559.11.10.1.3.1.42.8	SNOMED CT	2.16.840.1.113883.6.96	43677 44469
eHDSIMedicalImagesType	1.3.6.1.4.1.12559.11.10.1.3.1.42.55	LOINC	2.16.840.1.113883.6.1	2.59
eHDSIMedicalImagingReportType	1.3.6.1.4.1.12559.11.10.1.3.1.42.54	LOINC	2.16.840.1.113883.6.1	2.59
eHDSINullFlavor	1.3.6.1.4.1.12559.11.10.1.3.1.42.37	HL7 v3 NullFlavor	2.16.840.1.113883.5.1008	913-20091020
eHDSIOutcomeOfPregnancy	1.3.6.1.4.1.12559.11.10.1.3.1.42.62	SNOMED CT	2.16.840.1.113883.6.96	44469
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	44579
eHDSIPersonalRelationship	1.3.6.1.4.1.12559.11.10.1.3.1.42.38	HL7 v3 RoleCode	2.16.840.1.113883.5.111	913-20091020
eHDSIPregnancyInformation	1.3.6.1.4.1.12559.11.10.1.3.1.42.9	LOINC	2.16.840.1.113883.6.1	2.59
eHDSIProcedure	1.3.6.1.4.1.12559.11.10.1.3.1.42.10	SNOMED CT	2.16.840.1.113883.6.96	43677 44469
eHDSIQuantityUnit	1.3.6.1.4.1.12559.11.10.1.3.1.42.56	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	44579
eHDSIRareDisease	1.3.6.1.4.1.12559.11.10.1.3.1.42.63	ORPHAnet	1.3.6.1.4.1.12559.11.10.1.3.1.44.5	44683
eHDSIReactionAllergy	1.3.6.1.4.1.12559.11.10.1.3.1.42.11	SNOMED CT	2.16.840.1.113883.6.96	43677 44469
eHDSIResolutionOutcome	1.3.6.1.4.1.12559.11.10.1.3.1.42.30	SNOMED CT	2.16.840.1.113883.6.96	43677
eHDSIRoleClass	1.3.6.1.4.1.12559.11.10.1.3.1.42.39	HL7 v3 RoleClass	2.16.840.1.113883.5.110	913-20091020
e.g.,	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	44579
eHDSISection	1.3.6.1.4.1.12559.11.10.1.3.1.42.26	LOINC	2.16.840.1.113883.6.1	2.59
eHDSISeverity	1.3.6.1.4.1.12559.11.10.1.3.1.42.13	SNOMED CT	2.16.840.1.113883.6.96	43677
eHDSISocialHistory	1.3.6.1.4.1.12559.11.10.1.3.1.42.14	SNOMED CT	2.16.840.1.113883.6.96	43677 44469

Value Set name	Value Set ID	Code System(s)	Code System(s) ID	Version(s) of Code System used in MVC
eHDSIStatusCode	1.3.6.1.4.1.12559.11.10.1.3.1.42.15	SNOMED CT	2.16.840.1.113883.6.96	43677
eHDSISubstance	1.3.6.1.4.1.12559.11.10.1.3.1.42.61	EMA SMS Substance	1.3.6.1.4.1.12559.11.10.1.3.1.44.100000075825	44711
eHDSISubstitutionCode	1.3.6.1.4.1.12559.11.10.1.3.1.42.7	HL7 v3 substanceAdminSubstitution	2.16.840.1.113883.5.1070	913-20091020
eHDSITelecomAddress	1.3.6.1.4.1.12559.11.10.1.3.1.42.40	HL7 v3 AddressUse	2.16.840.1.113883.5.1119	913-20091020
eHDSITimingEvent	1.3.6.1.4.1.12559.11.10.1.3.1.42.41	HL7 v3 TimingEvent	2.16.840.1.113883.5.139	913-20091020
		FHIR Event Timing	2.16.840.1.113883.4.642.4.1371	4.0.1
eHDSIUnit	1.3.6.1.4.1.12559.11.10.1.3.1.42.16	UCUM Unified Code for Units of Measure	2.16.840.1.113883.6.8	April 2021
eHDSIVaccine	1.3.6.1.4.1.12559.11.10.1.3.1.42.28	ATC Classification	2.16.840.1.113883.6.73	2022-01
		SNOMED CT	2.16.840.1.113883.6.96	43677
				44469

Annex 4 – CP-eHDSI-063: Improve Medication Information Representation

Medicinal Product

- **Product Management Service Identifier (PMS ID)**

It is required as a specific identifier of medicinal products related to EMA. While not currently available, it should be provided when possible.

- **Medicinal Product Identifier (MPID)**

It is required as a specific national identifier of medicinal products, and it is most relevant for eD and PS. While not currently available, it should be provided when possible.

- **Authorised Pharmaceutical Form**

According to the eHN eP Guidelines[25]: "*Dose form of a product could be either authorised dose form (includes European Directorate for the Quality of Medicines – EDQM combination pack dose forms), administrable dose form or manufactured item dose form.* ***It must be made clear which type of dose forms are provided.*** *For example, for the same product several different dose forms can be provided: 'powder and solvent for solution for injection' as authorised dose form, 'solution for injection' as administrable dose form, and 'powder' and 'solvent' as the dose forms for the manufactured items in the inner packaging*."

Ideally the 3 attributes should be presented, however on the impossibility to provide them, it must be clearly specified which attribute is being provided.

'**Authorised Pharmaceutical Form**' should be preferred over 'manufactured dose form' and 'administrable dose form', since the former is the most used by Member States to describe the dose form and contains the complete description of the medicinal product dose form.

- **ATC code(s)**

It is required to define the product classification, and it is already in use on eHDSI services.

The Anatomical Therapeutic Chemical Classification – ATC code should be assigned at the level of the medicinal product pack. It is important to also add Defined Daily Dose (DDD) unit and DDD value, (which might be different for oral and parental forms of certain substances) and to calculate the number of DDDs per pack or per unit of presentation.

- **Full name**

It must be provided on eD and PS and optional on eP, considering the possibility of prescribing generic medicines and/or different medicinal product names between Member States.

Marketing Authorisation Information

- **Marketing Authorisation Holder (organisation)**

It must be provided on eD and PS and optional on eP. It describes the name of the organisation that holds the marketing authorisation of a medicinal product. It should be indicated as listed in SPOR – Organisation Management System (OMS), using the 'LOC-ID' linked to the organization in this system.

Packaged Medicinal Product

- **Packaged medicinal product Identifier (PCID)**

[25] https://health.ec.europa.eu/latest-updates/eprescription-and-edispensation-authorised-medicinal-products-guidelines-electronic-exchange-health-2022-06-10_en

It is required as a specific national identifier of medicinal products. It is more relevant for eD and PS and should be preferred over MPID. While not currently available, it should be provided when possible.

- **Pack size**

The definition of EMA "Pack size" is different from that used by eHN and eHDSI for "Package size".

- ***EMA IG***[20] ***'Pack Size'****: "For each Packaged Medicinal Product, the pack size defined as the total number of units of the manufactured item or package item and represented per unit of presentation shall be provided. For medicinal products with multiple pharmaceutical products (complex medicinal product packages)*[27] *(e.g., tablet and cream) the pack size shall be differentiated and repeated by manufactured item/package item."*
- ***eHDSI***[26] ***'Package size'****: Size of the package prescribed/dispensed in the Country of affiliation/treatment. As the package size can change, the size of the package of the medicine dispensed may differ from the one prescribed."*
- ***eNH eP Guideline***[25] ***'Pack size'****: "is the number of unit of presentations in the package. It could also be presented using units of measurement (ml, g). In some cases, there is a need to refine the package size that it describes the amounts of different manufactured items in more than one inner packages. However, the overall amount of a prescribed product must be calculable from the pack size description."*

Considering the above, this attribute should be required to describe complex packaging medicines. It must be provided when a medicinal product presents more than 2 different units of presentation. Example: Hiberix vaccine contains in each box 2 items: *1 vial + 1 syringe* (Table 5).

- **Package item (container)**
  - **Package item (container) type**

This attribute is required to describe complex medicinal product packages. It should be associated with *'Package item (container) quantity'*. For complex medicinal product packages[27], this attribute can be duplicated to indicate the structure of the package. For example (Table 5), \-Box; \--pre-filled syringe; \--Vial — in this case it includes a pre-filled syringe and a vial. It can also be used optionally to describe the content of a simple medicinal product package (example: \-Box; \--Blister) (Table 4).

  - **Package item (container) quantity**

This attribute is required to describe complex packaging medicines. It must be used to complement the information of the '*Package item (container) type*' to describe their content. (Example: Package item (container) type: *Blister* / Package item (container) quantity': *2*).

- **Manufactured Item**
  - **Unit of Presentation**

In line with eHDSI CP-066 (Annex 2 – CP-eHDSI-066: Prepare eHDSI Requirements Catalogue for ISO IDMP) for most cases 'unit of presentation' will be the same for 'manufactured item' and 'pharmaceutical product'. However, in some cases they can be different (e.g., eye drop product – for 'manufactured Item' – *'Container';* for pharmaceutical product: *'drop')*.

Ideally the 2 attributes should be provided, however in the impossibility of providing both, the '**Pharmaceutical product' 'Unit of presentation' should be preferred over 'Manufactured item'**.

In any case, it must be clearly specified which attribute is being provided.

  - **Manufactured Item Quantity**

[26] https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSI/06.01.+Create+the+eHDSI+ePrescription%28s%29+content
https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSI/07.01.+Create+the+eHDSI+eDispensation+content

[27] in this document, 'Simple medicinal product package' can be defined as a medicinal product that's presents in the same box only one dose forms. Example: tablets; vials; capsules, etc. and 'Complex medicinal product packages' can be defined as a medicinal product that's presents in the same box 2 or more different dose forms. Example: tablets + cream; powder for solution for injection + solution for solution for injection, etc.

It describes the quantity of the medicinal product (manufactured item) in the package and shall be mandatory accordingly the eHN eP guidelines[25] for eP. Example: 20 tablets or 1 vial.

This attribute corresponds to eHN and eHDSI “Package size” to represent the quantity of medicine on prescription and dispensations. See “pack size” above for more details.

- **Manufactured Dose Form**

As the name indicates, it represents the dose form presented in the manufactured item (e.g., powder for solution for injection).

Please see comments on ‘Authorised Pharmaceutical Form’.

Ingredient

- **Ingredient role**

It should be provided to indicate the role of the medicinal product ingredients (e.g., active, excipient advent, etc.). Currently, the designation of active ingredients is mandatory, while other ingredients such as excipients are optional. However, some ingredients (excipients) with allergenic potential may be provided (e.g., lactose, peanut oil, etc.), which is especially relevant for safe dispensing.

- **Substance**

It describes the name and code of the precise ingredient of a medicinal product, and it is mandatory. It shall be identified as listed in SPOR – SMS using the SMS ID.

- **Strength (quantitative composition)**
  - **Strength (Presentation single value or low limit) / Strength (Concentration single value or low limit)**

It describes the strength of ‘moiety + modifier’ (presentation or concentration) and it is referent to ‘substance’. All strengths have a unit and a value for the numerator, and a unit and a value for the denominator. It is important to have value sets for these concepts:

Presentation single value or low limit: the numerator should be expressed with a unit (numeric value) and a unit of measurement (e.g., mg, mL) / the denominator should be expressed with a unit (numeric value) and a unit of presentation (e.g., tablet, actuation).

Concentration single value or low limit: The numerator and the denominator should be expressed with a unit of numeric value and a unit of measurement (e.g., mg, ml).

It should be a complementary information to ‘Reference strength’.

- **Reference Strength**
  - **Reference Substance**

It describes the active ingredient without the modifier (active moiety). It should be provided to support the description of ‘Reference strength’. For prescriptions of generic product, this is the preferred attribute to describe the active substance.

- **Reference Strength (Presentation single value or low limit) / Reference Strength (Concentration single value or low limit)**

This attribute is the most frequently used in prescriptions. It considers only the strength of the active moiety (no modifier). This information will be consumed by eHealth services and reference strength should be preferred over ‘strength’.

Similar to ‘Strength’, the ‘Reference Strength’ also presents the values for numerator and denominator.

Example:

Table 3: comparison between 'Strength' and 'Reference Strength'

Strength (quantitative composition)	
Substance	Omeprazole magnesium
Strength (Presentation single value or low limit) Numerator Denominator	 20.6 milligram(s) (100000110655) 1 tablet
Strength (Concentration single value or low limit)	Not applicable
Reference Strength	
Reference Substance	Omeprazole (100000092047)
Reference Strength (Presentation single value or low limit) Numerator Denominator	 20 milligram(s) (100000110655) 1 tablet
Reference Strength (Concentration single value or low limit)	Not applicable

Pharmaceutical Product

- **Pharmaceutical Product identifier (PhPID)**

It is required as a specific identifier of medicinal products (same substance with role of precise active ingredient, strength, administrable dose form and unit). While not currently available, it should be provided when it is possible.

- **Administrable Dose Form**

As the name indicates, it represents the dose form intended for administration to the patient after any possible transformation of the manufactured dose form that have been necessary for this process.

Please see comments on 'Authorised Pharmaceutical Form'

- **Unit of Presentation**

Please see comments on 'Manufactured Item / Unit of Presentation'.

- **Route of Administration**

For most medicinal products there is only one possible 'Route of Administration' (RoA), however, in some cases, there are multiple possible RoA. In that case, all possible RoA for the product should be specified to the prescriber, and only the intended prescribed RoA must be specified on the clinical document over all possible RoA for a specific medicinal product.

For specific examples, the reader is advised to consult Table 4 and Figure 4 that contains the example of Losec Control 20mg gastro-resistant tablets; Table 5 and Figure 5 that contains the example of Hiberix. Haemophilus Type b (Hib) vaccine Powder and Solvent for Solution for Injection. These tables and diagrams present the MALeH populated with the EMA IG Chap. 8 Annex I[28] examples, for a structured view of the attributes.

[28] https://www.ema.europa.eu/documents/other/product-management-service-pms-implementation-international-organization-standardization-iso_en.pdf

Table 4: MALeH flat representation for Losec

#	Attributes from EMA IG V2.1	Example of Losec Control 20mg gastro-resistant tablets
1.	Medicinal Product	
1.1.	Product Management Service Identifier (PMS ID)	00006006
1.2.	Medicinal Product Identifier (MPID)	IE-100000833-00000003
1.5.	Authorised Pharmaceutical Form	Gastro-resistant tablet
1.13.	Product classification	
1.13.3.	ATC code(s)	A02BC01 (100000093631)
1.14.	Medicinal Product Name	
1.14.1	Full name	Losec Control 20 mg gastro-resistant tablets
2.	Marketing Authorisation Information	
2.8.	Marketing Authorisation Holder	Bayer Limited (LOC-100000833)
4.	Packaged Medicinal Product	
4.1.	Packaged medicinal product Identifier (PCID)	IE-100000833-00000003-0001
4.3.	Pack size	
4.7.	Package item (container)	
4.7.1.	Package item (container) type	Box (100000073498)
4.7.5.	Package item (container) quantity	1
4.10.	Manufactured Item	
4.10.1.	Unit of Presentation	Tablet (200000002152)
4.10.2.	Manufactured Item Quantity	7 unit(s)
4.10.3.	Manufactured Dose Form	Gastro-resistant tablet (100000073667)
5.	Ingredient	
5.1.	Ingredient role	Active (100000072072)
5.5.	Substance	
5.5.1.	Substance	Omeprazole magnesium (100000085918)
5.5.2.	Strength (quantitative composition)	
5.5.2.2.2.	Strength (Presentation single value or low limit) Numerator Denominator	 20.6 milligram(s) (100000110655) 1 tablet
5.5.2.3.2.	Strength (Concentration single value or low limit)	Not applicable
5.5.3.	Reference Strength	
5.5.3.1	Reference Substance	Omeprazole (100000092047)
5.5.3.3.2.	Reference Strength (Presentation single value or low limit) Numerator Denominator	 20 milligram(s) (100000110655) 1 tablet
5.5.3.4.2.	Reference Strength (Concentration single value or low limit)	Not applicable
6.	Pharmaceutical Product	
-	Pharmaceutical Product identifier (PhPID)	Not available
6.2.	Administrable Dose Form	Gastro-resistant tablet (100000073667)
6.3.	Unit of Presentation	Tablet (200000002152)
6.6.	Route of Administration	Oral use (100000073619)

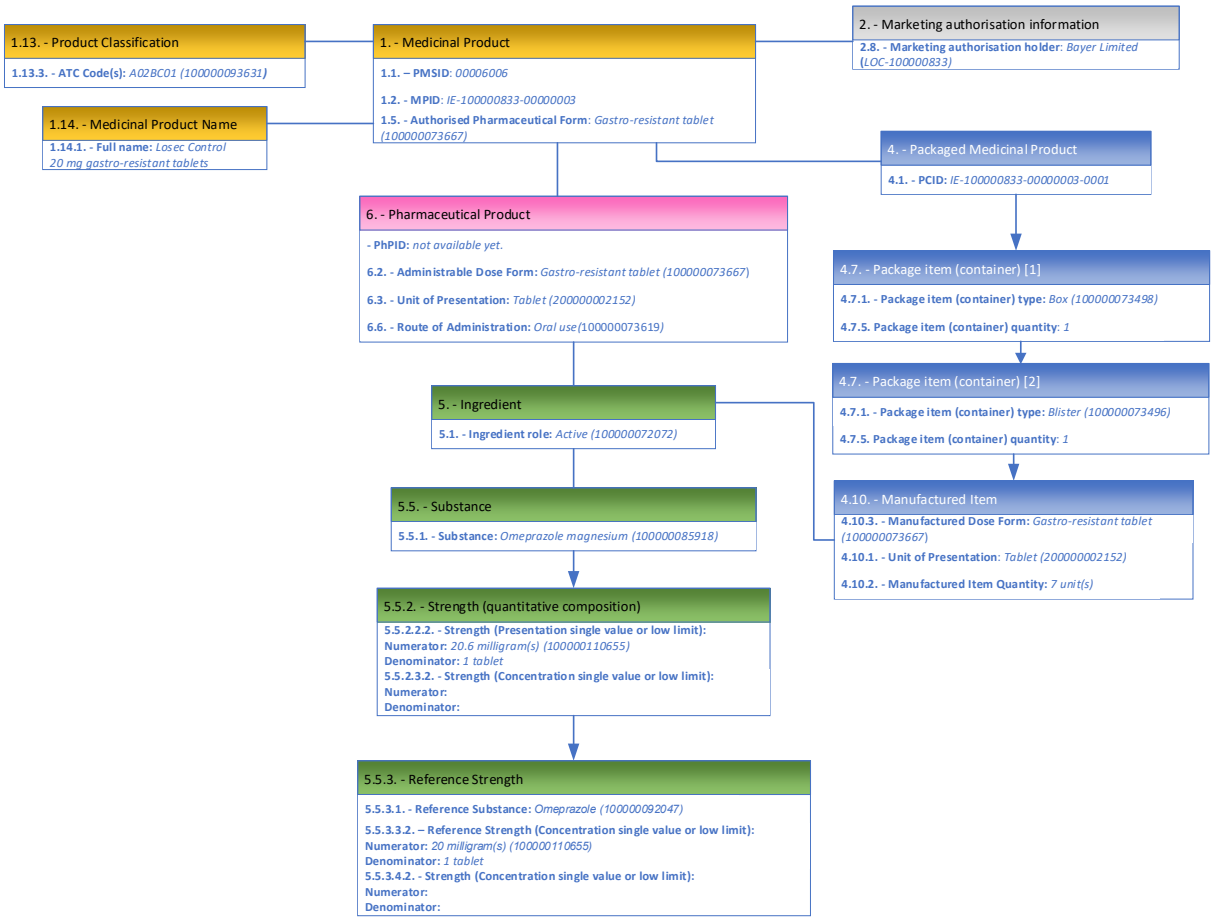

Figure 4: Adapted representation for Losec considering the MALeH

Table 5: MALeH flat representation for Hiberix

#	Attributes from EMA IG V2.1	Example of Hiberix. Haemophilus Type b (Hib) vaccine Powder and Solvent for Solution for Injection.	
1.	Medicinal Product		
1.1.	Product Management Service Identifier (PMS ID)	00007007	
1.2.	Medicinal Product Identifier (MPID)	IE-100001573-00000001	
1.5.	Authorised Pharmaceutical Form	Powder and solvent for solution for injection (100000073868)	
1.13.	Product classification		
1.13.3.	ATC code(s)	J07AG51 (100000096521)	
1.14.	Medicinal Product Name		
1.14.1	Full name	Hiberix. Haemophilus Type b (Hib) vaccine Powder and Solvent for Solution for Injection	
2.	Marketing Authorisation Information		
2.8.	Marketing Authorisation Holder	GlaxoSmithKline (Ireland) Limited(LOC-100001573)	
4.	Packaged Medicinal Product		
4.1.	Packaged medicinal product Identifier (PCID)	IE-100001573-00000001-0002	
4.3.	Pack size	1 vial + 1 syringe	
4.7.	Package item (container)		
4.7.1.	Package item (container) type	Box	
4.7.5.	Package item (container) quantity	1	
4.7.1.	Package item (container) type	Vial (100000073563)	Pre-filled syringe (100000073544)
4.7.5.	Package item (container) quantity	1	1
4.10.	Manufactured Item		
4.10.1.	Unit of Presentation	Vial (200000002158)	Syringe (200000002150)
4.10.2.	Manufactured Item Quantity	1 Unit(s) (100000110756)	0.5 millilitre(s) (100000110662)
4.10.3.	Manufactured Dose Form	Powder for solution for injection (100000073866)	Solution for solution for injection (100000174029)
5.	Ingredient		
5.1.	Ingredient role	Active	Excipient
5.5.	Substance		
5.5.1.	Substance	Haemophilus influenzae type b capsular polysaccharide (PRP) conjugated to tetanus toxoid (TT) (mean TT/PS ratio: 2.5) (100000089691)	N/A
5.5.2.	Strength (quantitative composition)		
5.5.2.2.2.	Strength (Presentation single value or low limit) Numerator Denominator	N/A	N/A
5.5.2.3.2.	Strength (Concentration single value or low limit)	N/A	N/A
5.5.3.	Reference Strength		
5.5.3.1	Reference Substance	Haemophilus influenza type b polysaccharide (polyribosylribitol phosphate) (PRP)	N/A
5.5.3.3.2.	Reference Strength (Presentation single value or low limit) Numerator Denominator	10 microgram(s) 1 vial	N/A
5.5.3.4.2.	Reference Strength (Concentration single value or low limit)	20 microgram(s) 1 millilitre	N/A
5.5.3.	Reference Strength		
5.5.3.1	Reference Substance	Tetanus toxoid	N/A
5.5.3.3.2.	Reference Strength (Presentation single value or low limit) Numerator Denominator	25 microgram(s) 1 vial	N/A
5.5.3.4.2.	Reference Strength (Concentration single value or low limit)	50 microgram(s) 1 millilitre	N/A
6.	Pharmaceutical Product		
-	Pharmaceutical Product identifier (PhPID)	Not available	
6.2.	Administrable Dose Form	Solution for injection	
6.3.	Unit of Presentation	Syringe	
6.6.	Route of Administration	Intramuscular use	

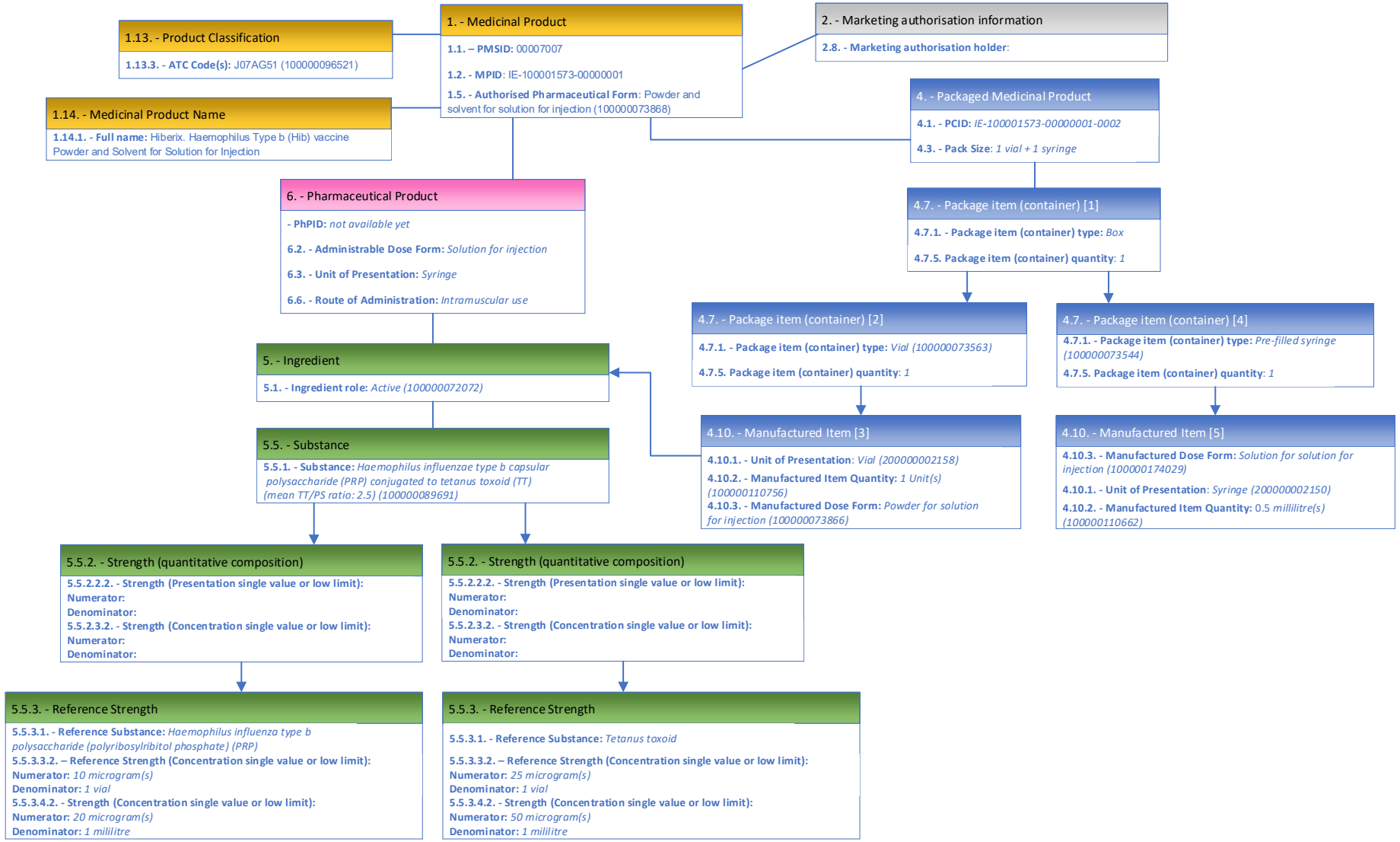

Figure 5: Adapted representation for Hiberix considering the MALeH

3.2 Preferred coding systems

In order to describe attributes of medicinal products in a standardised way, the use of international coding systems is highly recommended. International coding systems represent all the attribute variables in a coded and interoperable way[29]. Thus, it can support the national stakeholders to identify foreign products and assist in translations (when needed).

The eHDSI Master Value Sets 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 (Annex 3 – Code Systems in MVC 6.1.0) such as ICD-10, SNOMED CT, ATC Classification, EDQM Standard Terms, or UCUM.

The use of the preferred coding systems indicated below are in line with the specifications of the eHDSI MVC. The use of these specific coding systems eliminates the transcoding step, thus increasing the safety of the services by avoiding mismatches.

As part of UNICOM's work with the eHDSI communities, SPOR-SMS has been included in the new version of the MVC - MVC 6.1.0 - as the coding system for substance, which will impact Wave 6 of eHDSI (2022-2023).

The indicated preferred coding systems for representing IDMP attributes (Table 2 are further explained below.

3.2.1 EMA-SPOR[30]

The European Medicines Agency (EMA) through the Substances, Products, Organisations and Referentials (SPOR) data management services is centralising the codification of the information relating to medicinal products. SPOR databases were created to be compliant with ISO IDMP standards, supporting its implementation and removing the need to convert/transform the information.

The databases are split in four main services: SMS, PMS, OMS and RFS:

- **Substance Management Services (SMS)**

SMS provides a central dictionary of substance data in multiple languages, composed by "harmonised data and definitions to uniquely identify the ingredients and materials that constitute a medicinal product"[31]. SMS supports the continuous exchange of data between information systems across the European medicines regulatory network and across the pharmaceutical industry.

SMS is currently live as an EMA internal system. Until it is onboarded in the SPOR portal, external users should use the following systems:

- View and search substance data in European Union Telematics Controlled Terms (EUTCT)[32] or IRIS[33];
- Submit substance change requests in the EMA Service Desk[34] portal.

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[29] 1. Vander Stichele R, Kalra D. Aggregations of Substance in Virtual Drug Models Based on ISO/CEN Standards for Identification of Medicinal Products (IDMP). Stud Health Technol Inform. 2022 May 25; 294:377-381. doi: 10.3233/SHTI220478

2. Vander Stichele, Robert H., Joseph Roumier, and Dirk van Nimwegen. 2022. "How Granular Can a Dose Form Be Described? Considering EDQM Standard Terms for a Global Terminology" Applied Sciences 12, no. 9: 4337. https://doi.org/10.3390/app12094337

3. Karpetian N, Vander Stichele RH, Quintana Y. Alignment of two standard terminologies for dosage form: RxNorm from the National Library of Medicine for the United States and EDQM from the European Directorate for the Quality in Medicines and Healthcare for Europe. IJMI, accepted for publication, in press.

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

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

[32] http://eutct.ema.europa.eu/

[33] https://iris.ema.europa.eu/substances/

[34] https://servicedesk.ema.europa.eu/

This coding system was recently adopted by eHDSI (going live in wave 6 of eHDSI) to support the description of the substances on eHealth services and should be the preferred coding system in this regard.

- **Product Management Services (PMS)**

PMS encompasses "harmonised data and definitions to uniquely identify a medicinal product based on regulated information (e.g., marketing authorisation, packaging and medicinal information)"[31]. PMS will cover a subset of the authorised medicinal product part of the ISO IDMP standards. However, this database is not yet available. Future PMS iterations will implement other product data elements of the authorised medicinal product and the investigational medicinal product part of the ISO IDMP standards.

- **Organisation Management Services (OMS)[35]**

OMS provides a central dictionary of organisation data in multiple languages. It covers organisation names; location address details; communication details such as email address and telephone number per location.

It is already in use and should be the used to describe the organization name in the 'Market Authorization Holder' attribute.

- **Referentials Management Services (RMS)[36]**

RMS provides referentials lists and terms (such as routes of administration, dose forms, unit of presentation) in multiple languages (the 24 official languages of the EU, and 13 other languages relevant to the European Council). RMS supports the continuous exchange of data between information systems across the European medicines regulatory network and the pharmaceutical industry.

RMS replaces the European Union Telematics Controlled Terms (EUTCT) system as the repository of referentials and controlled terms. However, stakeholders should continue to use EUTCT to browse lists of substances until the new SMS become available.

It also presents lists of terms that are managed and maintained by organisations other than EMA, such as WHO-ATC and EDQM. Those lists are updated accordingly by the system owner. This update does not change the previous coding system.

The use of RMS as a coding system for the different attributes listed Table 2 should be considered in the future. Currently, eHDSI has no value sets or transcoding tables for RMS and if this coding system is the preferred choice of NCAs, then it shall be transcoded to the indicated preferred coding system to exchange clinical documents on cross-border context.

RMS provides a mapping between each RMS ID and the main sources used (e.g., EDQM, UCUM, ATC, etc). As a result, it constitutes an opportunity to connect different coding systems assuming that NCAs will provide the information of the exact coding system that being provided to the system to exchange eP/eD and PS throughout eHDSI.

3.2.2 WHO-ATC [37]

In the Anatomical Therapeutic Chemical (ATC) classification system, the active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. Drugs are classified into groups at five different levels (Table 6). This system is managed by the World Health Organisation (WHO) Collaborating Centre for Drug Statistics Methodology.

[35] https://spor.ema.europa.eu/omswi/

[36] https://spor.ema.europa.eu/rmswi/

[37] https://www.who.int/tools/atc-ddd-toolkit/atc-classification

Table 6: ATC levels description

ATC Level	Description
1st	The system has fourteen main anatomical or pharmacological groups (1st level).
2nd	Pharmacological or Therapeutic subgroup
3rd and 4th	Chemical, Pharmacological or Therapeutic subgroup
5th	Chemical substance

The ATC codes are broadly used for the classification of medicinal products among different countries. It is already in use on the eHDSI for the identification of 'active substance', which is not the proper use and, as such, it should be maintained for classification of medicinal product packages, in such a way that it is instrumental to drug utilisation research and drug consumption statistics. Assigning the ATC code at the Medicinal product package level is important, as DDD can differ according to oral and parenteral products. Also, it is at the medicinal product package level that the number of DDD per pack are calculated.

From now on, the identification of the 'substance' as the 'substance with the role of precise active ingredient' is achieved by using SPOR-SMS. On eHDSI infrastructure.

3.2.3 EDQM[38]

The European Directorate for the Quality of Medicines & HealthCare (EDQM) is responsible for, developing and monitoring the application of quality standards for medicines and their safe use, which is recognised as a scientific benchmark and applied worldwide.

It presents lists for the classifications of most attributes required on the MALeH and is the preferred coding system on eHDSI infrastructure. The NCA provide the EDQM code over the RMS code. In the future the eHDSI should also adopt the RMS as coding system, until it happens, the EDQM should be preferred.

3.2.4 UCUM[39]

The Unified Code for Units of Measure (UCUM) is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans.

This coding system can also be used to describe many attributes on MALeH and should also be preferred over RMS for the time being. The codification on UCUM or EDQM has the same impact once eHDSI has value sets to describe both coding systems, namely SPOR-RMS

3.3 ISO IDMP Identifiers

To describe medicinal products, there are a series of different attributes that can contribute to their identification for diverse proposes, such as i) eP/eD & PS; ii) pharmacovigilance; and iii) EMA communication, among others.

From those attributes described in the ISO IDMP standards, it is also possible to generate some identifiers that are based on the attributes and the market authorisation/registration in the national bodies. In the IDMP definition is possible to present 3 different identifiers:

- PhPID – Pharmaceutical Product Identifier
- MPID – Medicinal Product Identifier
- PCID – Package Medicinal Product Identifier

[38] https://www.edqm.eu/en/

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

Noteworthy, these identifiers are not yet available. However, the eHDSI has already included fields for their representation, allowing its use on the eP/eD and PS services in eHDSI infrastructure to be used in the future.

These identifiers will be described in detail below.

3.3.1 Attributes required to generate PhPID

- **ISO IDMP PhPID Overview**

The Pharmaceutical Product Identifier (PhPID) is a global-level identifier that is uniquely assigned at the pharmaceutical product level.

According to the ISO 11616[40], the PhPID is represented within two strata – **active substance stratum** and **specified substance stratum**, and both comprise four PhPID identification levels for each pharmaceutical product contained in a medicinal product.

PhPID is generated by using:

- **Substance standard** (ISO 11238 and ISO/TS 19844)
- **Strength** (ISO 11239 and ISO/TS 20440)
  - The reference strength shall be repeated in both PhPID strata, and is derived from the active moiety / moieties of an active substance (depending on the specific product characteristics)
- **Administrable dose form** (ISO 11239 and ISO/TS 20440)
- **Unit of measurement standard** (ISO 11240)

For products that requires reconstitution (e.g., powder + liquid for solution), the PhPID shall consider the administrable dose form, which already considers this initial reconstitution step.

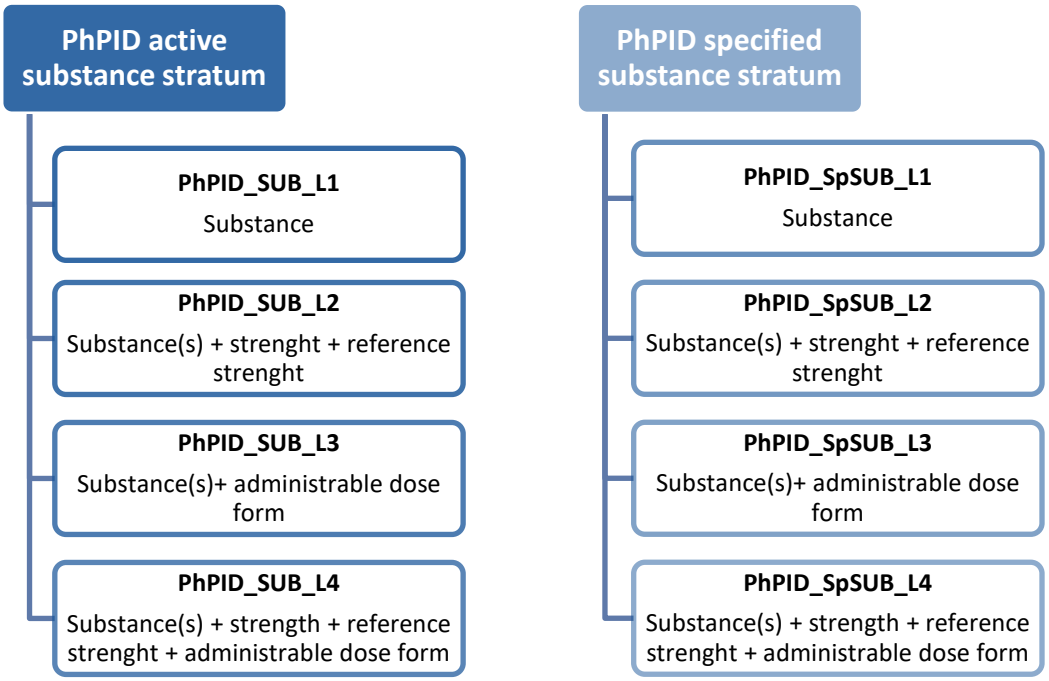


Figure 6: PhPID four levels.

[40] ISO 11616 - Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information

Table 7 shows the relationship between the elements of a pharmaceutical product and their respective cardinality.

Table 7: Cardinality relationships that shall be respected within the elements of a pharmaceutical product, according to ISO 11616

Cardinality relationship	
PhPID has one administrable dose form	1..1
PhPID may have zero to one unit of presentation [a)]	0..1
PhPID has one or more active substances	1..*
PhPID has one strength [b)] – based on one-to-many active substances or Specified substances	1..1 1..*
PhPID has one to many reference strengths (i.e., active moieties with a corresponding strength), as it relates to the strength of one-to-many active substances/specified substances	1..*

Notes: **a)** This is frequently employed specifically at the point of delivery to the patient in situations where a quantitative unit of measurement is not appropriate; **b)** For liquid preparations, the strength (presentation) and strength (concentration) shall both be represented. Moreover, a PhPID shall be generated to represent the strength concentration. In this case, this shall be known as product code concept, since it represents a calculation of the strength presentation of a liquid preparation as authorised.

As the PhPID is generated based on the attributes of the medicinal product, all the products that share the same exact attributes have the same PhPID code, irrespective of the country where the medicine is registered. Conversely, PhPID does not convey all the information to identify the dispensed product as a packed medicinal product, and further information could be required.

Taking this into consideration, the use of PhPID wherever possible will enhance the translating and transcoding of medicinal product information to assure the correct identification and thus the safe and accurate dispensation.

- **EMA SPOR Implementation Guide**

According to EMA PMS Implementation Guide Chapter 2 – Version 2.1[41], no information is provided on this report regarding on “additional identifiers such as the Pharmaceutical Product Identifier (PhPID). Further details on the related definitions and defining elements will be available at later stage as it requires further discussions prior the implementation. Moreover, additional clarifications on the PMS ID defining elements and the relationship with the MPID will be provided in the EU IG v2.2 release”.

Status and Attributes importance

- Currently, there is no process defined for the generation and governance of PhPID codes, as well as the timeline for this development.
- The use of the attributes needed to generate the PhPID codes will facilitate its implementation in future iterations.
- An automatic way of generating such identifiers and attributes codes will facilitate this implementation and decrease the probability of errors.
- Considering the global impact of PhPID codes, a governance model at this level should also be defined, which will involve institutions of different parts of the world. Currently, intense discussions between EMA, FDA, and WHO_UMC are ongoing regarding this issue in the Global IDMP Working Group GIDWIG.
- Medicinal product databases should include the attributes needed to generate PhPID:
  - Substance(s)
  - Reference strength
  - Reference strength

[41] Product Management Service (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe, Chapter 2: Data elements for the electronic submission of information on medicinal products for human use Version 2.1. EMA/285848/2020, 24 June 2021. Available at https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso_en-0.pdf

    - Administrable dose form
- Medicinal product databases should map these attributes, their compliance to ISO IDMP, and preferentially opt for structured coded data.

3.3.2 MPID generation

According to the ISO 11615:2017[42], the Medicinal Product Identifier (MPID) is uniquely associated to each medicinal product authorised in a country. It shall be associated to any national authorisation number.

The MPID shall "use a common segment pattern related to a Medicinal Product, which when each segment is valued shall define a specific MPID concept"[42]. The pattern is composed by:

a) country code segment (ISO 3166-1 alpha-2 code elements);
b) marketing authorisation holder (organisation identifier) code segment;
c) Medicinal Product code segment.

A new MPID shall be assigned if any of the values associated with these three codes changes.

According to the ISO IDMP 11615[42] standard, a new MPID can be assigned to a product following a substantial change in the product (e.g., change in indication) but also for administrative reasons (e.g., change in marketing authorisation holder).

The variability of an MPID and the complexity of its constitution means that many drug verbatims cannot have an MPID accurately coded based on the information provided if more than one MPID would be available for that product. The MPID is assigned in accordance with the country code segment, marketing authorisation holder and Medicinal Product code segment.

In a national context, it can be used to define specific brand product in the eP, however the identification of generic medicines on eD is challenging. Considering both contexts (national and cross-border), MPID may be used in both the eD report and PS document, to indicate accurately the product that was dispensed (eD) or used by the patient (PS).

3.3.3 PCID generation

According to the ISO IDMP 11615, the Package Medicinal Product Identifier (PCID)[42]**Error! Bookmark not defined.** is associated to each package medicinal product authorised in a country.

The PCID shall "use a common segment pattern related to a package of a Medicinal Product, which when each segment is valued, shall define a specific PCID concept"[42]. The pattern is composed by:

a) MPID for the Medicinal Product;
b) package description code segment, which refers to a unique identifier for each package.

A new PCID shall be assigned if any of the values associated to these code segments changes.

The PCID is more detailed than MPID because it includes the medicinal products' packaging information. Several PCIDs can be associated with one MPID, such as: same medicinal product in two different box presentations: box with 20 pills, or box with 30 pills.

As the PCID is a further refinement of product specification when compared to the MPID (the PCID only increases in the 'package description'), it has the same implications as MPID, so the same considerations mentioned above for MPID are also applicable for the use of PCID in the eHealth services.

[42] https://www.iso.org/standard/70150.html

4 Minimum data set specifications

Fully specifying a data set means, in our case, defining the structure of the data elements and populating that structure. In other words, the Minimum Data Set consists of the MALeH instantiated for a minimum set of products.

A formal definition of the MALeH should be structured (as opposed to verbose, human-readable), to ensure that such specifications are understood by everyone. This can be done in several ways – data dictionaries, formal (logical) data models, and using technical languages such as Unified Modelling Language (UML) or Fast Health Interoperability Resources (FHIR) for Logical Data Models).

These specifications are semantic specifications and as such are at the logical level – expressing entities, their definitions, relationships and constraints – following the same indications as in UNICOM Deliverable D1.2 – *'Requirements for a new ISO logical model [platform independent]'*[43], and the same approach that is used in the ART-DECOR® specifications for eHDSI.

The attributes that are required depend on the core attributes to identify a product, and additional operational attributes that are required to ensure proper operations. These required attributes depend on the intended use. It is therefore important to consider the scope of application when defining the minimum attribute list, and possibly validate and iterate with concrete examples. These functionalities may require slightly different semantic specifications, or "dialects", (for example in terms of required data elements) – which should be supported, as long as they remain compatible with the common data specifications.

These "dialects" are identified with an analysis of the intended application of IDMP – they are "sub-scopes" of the broader scope for IDMP adoption and usage:

- ePrescription
- eDispensation
- Patient Summary

Also, there are other attribute sets for other purposes, such as the subset of data needed to produce and maintain unique and global PhPIDs.

Such a breakdown provides a checklist that can be used for monitoring the progress of adoption - i.e., whether a Member State adopts IDMP specifications for ePrescription, or eDispensation, or Patient Summary, or all.

While it is expected that the data needs will be different for the different use cases, they all should share the common specifications in the MALeH. For this reason, the specification is done for the entire MALeH at once (from where it can be focussed on for the different use cases if needed).

Another advantage of allowing and documenting such sub-scopes and respective semantic dialects is that later scopes can be added, as long as they remain compatible with the same model – which in turn is compatible with the adjacent models like the regulatory model, the eHDSI specifications, etc. The diagram below (Figure 7) presents another perspective on how these models relate to each other:

[43] https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D1.2-Logical-Model_Final.pdf

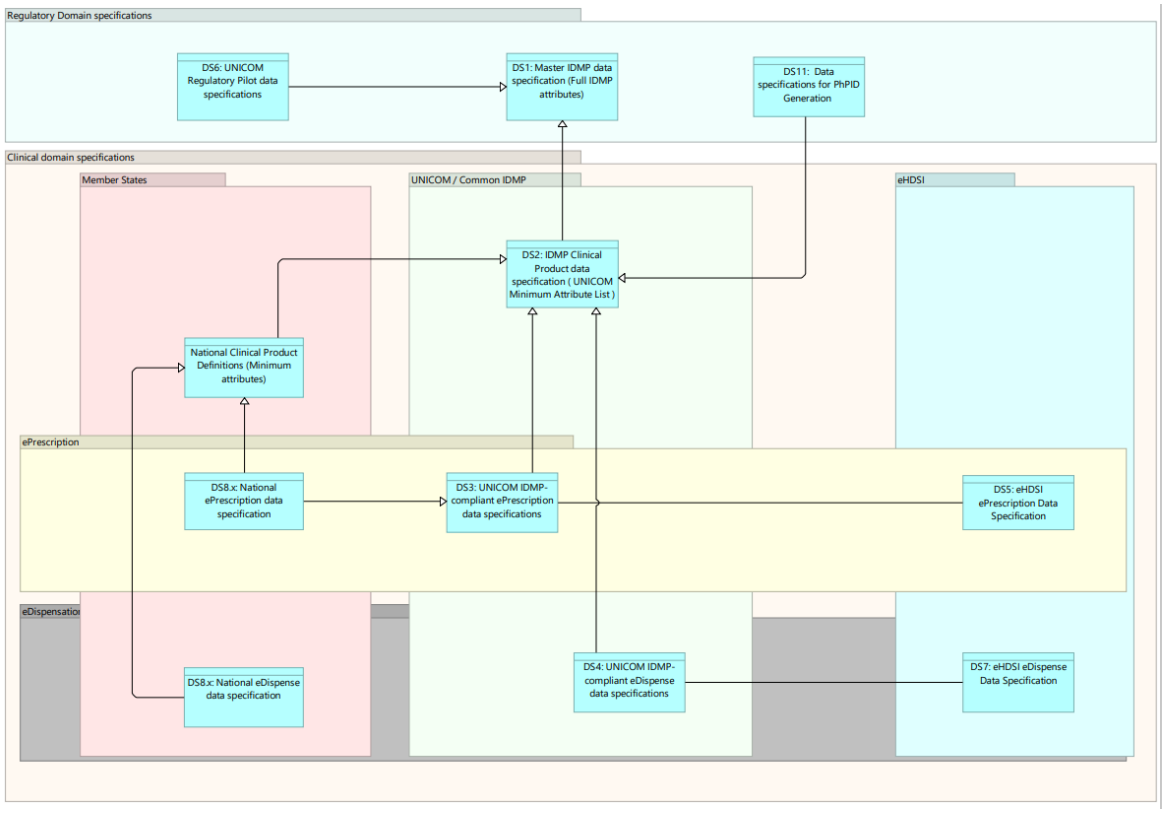


Figure 7: IDMP related data models and their relationship

Figure 7 illustrates that all the models are a specification of IDMP – DS1 being the Data Specifications for the "full" IDMP, and the UNICOM Minimum Attribute List (represented by DS2) provides a "core" semantic specification, which is then sub-specialised in the ePrescription and eDispensation models (as well, for example, as the national drug databases and the data specifications for the PhPID generation) and they are related to the eHDSI specifications – following the alignment and recommendations done from UNICOM towards the eHDSI change procedure.

These are not technical format specifications - i.e., they are not Clinical Document Architecture (CDA) or FHIR or any other technical format – the logical specifications can then be realised in different technical specifications as Clinical Document Architecture (CDA), FHIR, or others.

Analysing the specifications in this and previous UNICOM deliverables, the following diagram presents the MALeH expressed as a Logical Data Model.

This Logical Data Model[44] is expressed in UML and is "flatter" than the FHIR resources being currently designed – for 3 main reasons:

1. Logical data models can be inspired by physical implementations, but they should be independent from any physical implementation like FHIR resources;
2. Logical data models define the data that is needed, and that is less likely to change than technical specifications – for example the FHIR resources are still in low maturity and some changes can be expected, while the logical data model is expected to remain more stable.
3. A flatter attribute list can be implemented in clinical systems or regulatory systems, where the necessary hierarchies can be created. An example: in a prescription, we can prescribe either a medicinal product or a packaged product, or something in between, or a combination of attributes of each. There is no need to force a hierarchical model, for example using 2 or 3 data structures to represent something simple like a Virtual Medicinal Packaged Product (VMPP). In the clinical document (prescription) this can be represented as a single data object, while in the

[44] The current Logical Model for the MALeH is available under: https://build.fhir.org/ig/hl7-eu/unicom-ig/branches/D5.7/StructureDefinition-MinimumAttributeList.html#tabs-diff and will be published in its final destination once UNICOM technical FHIR specifications have a first release.

regulatory databases this can still be represented as a single data object or as multiple data objects for EMA submission purposes, for example.

This way, by focusing on the data that is needed, and not present more data or additional structures, the MALeH can be implemented in different "technical flavours", as required. This presents the least impositions on the architecture – choosing a more complex structure will impose some technical architecture constraints.

One conclusion that can be taken is that the semantic specifications can be defined in different ways – and the key specifications can be captured in slightly different models – in other words, there are different ways to specify a model based on the semantic requirements.

For this document we use the FHIR representation of a logical data model (which is not the same as FHIR specifications, as it does not consider any specific FHIR resources, only the data structures).

This further reveals the interest of having a formal, documented logical data model for IDMP (as proposed in UNICOM D1.2[43] - an effort that is being developed by ISO TC215 WG6[45]). Once that model is available (DS1 in Figure 7, then it will be even easier to confer the alignment between the logical data model for the MALeH.

A note on the value sets in the logical data model: Adding them to a logical data model would ideally require a unique identifier of the value set (e.g., a unique URL (Uniform Resource Locator) or OID (standard Object Identifier[46]) for "Authorised Pharmaceutical Form" and another for "Package type", - as well as for "Route of Administration", etc.). At the moment, what is known is that Authorised Pharmaceutical Form and Pack are both from EDQM, but the value sets need to be defined. While these are not technically available from SPOR (and made available on a terminology server), the logical data model captures the need for the value sets but cannot point to a published value set.

5 Adoption Assessment

Understanding that IDMP adoption is a major and complex migration, there should be no expectations of a rapid "big bang" approach by all Member States simultaneously. Like the rest of the eHealth specifications, Member States require the preparedness and autonomy to phase in such changes. Therefore, it is fundamental to facilitate and monitor the adoption by the Member States – and ideally the consequent effectiveness of interoperability.

This in turn requires consistent criteria for such monitoring, as well as providing facilitators (methods, tools) for the adoption of IDMP / UNICOM recommendations.

The MALeH presents both the common semantic specifications that can be used as a target, and the content, which can be used as a facilitator and some test criteria/test data.

5.1 Semantic compatibility assessment

As described in previous deliverables in this work package, the establishment of a reference semantic specification is a fundamental step towards assessing semantic compatibility of systems, by providing a common specification that both systems should adhere to.

This materialises the need of Semantic Compatibility (or semantic interoperability): whether 2 or more systems express data that has a common or compatible meaning.

This notion of "compatibility" normally introduces some pitfalls, so it is important to clarify a few aspects:

- **Using a single database vs allowing different interoperable systems**:

  Semantic compatibility means that systems are compatible, not that they are the same system. One common pitfall is to resort to a central data store that stores everything, but while that may appear

[45] http://isotc215-wg6.team/

[46] https://en.wikipedia.org/wiki/Object_identifier

easier to govern (as it centralises technical decisions), it is not required, and may not be possible. For example, different countries may have specific national or regional needs that may add to the IDMP data attributes. Using a single central database would mean that such central database would accommodate all the countries' variances (including some conflicting ones), or would imply abandoning this variance, which would possibly impose or oppose Member States' legislation and autonomy.

- **Compatibility vs identity**:

The requirement that systems are compatible does not mean they need to be identical. For systems to be compatible, they have to share key common specifications. This means that the systems specifications may of course present some differences, but in their interoperability mechanisms, any differences must be compatible with the common model. For example, Member States Databases may consider their own identifiers, concepts and attributes, as long as they can exchange the required data elements (in the MALeH) and follow the respective specifications.

Establishing the "target" situation - I.e., when systems are compatible with each other by being compatible with the minimum semantic specification – is required but monitoring the progress of adoption and compatibility is also required.

After the target setting, we can monitor the planned and actual convergence.

A few suggestions in the form of possible requirements to be implemented are presented as follows:

- The semantic compatibility should be broken down in these purpose-specific dialects
- With the breakdown, it should be clear which Member States support which intended scope of application of UNICOM. This is the detailed roadmap in Table 1 – to see which countries will adopt IDMP for eP/eD, or for PS, etc.
  - Member States should document and publish the scope they adhere to – and there should be a way to report that.
  - UNICOM or the appropriate authorities need to define and document the models for the "target" specifications
  - Member States should document, for each of the scope(s), their semantic specifications
  - The Member State specification may contain deviations from the target – Member States should capture those whenever there is a conflict
  - A process and / or tooling should be in place for assessing compliance to a given specification by a member state with the UNICOM target specification. This may include
    - Common tools
    - Common ways to document the specifications (and use the tools mentioned above)
- Technical specifications should be linked to these semantic specifications in a way that one can assert how compatible is a technical specification with the target semantic specification.
- There should be common data for such testing

Such a process, based on the semantic specifications produced by UNICOM, support the semantic alignment and validation across implementations. This can be achieved or facilitated with the following recommendations from UNICOM to the implementers at Member States:

- UNICOM defined the common EU target semantic specifications (MALeH and corresponding Model),
- Each Member State can (and should) define their own target semantic specifications, possibly from their legislation or reverse engineering from existing implementations. From here, we have the MALeH and the Member State's semantic definitions (i.e., data models).
  - This then allows evaluating how the national semantic specifications are compatible (not necessarily identical) to the target EU semantic specification – considering data definitions, value sets, etc.

Semantic consistency validation at EU and at Member State level can be done by mapping the technical specifications to the reference semantic specifications – this will indicate how much has the technical implementation to become compatible (not identical) to the semantic specification.

Figure 8: use of the MALeH semantic specifications in aligning specifications (and their relation to IDMP and UFIS).below illustrates this principle: the UNICOM Minimum Attribute List is a specialization of the

ISO IDMP semantic specifications (which are also implemented in the UFIS demo server). Member States can define their specifications aligned with the Minimum Attributes necessary to enable interoperability in the essential clinical data exchange (while preserving forward compatibility to the full IDMP specification), and derive their technical specifications from their models. This is similar to what UNICOM has done for the eHDSI specifications. Such an approach allows Member States to be the owners of their own semantic specifications, while ensuring a path to compatibility.

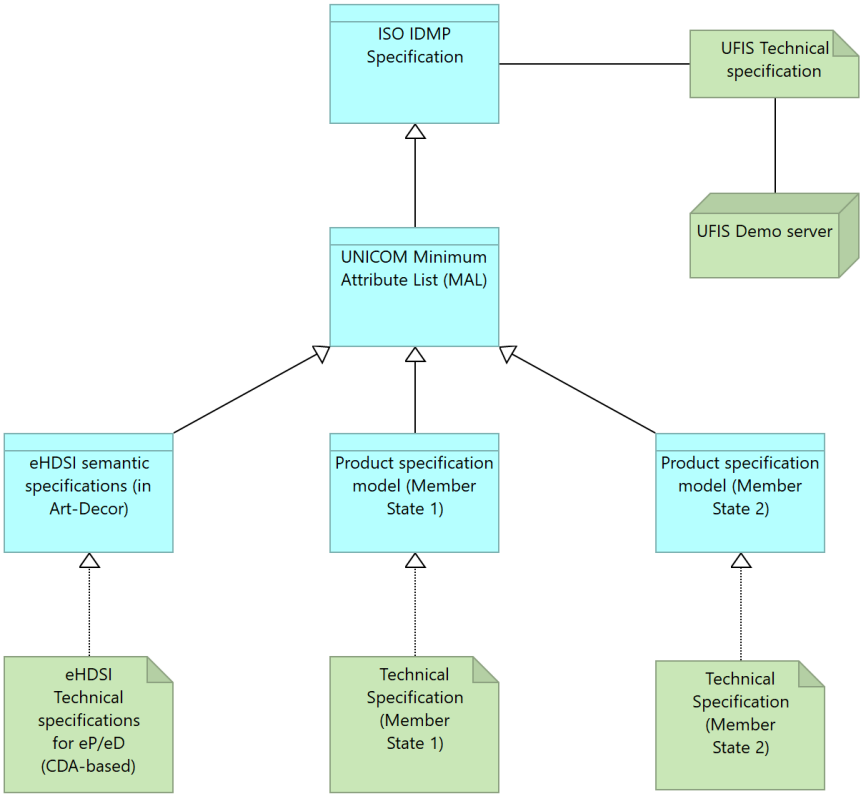


Figure 8: use of the MALeH semantic specifications in aligning specifications (and their relation to IDMP and UFIS).

This follows from the UNICOM Community of Expertise[47] (CoE) in April 2022 (IDMP Semantic Specifications for eHealth Services) – by defining the target semantic specifications, we can assess whether different designs are compatible with those specifications.

Most interestingly, there are, as seen above, several models and several implementations – FHIR for regulatory use, FHIR for clinical use, CDA, etc. and these specifications should be aligned with the semantics defined in the MAL and, consequentially, with IDMP.

[47] https://www.youtube.com/watch?v=bu-lcXYG1xk

6 Roadmap with the eHDSI implementation

On June 30th, 2022, eHMSEG and eHealth Operational management Board (eHOMB) approved change proposals (CPs) for implementation in the Wave 6 (2022-2023) of eHDSI. Among these change proposals, CP-66 and CP-63 were approved (Annex 2 – CP-eHDSI-066: Prepare eHDSI Requirements Catalogue for ISO IDMP Annex 4 – CP-eHDSI-063: Improve Medication Information Representation), which aim to prepare the eHDSI infrastructure to be compatible with IDMP data. Thus, from Wave 6 onwards, Member States can exchange clinical documents using IDMP attributes with the appropriate indicated coding system.

To ensure the appropriate implementation of IDMP data in Member States' infrastructure, it is important to define a roadmap in order to support the planning of the strategy that best fits with each country in line with the eHDSI calendar and their national objectives. This will be important to start the initial activities towards a sustainable process for the long-term implementation of ISO IDMP.

Member States authorities (NCAs and eHealth agencies) should be aligned to plan the implementation of ISO IDMP according to its availability. It is important to note that the 'eHealth pilots' envisaged in UNICOM should be seen not just as a project pilot, but in fact, as the first step in implementing IDMP in the national infrastructure and cross-border data exchange. The eHealth Pilots use real data provided by the NCAs (according to the PPL and MALeH lists) to perform real clinical document exchange through the eHDSI infrastructure. After the end of the UNICOM project, Member States are encouraged to continue IDMP implementation in their databases, as the IDMP data can be continuously updated and used in eHealth services, in addition to other use cases of the medicinal product lifecycle.

The UNICOM partners willing to participate in the Pilots must be able to provide IDMP data – aligned with MALeH/PPL – in accordance with the eHDSI Wave 6 calendar. Furthermore, even after the eHDSI Wave 6 implementation, Member States can use IDMP data for the eHealth services and expand accordingly. The pilots can be divided into five phases as shown in Figure 9:

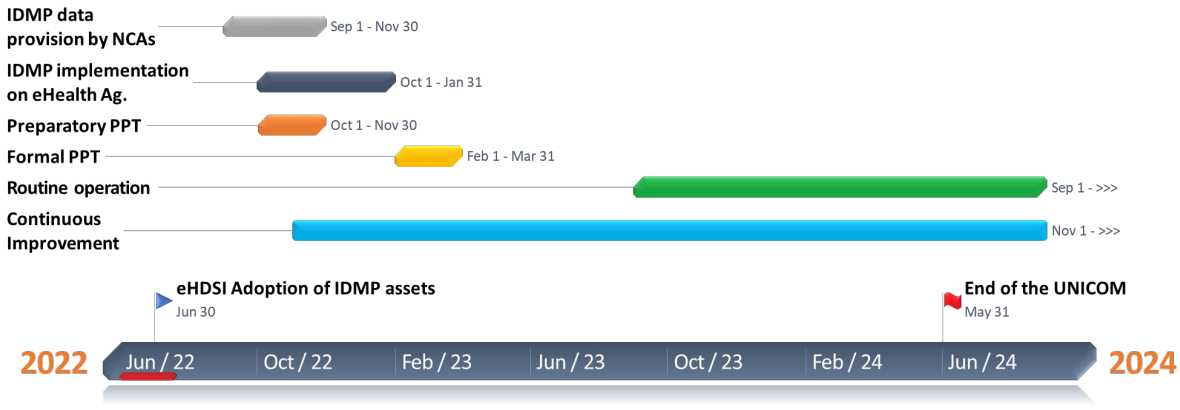


Figure 9: Roadmap for IDMP implementation for cross-border services.
Roadmap aligned with the eHDSI Wave 6 calendar for eP/eD and PS. Abbreviations: Ag – agency; PPT – Pre-Production test.

The NCAs and eHealth Agencies participating in the UNICOM consortium have defined their ISO IDMP implementation plan, which must be respected by all stakeholders involved. The steps presented below are a generic roadmap that should be considered for implementation. However, each Member State has the autonomy to adapt this plan according to its reality.

- **IDMP data provision by the NCAs (until Oct 22)**

As competent authorities responsible for providing data on medicinal products, NCAs should be able to provide the IDMP-compliant data needed for the UNICOM eHealth pilots. This data should be aligned with the PPL and MALeH lists, according to the specifications described in this document.

In an ideal scenario, IDMP-compliant data would be provided from the NCA database (Ref. Minimum Attributes List for eHealth (MALeH) to eP/eD & PS). This model would support the expansion of IDMP data in the database in accordance with the NCA plan, without the need to redesign the IDMP database.

Importantly, if it is not possible to provide the complete database by October 2022 (on the preparatory PPT the Member States starts the Wave 6 implementation/tests in their own systems – no connection with eHDSI), NCAs should provide at least some complete examples, which ideally should be similar across the different countries participating in the pilots for the eHealth service.

The complete database for the pilot must be provided by January 2023 (on formal PPT, the Member States will implement/test the wave 6 extensions with the eHDSI System. In this phase, the database should be completed to support eHDSI testing).Overview of the state of play from NCAs and eHealth agencies

- **IDMP implementation on eHealth Agencies (Oct 22 / Jan 23)**

With the provision of the IDMP data by the NCAs, the eHealth Agencies or the eHealth national provider (Including the NCPeH infrastructure) will need to create the extensions and mappings to use the IDMP data on the cross-border eP/eD and PS. The systems updates should be in line with the eHDSI Wave 6 calendar to ensure that the correct IDMP data (preferred coded as highlighted in Minimum Attributes List for eHealth (MALeH) to eP/eD & PS). Also, the national agencies should create the connections with the pharmacies and hospitals (including mappings when needed) in order to correlate the IDMP data with the current cross-border data.

- **Preparatory Pre-Production Tests (pre-PPTs) (Oct / Nov 2022)**

Preparatory-PPTs are intended to better understand the mechanics of the test session and discover shortcomings in the implemented solutions before the FORMAL test session. The NCPeH must ensure that the technical environment used mimics to the maximum possible extent the production environment, namely with regard to the connection with the National Infrastructure. Test data is used in this phase. Most critical test data is included in the UFIS/PPL, which can be used by Member States.

Although being optional, preparatory-PPTs are highly recommended before the formal PPTs

- **Formal Pre-Production Tests (Formal PPTs) (Feb / Mar 2023)**

Formal PPTs are intended to allow NCPeHs to formally demonstrate the conformance and compliance with eHDSI solution specifications and requirements. The NCPeH must ensure that the technical environment used mimics to the maximum possible extent the production environment, namely with regard to the connection with the National Infrastructure. In this phase, the NCPeH must perform the test with eHDSI critical test data in order to obtain authorisation for routine operation.

This session is mandatory for all NCPeH that launch new services, and for countries in operation that must update to new specifications.

- **Routine Operation (from Sep 2023)**

After all tests have been performed and approved by the eHDSI, the new updates and data start the routine operation. The Member States participating in the UNICOM eHealth Pilot must use Certified Medicinal Products Databases (IDMP format) based on the PPL. The Member States without Certified Product Databases may continue to use the Pre-Production Environment and UFIS/PPL.

7 Considerations for IDMP roadmap for NCAs and solution providers

In a "*perfect scenario*":

- The NCA and eHealth agencies define the adoption of the MALeH as the initial data set for implementation (or adapted if it is needed), and there would be a synchronous transition to IDMP adoption by all the Member States.
- The timeline for adoption would coincide with the readiness and availability of EMA / SPOR, and by the availability of data by Member States.
    - Each NCA has their products expressed in the target data specifications – with the correct data attributes and using the indicated preferred coding system (EMA-SPOR / EDQM / ATC, etc.) after some mapping/cleansing/refractory of the data model.
- After a successful implementation of the first batch, the NCA defines the 2nd priority attributes for implementation (attending other NCA needs, such as communication with EMA, pharmacovigilance, etc).

However, it is not expected that such synchronous transition will happen, or even Member States will necessarily be ready, and at the same stage simultaneously. The key factor to consider, judging from the UNICOM experience so far, is that different countries may be closer to the "IDMP" model than others, and using value sets that are closer aligned to the IDMP value sets. This (the current state) has potentially a much bigger influence in the Member State readiness and adoption than other factors such as availability of resources.

We should be prepared for a progressive adoption, which should be planned and monitored. For monitoring such progress consistently, it is important to have cross-border standards, thresholds, and metrics.

This chapter presents some of these metrics, guidance, thresholds, and metrics for progress.

Finally, to have comparable data, it is important that member states use similar approaches. Since this work is about semantic specifications in the first place, this means that member states should adopt common, comparable ways to define such specifications at the conceptual and logical data models. As indicated in UNICOM D1.2[43], producing, maintaining and comparing logical data models is facilitated by having computable representations of such semantics. The current models of UNICOM are represented in the FHIR logical data model specification, which makes them maintainable, mappable, and monitorable. Other approaches can be adopted, but preferably computable specifications such as UML, or proprietary tools like Art-decor. If member states use consistent, shareable tools, the monitoring of progress is much facilitated.

7.1 Minimum data specifications vs national declinations

The data specifications start with the specific data scopes / sub-scopes listed in Minimum data *set specifications* – ePrescription, eDispensation, and Patient Summary. Different countries may adopt different scopes and therefore may have slightly different timelines for the adoption of the attributes. For example, one country adopts ePrescription and eDispensation first, while another adopts Patient Summary first – as a consequence, their priority data attributes may differ.

Another thing to acknowledge is that in a transition or even in the target situation, Member States may have different data specifications than the target. For example, the value set used in national dose forms may not have the same values as those exposed in the MALeH / SPOR. Sometimes, even the attributes may have a slightly different meaning.

It is therefore important to capture such deviations - whether they are intentional or accidental, temporary or definitive. Monitoring how closely a national data specification (already) follows the target cross-border specification is a key parameter in monitoring the progress of overall adoption. As an example, this allows for progress metrics like "country A is 80% compatible with the semantic specifications for ePrescription", while country B is 87% compatible.

This also allows countries to prioritise their interventions according to their goals, providing the autonomy that Member States may require.

Member States may need to have their products in the "current" data structure, and in the target model. This may mean that Member States may adopt some data transformation processes from the previous data structure to the target IDMP data specifications. This may be a live mapping process (where the data is transformed on the spot between the 2 structures) or a one-off data transformation process where the Member States migrates some product data to the target specification and thus progressively adopts the new specifications. Member States will have to handle whatever technical specifications they may have from the old format to the new format.

In short, it would be highly beneficial if Member States adopt the same process as UNICOM does – which is nothing but a formal data specification process:

- Document the current semantic specifications – based on their current data models:
- Document and implement their target semantic specifications – which may evolve, but serves as a comparable reference
- Use similar / exchangeable tools and standards – HL7 FHIR logical data models, or computable UML metadata, or Art-decor.
- Maintain a gap analysis and mapping between the Member State's semantic specifications and the common UNICOM / IDMP data specifications
    - Monitor the coverage of such mapping and any discrepancies – accidental or not – and implement a change management processes for the changes to these specifications.
- Validate the specifications by providing examples – namely those defined in the Pilot Product List.)

8 Recommendations for adoption

Finally, the activities defined above would greatly benefit from some guidance – instead of simply listing the desired goals and activities, it is better to identify the key roles and some processes, so that we can support the progress across member states.

These roles and processes reflect the targets defined above:

1. There should be a clearly stated scope plan by the member states – which of the areas are addressed first (ePrescription, eDispensation) and a contact person for stating and following up on the plan (A role like a project manager, but more likely a representative group of people maintaining such a project)
2. Semantic specifications shall contain (and be used to compare), at least,
    a. Data elements
    b. Their definition
    c. Their structure (i.e., hierarchies)
    d. Cardinalities (mandatory, repeating fields)
    e. Rules like conditional elements
    f. When applicable, value sets that are required for the data elements.

    All of this independently of any technical solution such as FHIR, CDA, etc. There should be a process at each member state to produce such a standard set of artifacts for comparison and monitoring.
3. There should be a designated person/working group per member state documenting the national semantic specifications – current and target;
    a. This person/organization should be using the common tooling as much as possible;
        i. Common tooling should be made available by UNICOM, or others, as well as references to training / troubleshooting, and potentially Communities of Practice.

4. Semantic specifications shall be compared with the target / UNICOM MALeH specifications – each member state should keep a correspondence between the national specifications and the common specifications – noting where there are conflicts or gaps.
    a. Conflicts are actual differences for example completely different value sets, or different definitions. Gaps are missing correspondences e.g., an attribute that exists in the national specification but not in the MALeH or vice-versa.
5. All changes to the semantic specifications should be controlled changes – Member States should keep track of the changes that are needed or that were implemented.
    a. An overview of the data structures and data elements, with their full definition, and the statuses like “matching”, “compatible” or “different” - where “compatible” means that there are gaps but no conflicting discrepancies.
6. A common list of products should exist, to validate the models
    a. There should be a process (and possibly a set of roles like a committee or contact person) to validate the models with the products, namely the common products in the minimum data set.
    b. There should be a process to enter national product data into a IDMP compatible format. This can be aligned with the regulatory activities, or taken from existing data, or any other way decided by the NCA.
    c. It is expected that not all the data will be immediately converted to the IDMP compatible It is highly recommended that NCAs start their conversion and adoption from the Minimum Attribute List (as defined above) and with limited set of products (the lot products that contain the 35 substances identified as more relevant)
7. There should be a clear, documented mapping between the national semantic specifications and the technical implementations –
    a. to the national drug databases
    b. To the national ePrescription / eDispensation / Patient Summary specifications
    c. To the common eHDSI specifications

With these principal processes and roles in place, the monitoring of progress will be facilitated, and most importantly, the actual progress of the member states will be facilitated, as there can be Communities of Practice, common solutions to common problems, guidance on key aspects, good practices, etc. In other words, some degree of industrialisation of the process will greatly benefit the work that needs to be done, and the monitoring of the progress.

9 Annexes

Annex 1 – Pilot Product List (PPL)

The PPL contains 35 substances (PhPID L1) that have been selected for the UNICOM pilots and should be considered by NCAs and eHealth Agencies when planning the Pilots / data provision.

Table 8: Pilot Product List

#	Moiety	Salt/ester/modification (and notes, synonyms)
1	simvastatin	
2	enalapril	enalapril sodium
		enalapril maleate
		enalaprilat
3	omeprazole	omeprazole sodium
		omeprazole magnesium
4	diclofenac	diclofenac sodium
		diclofenac potassium
		diclofenac diethylamine (synonym: diclofenac diethylammonium)
		diclofenac epolamine
5	cefuroxime	cefuroxime sodium
		cefuroxime axetil
6	salbutamol	salbutamol sulfate
7	amoxicillin and clavulanic acid	amoxicillin (anhydrous, explicitly)
		amoxicillin (unspecified)
		clavulanic acid
		amoxicillin sodium
		amoxicillin trihydrate
		potassium clavulanate
8	insulin glargine	
9	teriparatide	
10	drospirenone and ethinylestradiol	drospirenone
		ethinylestradiol
11	atorvastatin, amlodipine and perindopril	
12	calcium + vitamin D	calcium carbonate
		ergocalciferol
13	paracetamol	
14	diazepam	
15	morphine	morphine hydrochloride
		morphine sulfate
		morphine tartrate
		morphine liposomal (sulfate)
16	enoxaparin	enoxaparin sodium
17	hydrocortisone	hydrocortisone sodium succinate
		hydrocortisone valerate
		hydrocortisone acetate

#	Moiety	Salt/ester/modification (and notes, synonyms)
		hydrocortisone butyrate
		hydrocortisone aceponate
		hydrocortisone probutate (synonyms: butyrate propionate; buteprate)
		hydrocortisone cypionate
		hydrocortisone sodium phosphate
18	lidocaine	lidocaine hydrochloride
		also tosilate, hydrocarbonate, bicarbonate, maleate, carbonate - but not used in products?
19	trastuzumab	trastuzumab emtansine (synonym: ado-trastuzumab emtansine)
		trastuzumab deruxtecan
20	imatinib	imatinib mesilate
21	clomipramine	clomipramine hydrochloride
22	carbamazepine	
23	metformin	metformin hydrochloride
		metformin pamoate (synonym: metformin embonate)
24	amlodipine	(racemic)
		amlodipine besilate
		amlodipine benzoate
		amlodipine maleate
25	perindopril	perindopril arginine
		perindopril erbumine (synonym: perindopril tert-butylamine)
		perindopril erbumine monohydrate
		perindopril tosilate
26	tramadol	(racemic)
		tramadol hydrochloride
27	ciclosporine	Synonym: ciclosporin A
28	itraconazole	itraconazole trihydrochloride
29	goserelin	goserelin acetate
30	glyceryl trinitrate	nitroglycerin
31	chloroquine	chloroquine phosphate
		chloroquine sulfate
		chloroquine hydrochloride
32	clotrimazole	
33	varenicline	
		varenicline tartrate
		varenicline dihydrochloride
34	ibuprofen	(racemic)
		ibuprofen sodium
		ibuprofen lysine
35	tafluprost	

Annex 2 – CP-eHDSI-066: Prepare eHDSI Requirements Catalogue for ISO IDMP

Change Proposal Summary information

Change Proposal Title:	**ISO IDMP Adoption by eHDSI – Business Requirements**
Submitter's Name(s) and e-mail address(es):	Oskar Thunman ext.oskar.thunman@ehalsomyndigheten.se
Submission Date:	08/10/2021
Component(s) or Configuration item(s) to be changed[48]:	eHDSI Business requirements
Actor(s) affected:	
Business and Solution Requirements impacted:	05.01. Create the eHDSI Patient Summary content 05.02. Transcode, translate and exchange cross-border the Patient Summary 06. Make ePrescription available to HP 06.01. Create the eHDSI ePrescription(s) content 06.02. Transcode, translate and exchange cross-border the ePrescription 07. Handle Dispensation of medicine and Substitution 07.01. Create the eHDSI eDispensation content 07.02. Transcode, translate and exchange cross-border the eDispensation 09. Ensure high quality information (structured, equivalent, understandable) is exchanged between countries
Specifications/documentation impacted:	See the list above
Change estimated impact[49] (minor, major):	Minor

[48] Component examples: Client connector, WS server, OpenNCP Portal, epSOSWeb, OpenATNA, TRC-STS, Security Manager, TSL-Sync, TSL-Editor, TSL-Util, Protocol Terminators, TSAM Sync, Stork Plugin, CDA display tool, xslttransformer, tsamexporter, cdautils, epsos-util, configuration manager, epsos-common-components, e-SENS eID richclient, e-SENS eID design-main…

[49] Change estimated impact is the estimated order of magnitude of the change: a change will be qualified as major if it introduces for instance a component that already exists or a new component, impacting the architecture; it will be qualified as minor if it improves the existing behavior without impacting the architecture.

Change Proposal Description

Please consider that this is the section used by the eHDSI stakeholders when assessing the impact of the requested change proposal.

REASON/BUSINESS JUSTIFICATION (WHY this change is needed)

The implementation of the ISO IDMP standard in EMA SPOR databases is changing how medicinal products are (a) identified and (b) described by the National Competent Authorities, which will inform future eHealth System implementations at both national and regional level.

The goal with this change proposal is to enable the eHDSI services to make use of ISO IDMP to solve known challenges in representing medicinal products for the cross-border use cases. This includes known challenges such as complex packages, different representations of dose forms and strengths and identifying prescribed and dispensed medicinal products using unique identifiers. The CP is therefore related to the CP "Medication Information Representation Improvements", which is being processed in parallel.

It is important to provide support for the new way of identifying and describing medicinal products because this information is used in the ePrescription/eDispensation & Patient Summary (Medication Section) data sets.

There are significant benefits to making use of ISO IDMP standard including, but not limited to, improving the presentation of information about medicinal products, and streamlining the dispensation process in many cases.

The implementation of ISO IDMP is predicted in the Commission Implementing Regulation (EU) Nº 520/2012, articles 25 and 26, which obliges EU MS, marketing authorisation holders and EMA to make use of the ISO IDMP standards. In order to ensure a correct implementation of ISO IDMP in the eHDSI specifications, this CP aims at introducing new phrasings for relevant identified business requirements to the ePrescription & Patient Summary services. It is noted (also mentioned in UNICOM D5.1 - Business requirements for the adoption of IDMP in eHealth Services) that the adoption of IDMP does not impose that countries must use exclusively IDMP in their national processes – in short, national processes shall still be able to use national models). Therefore, IDMP adoption appends, but not necessarily restricts, data exchange at national and cross-border levels. Those identified changes were previously evaluated through intense study and their implementation will support the further ISO IDMP implementation.

This CP focuses on eP/eD related requirements. The work done is also beneficial to update PS related requirements. It is suggested that, when implemented, PS Cluster is involved to get aligned requirements.

In preparation of this CP, a few missing data elements were discovered in the Data elements descriptions in the eHDSI Requirements Catalogue. This CP also contains a few suggested clarifications and suggested additions to the Data elements descriptions to better reflect the current CDA implementation, although this is not directly IDMP-related.

DESCRIPTION OF THE REQUESTED CHANGE

Background information

Glossary

General	
EMA SPOR	Data management services by European Medicines Agency. The four SPOR data management services are: - SMS: substance management service - PMS: product management service - OMS: organisation management service

	- RMS: referentials management service (value sets) More information can be found on EMA SPOR web site.
Identifiers	
MPID	Medicinal product identifier. Unique identifier assigned to a branded product. The MPID is tied to the marketing authorisation life cycle and the same product is assigned a new MPID when the marketing authorisation changes.
PMS ID	Product Management Service identifier. PMS ID is a unique identifier of the medicinal product in EMA SPOR PMS system. Unlike the MPID, PMS ID remains unchanged during the entire lifecycle of the product. PMS ID is not in the original data model of ISO IDMP, but an extension by EMA.
PhPID	Pharmaceutical product identifier is a unique identifier of the product on a generic level. The PhPID is calculated on the basis of ingredients, strength, administrable dose form. Unique PhPIDs and different levels of PhPID will be available in the future.
PCID	Packaged medicinal product identifier. PCID consists of two parts: the corresponding MPID and the package description code segment. A unique PCID is assigned for each package that has a different set of size, package type/material or manufactured items.
Dose forms	
Authorised dose form	The pharmaceutical dose form as authorised by regulatory authorities. This includes combined pharmaceutical forms like *Powder and solvent for solution for injection*. Authorised dose form is not in the original data model of ISO IDMP, but an extension by EMA.
Administrable dose form	Pharmaceutical dose form in which the product is administered to the patient. For example, in case of the example given for the authorised dose form section, the corresponding administrable dose form is *Solution for injection*.
Manufactured dose form	Pharmaceutical dose form of a manufactured item (before transformation into the pharmaceutical product). One medicinal product may consist of several manufactured products with different manufactured dose forms, e.g., *Solution for solution for injection*, *Powder for solution for injection*.
Strengths	
Reference strength	Reference strength represents the strength of the active moiety to express the strength of the product. If the active substance in the product is salt or ester, the reference strength would be different from the presentation/concentration strength. For example: if the strength for omeprazole magnesium is 20.6mg/tablet; the reference strength of the product would be described as omeprazole 20mg/tablet.
Concentration strength	Concentration strength represents the amount of an active ingredient per single unit of measure. This is the regular way of describing the strength for liquid dose forms, e.g., 10mg/g.

Presentation strength	Presentation strength represents the amount of an active ingredient per one unit of presentation. This is the regular way of describing the strength for tablets, capsules and other solid countable items. This information would also be available for other dose forms, e.g., 10mg/vial, 120mg/bottle, 50mcg/actuation.
Units	
Unit of measurement	Units of measurements are standardized quantities of measurement. The eHDSI and EMA SPOR both make use of the UCUM list of units of measure.
Unit of presentation	Unit of presentation describes the single countable entity in which a pharmaceutical product or manufactured item is presented. Although unit of presentation has an overlapping content with package types as well as dose forms, it should not be confused with either of them.

Full ISO IDMP data model is a complex set of data elements in a specific structure. The granularity of this information is suitable for the regulatory authorities. Even though it is expected, that having unified and more detailed medication data available on a national and international level will change the way this data is represented in all the information systems, there is no clear guidance on if, how or when these changes should be implemented in national prescription systems.

eHDSI is not aiming to implement full ISO IDMP in the eHDSI services, but to make use of ISO IDMP data model and EMA SPOR value sets to improve our services and make it possible for member states to send their data in a similar (but simplified) format. However, it must be stated, that if a member state is not capable of sending this data, it can still use the services, and the new attributes and layers of information will be optional on country A side.

To plan the upcoming changes, some changes have to be made in the business requirements that are listed below. In many cases, the actual change is still up for discussion, but it is important to show the relations between current business requirements, parallel change requests and possible future implementation changes that are still up for discussion.

For more information about implementing ISO IDMP in EMA SPOR, please refer to EU ISO IDMP Implementation Guide.

List of improvements and discussion points

05.01 Create the eHDSI Patient Summary content

Requested change

The table named “The dependencies between the information exchanged in both services” should be removed/replaced, as it is partly misleading.

Further analysis needed

There is an overlapping content in Patient Summary’s medication summary and ePrescription and eDispensation. These data sets should be harmonised where necessary and the ePrescription content changes described below (requirement 06.01) should be taken into account.

Impact

No impact at this point.

Requested change aims to clarify the actual existing content.

Any decisions emerging from the analysis of the PS content will be communicated to the member states separately and member states will have an opportunity to agree or disagree with the change.

05.02 Transcode, translate and exchange cross-border the Patient Summary.

Change requests

No changes are required to the business requirement text at this time.

Further analysis

Additional translations and transcodings might be required, in the event of new code systems and value sets being developed and introduced, switching to EMA SPOR value sets where necessary.

The use of ISO IDMP will positively contribute to the implementation of this business requirement in the future by replacing some of the textual elements with coded entries and improving the data structure.

Impact

No impact, as the possible future changes will be approved by member states before implementation.

06.01 Create the eHDSI ePrescription content.

GENERAL

Further analysis needed

The data sets used for the Medication Summary section in Patient Summary, ePrescription and eDispensation should be harmonised (use of the same attributes and elements to describe the medicinal products, for the different use cases) across the use cases; eP/eD and PS.

While product information should be harmonised, it is important also to acknowledge that the level of detail about products in an ePrescription may differ from the level of detail in a eDispense – in a prescription, the product information can be more or less granular, but dispenses are reported with much more detail (as reported in UNICOM D5.2). Therefore, we suggest to start by splitting the notion of Prescribed Product and Dispensed Product.

The exact content and cardinality of data elements is yet to be discussed more thoroughly and agreed with the member states.

Impact

The change has no impact on member states at this point.

The exact changes are negotiable and have to be agreed by member states. Any changes in the cardinality of data elements must take into account that member states who are already active in the eHDSI services must be able to continue data exchange.

IMPROVE DESCRIPTION OF DATA ELEMENTS

Requested changes

Add *ATC code* to the specification as it is already supported by the technical specifications but absent from the business requirements.

Add *Packaged product description* text field into the data set specification to provide a sufficiently detailed description of the prescribed medicinal product/package.

Add and clarify information according to the parallel CP "Medication Information Representation Improvements". The business requirements should help understand how to describe layers of complex packages and how to use MPID and PCID or their national equivalents.

Impact

No impact. The changes are simply rephrasing the business requirements to give better explanation of the existing solution and the parallel CP (agreed by Member States independently from this CP).

NEW DATA ELEMENTS FOR DISCUSSION

IDMP identifiers

Further analysis needed

ISO IDMP and EMA SPOR introduce a list of identifiers to be used on different levels for identifying a medicinal product or its package.

Enable provision of ISO IDMP identifiers in addition to the currently supported "national code": PCID, MPID, PhPIDs; assuring that the type of each IDMP ID is correctly identified, including the multiple levels of PhPID.

Introducing new identifiers requires corresponding data structure to be implemented. Any changes in the implementation needs to take into account that not all member states have this data available at the same time and using new identifiers must remain optional.

Parallel CP "Medication Information Representation Improvements" proposes adding PCID, but also states that using this data element is optional and a national package identifier can be used.

Impact

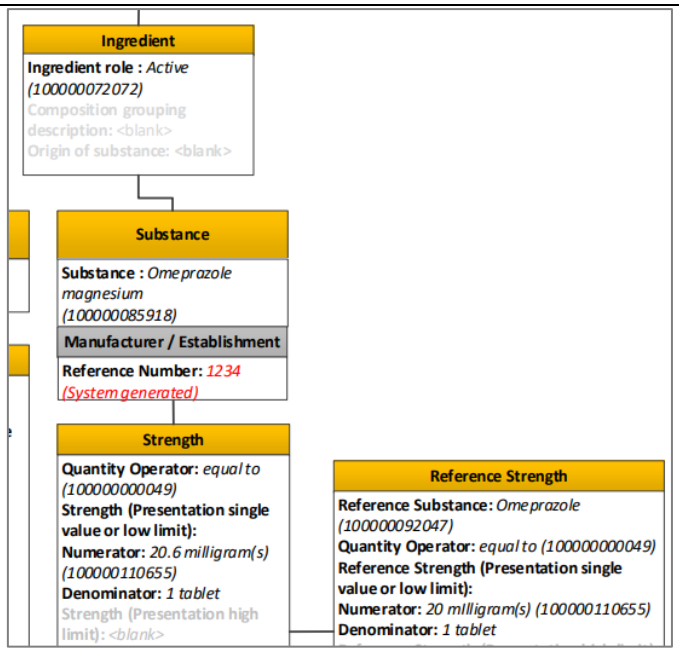
No impact at this point.

Ingredients and strenghts

Further analysis needed

ISO IDMP and EMA SPOR SMS provide an opportunity to identify all the ingredients in the product: active ingredients as well as other ingredients such as adjuvants or additives (e.g., lactose). It should be thoroughly analysed how this information could improve the quality of eHDSI services.

The strength of active ingredients could also be described more precisely by adopting the ISO IDMP model for expressing strength. For example, by adding reference strength, it would be possible to express the strength by the quantity of salt (omeprazole magnesium) as well as by the active moiety within the salt (omeprazole). The example below is a piece of ISO IDMP data model from EU ISO IDMP Implementation Guide (Chapter 8, Annex I "Complete Representation").



Impact

No impact at this point. Member states are invited to discuss the need and opportunities to express additional information about ingredients and strengths.

Package size

Requested changes

The most important changes in representing the contents of the package are proposed as a separate CP “Medication Information Representation Improvements”. These changes follow the structural and conceptual logic of ISO IDMP and would help us overcome the main problems we’re facing today: representing multi-layer packages (e.g., 5 vials of 3ml as one product) and complex packages (e.g., creme + tablets marketed as one product).

The business requirements must be renewed according to these changes, so that the description of the data element *Medicinal product package* would explain how the nested structure helps calculate the total amount of the product within a package or the overall amount prescribed on an ePrescription.

Impact

No impact to the member states as this change requests only states the need to renew the business requirements. The actual change request for implementation changes is processed separately.

The change itself will improve the reliability of crossborder eP by removing ambiguities and increasing dispensability.

Dose forms and unit of presentation:

Further analysis needed

ISO IDMP structure includes different dose forms with different meanings. For better understanding, please see the dose form section in the glossary. Also, concept of *Unit of presentation* is introduced to describe the product as well as the quantity of the product.

It is important to analyse the possibilities to better reflect the dose form concept and highlight the distinction between the authorised, manufactured and administrable dose form on the eP and eD documents. Clarifications are needed on how to understand if *Unit of presentation* or *Dose form* should be used in the description of medication or posology. These value sets have overlapping content, but they should not be confused as they represent a different concept.

The future solution should also support different levels of granularity of dose forms (e.g., capsule, hard; capsule), providing relationships between them.

In order to make use of the variety of dose forms and units, the representation of medication must follow the general structure of ISO IDMP.

Impact

No impact at this point. Member states are invited to discuss the need and opportunities to express additional information about dose forms.

06.02 Transcode, translate and exchange cross-border the ePrescription.

Change requests

No changes are required to the business requirement text at this time.

Further analysis

Additional translations and transcoding might be required, in the event of new code systems and value sets being developed and introduced, switching to EMA SPOR value sets where necessary.

The use of ISO IDMP will positively contribute to the implementation of this business requirement in the future by replacing some of the textual elements with coded entries and improving the data structure.

The changes applied to data elements on eP might also lead to improved prescription list, which is described under this requirement.

Impact

No impact at this point, as the possible future changes will be approved by member states before implementation.

07 Handle Dispensation of medicine and substitution

Change requests

No changes are required to the business requirement text at this time.

Further analysis

The business requirement has a reference to a flag indicating whether substitution was performed as part of the dispensation process. The process of substitution is not standardized, but further details may be provided during UNICOM. It is still useful to maintain the attribute “Substitution performed” (in the dispense dataset) differently from “substitution allowed” (which is appropriate in the prescription dataset).

Impact

No impact, as the possible future changes will be approved by member states before implementation.

07.01 Create the eHDSI eDispensation content.

Requested changes

Align the product description with the ePrescription model (see the changes to the requirement 06.01 Create the eHDSI ePrescription content).

Add *also Patient gender* to the specification as it is already supported by the technical specifications but absent from the business requirements.

Remove or clarify “Dispensed medicine ID” as it can be confused with “Medicinal product code”.

Rephrase „Medicinal product description“ to „Dispensed product description“. The requirement text should explain, that unlike the ePrescription, where the main product code refers to different ‘concepts’ of products (e.g., prescription can refer to brand, generic or substance levels), in dispensation the most specific product identifier is usually captured (i.e. medicinal product package code or similar).

Improve description of the package size and quantity of the dispensed medication within the “Dispensed product description” element. The requirements for describing the package size are explained above at “06.01 Create the eHDSI ePrescription content”. In the context of eDispensation, the requirement text should explain how the number of packages and different layers of package description result in an overall amount of dispensed items.

Move “Number of packages” from “Medicinal Product Description” group to “Dispensed Medicine Data” group.

Impact

No impact to the member states at this point. The changes aim to add clarity to the requirement text and do not impose any changes in the implementation.

Further analysis needed

In the ISO IDMP mode, an additional “Pack(age) size” attribute is available, but as this is just a textual element (e.g., *1 vial and 1 syringe*), it would not contribute to calculating the amount. However, introducing the data element may help understanding the most difficult cases, even if it was readable for a human eye only.

It would also be possible to add the data element “Package size” and analyse if member states would be able to provide structured, automatically processable data in it, or would it merely be the multiplication of quantities provided in the nested layers of the description of package.

The total amount of dispensed product is a required information. The total amount can be expressed either as an explicit data element, or as the combination of the number of packages dispensed and the quantity per package. It is up for discussion if the distinct data elements should be provided to express:

- Total dispensed amount: The total quantity of dispensed product items (including units) that has been dispensed.
- Number of dispensed packages – the number of items that have been dispensed, where each item is identified by the dispensed medicinal product code above. The total amount of dispensed product corresponds to the number of packages multiplied by the package size.

The way of describing dispensed amount (total quantity vs number of packages x package size) will depend on local regulations and each clinical case, so one cannot be enforced over the other. Given

that there are two ways of achieving the same goal, further guidance should be given on the use of these attributes, and Member States should have support in selecting which one(s) to use.

Impact

No impact, as the possible future changes will have to be approved by member states before implementation.

07.02 Transcode, translate and exchange cross-border the eDispensation.

Change requests

No changes are required to the business requirement text at this time.

Further analysis

Additional translations and transcoding might be required, in the event of new code systems and value sets being developed and introduced, switching to EMA SPOR value sets where necessary.

The use of ISO IDMP will positively contribute to the implementation of this business requirement in the future by replacing some of the textual elements with coded entries and improving the data structure.

Impact

No impact, as the possible future changes will have to be approved by member states before implementation.

09 Ensure High quality information (structured, equivalent, understandable) is exchanged between countries.

Requested changes

No changes requested in the text of business requirement at this point.

Further analysis needed

However, adopting ISO IDMP identifiers and adopting the common EU terminology provided by EMA SPOR value sets will significantly provide more possibilities to deal with the unified meanings regarding medicines.

Once these improvements have made their way in the eHDSI service, the business requirement should be updated with relevant information.

Impact

No impact to the member states at this point.

OVERVIEW OF THE EXPECTED OUTCOMES/BENEFITS

The CP aims to clarify the current business requirements and start a fruitful discussion with member states about implementing future changes related to the ISO IDMP and the parallel work in the UNICOM project. It also aims to provide functional requirements to match the discussions around “complex packages” in the CP from the STF Architecture WG “Medication Information Representation Improvements” (targeting the CDA IG).

As the result of this project the health professional in the country of treatment will receive more detailed and understandable information about the medicinal product that appears on a Patient Summary or an ePrescription document:

- Ingredients and ingredient roles (coded and translatable)

- Product identifiers on different levels (e.g., PhPID, MPID, PCID)
- Package content (clear quantities, device), package types (coded and translatable)
- Dose form (multiple dose forms of different types, coded and translatable)
- Units of presentation in addition to units of measurement (coded and translatable)
- Strength (reference strength in addition to current solution)

When a dispensation is performed abroad, the same approach will be taken when providing the eDispensation document allowing country of affiliation to better integrate information about dispensations performed abroad in their national infrastructure.

Additional information about substances, dose forms etc might also be added to the prescription list, allowing the pharmacist to better understand its contents in order to choose the correct medicinal product to be dispensed.

The new information elements and their consistent use in ePrescription, eDispense and Patient Summary, aligned with IDMP concepts and common SPOR vocabulary, will help the entire cycle of product information:

- The pharmacist in the Country of Treatment to better assist in the selection of the medicinal product to be dispensed to the patient.
- The responsible physician to better understand what has been dispensed.
- The Patient Summary to contain coherent and reconciled data.

Annex 3 – Code Systems in MVC 6.1.0

The Table 9 presents the coding systems and their identifiers codes used in the eHDSI MVC 6.1.0 for eHDSI wave 6 (2022-2023).

Table 9: Code Systems in MVC 6.1.0

Value Set name	Value Set ID	Code System(s)	Code System(s) ID	Version(s) of Code System used in MVC
eHDSIAbsentOrUnknownAllergy	1.3.6.1.4.1.12559.11.10.1.3.1.42.47	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	0.2.0
eHDSIAbsentOrUnknownDevice	1.3.6.1.4.1.12559.11.10.1.3.1.42.48	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	0.2.0
eHDSIAbsentOrUnknownMedication	1.3.6.1.4.1.12559.11.10.1.3.1.42.49	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	0.2.0
eHDSIAbsentOrUnknownProblem	1.3.6.1.4.1.12559.11.10.1.3.1.42.50	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	0.2.0
eHDSIAbsentOrUnknownProcedure	1.3.6.1.4.1.12559.11.10.1.3.1.42.51	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	0.2.0
eHDSIActiveIngredient	1.3.6.1.4.1.12559.11.10.1.3.1.42.24	ATC Classification	2.16.840.1.113883.6.73	2022-01
eHDSIAdministrativeGender	1.3.6.1.4.1.12559.11.10.1.3.1.42.34	HL7 v3 AdministrativeGender	2.16.840.1.113883.5.1	20210930
eHDSIAdverseEventType	1.3.6.1.4.1.12559.11.10.1.3.1.42.18	SNOMED CT	2.16.840.1.113883.6.96	44469
eHDSIAllergenNoDrug	1.3.6.1.4.1.12559.11.10.1.3.1.42.19	SNOMED CT	2.16.840.1.113883.6.96	43677 44469
eHDSIAllergyStatus	1.3.6.1.4.1.12559.11.10.1.3.1.42.59	FHIR Allergy Intolerance Clinical Status Codes	2.16.840.1.113883.4.642.4.1373	4.0.1
eHDSIBloodGroup	1.3.6.1.4.1.12559.11.10.1.3.1.42.20	SNOMED CT	2.16.840.1.113883.6.96	43677
eHDSIBloodPressure	1.3.6.1.4.1.12559.11.10.1.3.1.42.21	LOINC	2.16.840.1.113883.6.1	2.59
eHDSICertainty	1.3.6.1.4.1.12559.11.10.1.3.1.42.58	FHIR Allergy Intolerance Verification Status Codes	2.16.840.1.113883.4.642.4.1371	4.0.1
eHDSICodeProb	1.3.6.1.4.1.12559.11.10.1.3.1.42.23	SNOMED CT	2.16.840.1.113883.6.96	43677
eHDSIConfidentiality	1.3.6.1.4.1.12559.11.10.1.3.1.42.31	HL7 v3 Confidentiality	2.16.840.1.113883.5.25	913-20091020
eHDSICountry	1.3.6.1.4.1.12559.11.10.1.3.1.42.4	ISO 3166-1 Country codes (Alpha-2 code)	1.0.3166.1	Second Edition 2006
eHDSICriticality	1.3.6.1.4.1.12559.11.10.1.3.1.42.57	FHIR Allergy Intolerance Criticality	2.16.840.1.113883.4.642.4.130	4.0.1
eHDSICurrentPregnancyStatus	1.3.6.1.4.1.12559.11.10.1.3.1.42.60	SNOMED CT	2.16.840.1.113883.6.96	44469
eHDSIDisplayLabel	1.3.6.1.4.1.12559.11.10.1.3.1.42.46	epSOSDisplayLabel	1.3.6.1.4.1.12559.11.10.1.3.1.44.4	1.5
eHDSIDocumentCode	1.3.6.1.4.1.12559.11.10.1.3.1.42.32	LOINC	2.16.840.1.113883.6.1	2.59
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	44579
eHDSIHealthcareProfessionalRole	1.3.6.1.4.1.12559.11.10.1.3.1.42.1	ISCO-08	2.16.840.1.113883.2.9.6.2.7	2008

Value Set name	Value Set ID	Code System(s)	Code System(s) ID	Version(s) of Code System used in MVC
eHDSIHospitalDischargeReportType	1.3.6.1.4.1.12559.11.10.1.3.1.42.53	LOINC	2.16.840.1.113883.6.1	2.59
eHDSIIllnessandDisorder	1.3.6.1.4.1.12559.11.10.1.3.1.42.5	ICD-10 International Statistical Classification of Diseases and Related Health Problems 10th Revision	1.3.6.1.4.1.12559.11.10.1.3.1.44.2	2016
eHDSILaboratoryReportType	1.3.6.1.4.1.12559.11.10.1.3.1.42.52	LOINC	2.16.840.1.113883.6.1	2.59
eHDSILanguage	1.3.6.1.4.1.12559.11.10.1.3.1.42.6	ISO 639-1 + ISO 3166-1	1dd183a6-6d2b-4a9d-8f5d-be09d6bb5a6e	March 2017
eHDSIMedicalDevice	1.3.6.1.4.1.12559.11.10.1.3.1.42.8	SNOMED CT	2.16.840.1.113883.6.96	43677 44469
eHDSIMedicalImagesType	1.3.6.1.4.1.12559.11.10.1.3.1.42.55	LOINC	2.16.840.1.113883.6.1	2.59
eHDSIMedicalImagingReportType	1.3.6.1.4.1.12559.11.10.1.3.1.42.54	LOINC	2.16.840.1.113883.6.1	2.59
eHDSINullFlavor	1.3.6.1.4.1.12559.11.10.1.3.1.42.37	HL7 v3 NullFlavor	2.16.840.1.113883.5.1008	913-20091020
eHDSIOutcomeOfPregnancy	1.3.6.1.4.1.12559.11.10.1.3.1.42.62	SNOMED CT	2.16.840.1.113883.6.96	44469
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	44579
eHDSIPersonalRelationship	1.3.6.1.4.1.12559.11.10.1.3.1.42.38	HL7 v3 RoleCode	2.16.840.1.113883.5.111	913-20091020
eHDSIPregnancyInformation	1.3.6.1.4.1.12559.11.10.1.3.1.42.9	LOINC	2.16.840.1.113883.6.1	2.59
eHDSIProcedure	1.3.6.1.4.1.12559.11.10.1.3.1.42.10	SNOMED CT	2.16.840.1.113883.6.96	43677 44469
eHDSIQuantityUnit	1.3.6.1.4.1.12559.11.10.1.3.1.42.56	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	44579
eHDSIRareDisease	1.3.6.1.4.1.12559.11.10.1.3.1.42.63	ORPHAnet	1.3.6.1.4.1.12559.11.10.1.3.1.44.5	44683
eHDSIReactionAllergy	1.3.6.1.4.1.12559.11.10.1.3.1.42.11	SNOMED CT	2.16.840.1.113883.6.96	43677 44469
eHDSIResolutionOutcome	1.3.6.1.4.1.12559.11.10.1.3.1.42.30	SNOMED CT	2.16.840.1.113883.6.96	43677
eHDSIRoleClass	1.3.6.1.4.1.12559.11.10.1.3.1.42.39	HL7 v3 RoleClass	2.16.840.1.113883.5.110	913-20091020
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	44579
eHDSISection	1.3.6.1.4.1.12559.11.10.1.3.1.42.26	LOINC	2.16.840.1.113883.6.1	2.59
eHDSISeverity	1.3.6.1.4.1.12559.11.10.1.3.1.42.13	SNOMED CT	2.16.840.1.113883.6.96	43677
eHDSISocialHistory	1.3.6.1.4.1.12559.11.10.1.3.1.42.14	SNOMED CT	2.16.840.1.113883.6.96	43677 44469
eHDSIStatusCode	1.3.6.1.4.1.12559.11.10.1.3.1.42.15	SNOMED CT	2.16.840.1.113883.6.96	43677
eHDSISubstance	1.3.6.1.4.1.12559.11.10.1.3.1.42.61	EMA SMS Substance	1.3.6.1.4.1.12559.11.10.1.3.1.44.100000075825	44711

Value Set name	Value Set ID	Code System(s)	Code System(s) ID	Version(s) of Code System used in MVC
eHDSISubstitutionCode	1.3.6.1.4.1.12559.11.10.1.3.1.42.7	HL7 v3 substanceAdminSubstitution	2.16.840.1.113883.5.1070	913-20091020
eHDSITelecomAddress	1.3.6.1.4.1.12559.11.10.1.3.1.42.40	HL7 v3 AddressUse	2.16.840.1.113883.5.1119	913-20091020
eHDSITimingEvent	1.3.6.1.4.1.12559.11.10.1.3.1.42.41	HL7 v3 TimingEvent	2.16.840.1.113883.5.139	913-20091020
		FHIR Event Timing	2.16.840.1.113883.4.642.4.1371	4.0.1
eHDSIUnit	1.3.6.1.4.1.12559.11.10.1.3.1.42.16	UCUM Unified Code for Units of Measure	2.16.840.1.113883.6.8	April 2021
eHDSIVaccine	1.3.6.1.4.1.12559.11.10.1.3.1.42.28	ATC Classification	2.16.840.1.113883.6.73	2022-01
		SNOMED CT	2.16.840.1.113883.6.96	43677
				44469

Annex 4 – CP-eHDSI-063: Improve Medication Information Representation

Change Proposal Summary information

Change Proposal Title:	Medication Information representation improvements
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Submission Date:	30/09/2021
Component(s) or Configuration item(s) to be changed[50]:	CDA IG, OpenNCP, CDA Display Tool
Actor(s) affected:	• eHMSEG STF Architecture workgroup • eP cluster
Business and Solution Requirements impacted:	-
Specifications/documentation impacted:	-
Change estimated impact[51] (minor, major):	minor

Change Proposal Description

Please consider that this is the section used by the eHDSI stakeholders when assessing the impact of the requested change proposal.

REASON/BUSINESS JUSTIFICATION (WHY this change is needed)
Since some time, the concern was raised by Member States that it is impossible to represent some complex medication packages using the existing CDA IG template definitions. Examples of complex medicinal packages were collected by Member States and the analysis and investigation was started in the eHMSEG STF Architecture WG on how these examples could be represented in the CDA IGs: this allowed us to identify shortcomings in our current CDA IGs and by looking at the HL7 standard and the extended XML schema definitions, it was considered what modifications need to be introduced to solve our current issues. During this analysis and thinking process, other projects like ISO IDMP and UNICOM were kept in mind. As a conclusion, 5 changes to the CDA IGs were identified, that could solve almost all shortcomings in our current CDA IGs and would allow Member States to present their complex medication packages. These suggestions were presented to the eP Cluster, where the analysis was continued and feedback was collected from the Member States. Analysis and feedback from both groups were collected and combined in this change proposal. Final remark is that special attention must be paid to writing explanatory documentation of the elements to be adapted the CDA IGs. It must be clear for implementers how to specify complex medication packages by just reading the provided documentation.

[50] Component examples: Client connector, WS server, OpenNCP Portal, epSOSWeb, OpenATNA, TRC-STS, Security Manager, TSL-Sync, TSL-Editor, TSL-Util, Protocol Terminators, TSAM Sync, Stork Plugin, CDA display tool, xslttransformer, tsamexporter, cdautils, epsos-util, configuration manager, epsos-common-components, e-SENS eID richclient, e-SENS eID design-main…

[51] Change estimated impact is the estimated order of magnitude of the change: a change will be qualified as major if it introduces for instance a component that already exists or a new component, impacting the architecture; it will be qualified as minor if it improves the existing behaviour without impacting the architecture.

DESCRIPTION OF THE REQUESTED CHANGE

In total, 5 improvements and fixes were identified that could improve the presentation of the medicinal product packaging:

1. **To represent the package structure in more detail, one or multiple (up to 3) optional intermediate layers of asContent element could be defined in the CDA IGs.**

In order to represent complex medicinal product packages, there is the current limitation that we only have one *epsos:asContent* element which makes it impossible to represent layering of packages.

Therefore we want to follow the approach taken in the HL7 IPS CDA where nested *epsos:asContent* elements can be provided.

The product might have a single (30 pills bottle) or multiple (5 vials 10 ml; box with 2 blisters of 20 tablets) layers of packaging.

In the latter case, the most inner (nested) item represents the most outer package item.

For example the case

\--Box

\-----2 blisters

\--------20 tablets

is described as "20 tablets" contained by "a blister"; "2 blisters" contained by one box.

The most inner package represents the Packaged Medicinal Product.

When the IDMP Packaged Medicinal Product ID (PCID) will become actually available for usage, the most inner package <code> element will be used to convey the IDMP PCID. Until then a national package identifier can be used. The second improvement will go more in detail on the package identifier.

Example of a Packaged Medicinal Product with multiple layers packaging:

```
<asContent>
  <containerPackagedProduct>
    <!--                Inner                  Package                  -->
    <code codeSystem="..." code="..." displayName="..."/>

    <asContent>
      <containerPackagedProduct>
        <!--              Intermediate              Package              -->
        <asContent>
          <containerPackagedProduct>
            <!--   Outer   Package   /   Packaged   Medicinal   Product   -->
          </containerPackagedProduct>

        </asContent>

       </containerPackagedProduct>

     </asContent>

  </containerPackagedProduct>

</asContent>
```

Impact

Since the additional asContent layers are optional, Member States that can provide this information will be able to represent it in the new structure. Member States receiving this information must be able to visualize it in the CDA Display Tool for display, that will need to be adapted.

2. An optional code element (which is available in the schema definitions) could be added to the innermost package element (outermost package) to contain the package identifier. In the future, this could be used to contain the ISO IDMP PCID.

In the current version of the CDA IGs, there is the possibility to put the regional/national medicinal product code or MPID compliant with the IDMP system in the *hl7:code* element inside the *hl7:manufacturedMaterial* element. It is noted that this element contains often the regional/national medicinal product package identifier. Currently there is no way to define this package identifier. The idea of this improvement is to provide an additional (optional) code element at the outermost package level inside the *epsos:asContent* structure.

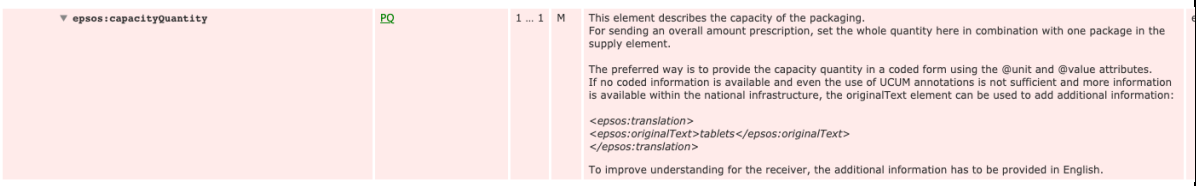
Since this element is optional, it does not need to be filled in, but it allows Member States to fill in the correct identifiers at the correct location.

Impact

Member States need to consider where they put the regional/national medicinal product code and package codes. Also the CDA Display Tool needs to be adapted to display both codes.

3. epsos:capacityQuantity on containerPackagedMedicine level (which is the capacity of the package) is not used according to the CMET specifications, instead epsos:quantity on the asContent level should be used to capture the capacity of the package.

In the current version of the **eHDSI Material** template (https://art-decor.ehdsi.eu/html/publication/epSOS/epsos-html-20210621T103924/tmp-2.16.840.1.113883.3.1937.777.11.10.143-2020-09-09T141531.html), the *epsos:capacityQuantity* element is used to contain the package size of a product.



epsos:capacityQuantity	PQ	1 .. 1	M	This element describes the capacity of the packaging. For sending an overall amount prescription, set the whole quantity here in combination with one package in the supply element. The preferred way is to provide the capacity quantity in a coded form using the @unit and @value attributes. If no coded information is available and even the use of UCUM annotations is not sufficient and more information is available within the national infrastructure, the originalText element can be used to add additional information: <epsos:translation> <epsos:originalText>tablets</epsos:originalText> </epsos:translation> To improve understanding for the receiver, the additional information has to be provided in English.

This is a wrong interpretation from the past: The capacityQuantity is supposed to represent the functional capacity of the container: e.g., blister containing 20 tablets or a bottle of 1L. But this container could only be filled partially: Maybe a blister with space for 20 tablets, only contains 10 tablets or a 1L bottle is only filled by half. The real package size is supposed to be contained in the *epsos:quantity* element on the *epsos:asContent* level.

The *epsos:quantity* element needs to be added as mandatory to the *epsos:asContent* level to contain the real package size and the *epsos:capacityQuantity* can be omitted to avoid further misuse.

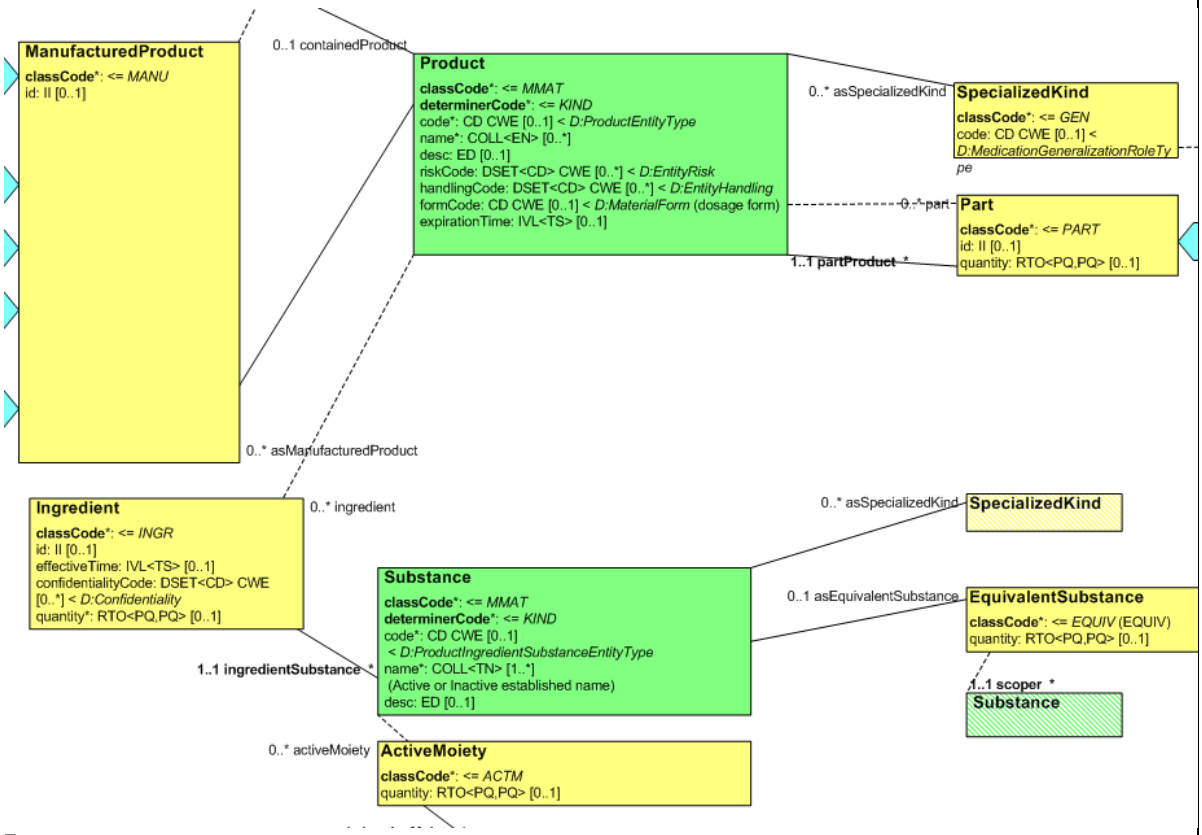
Impact

Member States need to provide the package size in the epsos:quantity element and no longer in the *epsos:capacityQuantity* element. The CDA Display Tool needs to be updated accordingly.

4. There are a lot of situations where a box consists of different parts where each part has its own ingredients or strength. To represent this, the part element can be introduced.

Most of the medicinal products can be represented well using the current structure, but for some cases, the package consists of different parts with every part having its own ingredients/strength. This can currently not be represented by the CDA IGs. However, in both the epsos extensions of the CDA schema definitions and the HL7 pharmacy extensions, the *epsos:part* element is defined which allows to define different parts of the medicinal product. This part element can be added as optional and can be used in the case the medicinal product package consists of different parts, which in turn, possibly may have different active ingredients and strength.

In the CMET model below, it can be seen that a product can have one or multiple optional part elements, which in turn contains again partProducts with all the elements available for a medicinal product.



Impact

Since the part elements are optional, the part elements can only be provided by Member States that are capable of providing this type of information. Like the other items, Member States receiving this information must be able to represent it in their CDA Display Tool.

5. Consider the switch of the epSOS medication CDA extensions to the hl7 pharmacy profile.

Background

The exchange of clinical documents in the eHDSI project is based on the eHDSI CDA implementation guides normative specifications based on the CDA R2 specifications. For inspiration, the IHE PCC and CCD template definitions where used to define the templates. Since for the electronic prescriptions and patient summaries, specific requirements are needed that could not be fulfilled using the standard CDA R2 XML schema definitions, an extension was created. The epSOS CDA extensions for the medication are handled under the XML namespace identifier *urn:epsos-org:ep:medication* and typically use the namespace prefix *epso*s.

More recently, the HL7 pharmacy profile is defined, which almost completely matches the epSOS medication profile. The HL7 pharmacy profile uses the XML namespace identifier *urn:hl7-org:pharm* and typically use the namespace prefix *pharm*.

Motivation

Some issues were encountered with the current epsos medication extensions that need to be fixed. Since these problems are already fixed in the HL7 Pharm extensions, it is a good moment to align our specification with existing initiatives. With the move from the epSOS medication profile towards the HL7 pharmacy profile it is not our intention to change the specifications, but just to align better with the different initiatives and standards. The HL7 pharmacy project is already used in the HL7 IPS (International Patient Summary) CDA and can be seen as a joint work item with the UNICOM project and HL7 Europe.

Impact

- The biggest difference / improvement is the usage of the subordinated SBADM that allows to resolve some inconsistencies with the effectiveTime and have a single template structure independent of the type of administration.
- Currently the HL7 pharmacy profile has no support for defining the marketing authorization holder, which is defined in the specifications on the ManufacturedProduct level in the epSOS medication extension.
- Namespace and namespace prefix will change.
- Some element names will change.

Conclusion

- In the eHDSI project a switch could be made to the HL7 pharmacy profile with a relative small impact for the Member States, that will solve some issues in the epSOS medication extension. It is always good to adhere to a standard. To avoid an ad hoc solution to write an eHDSI specific extension to support the marketing authorization holder, it could be integrated in the HL7 pharmacy extension.

OVERVIEW OF THE EXPECTED OUTCOMES/BENEFITS

Current CDA IG definitions can be used to represent the vast majority of the medicinal product package structures. The goal of this change proposal is to fix the remaining cases and to improve the quality of the ePrescription service and the patient care in Europe.

Although not all Member States are able to provide the medicinal product packaging structures in the proposed form, there is at least the possibility for Member States that are requesting this feature.

Linked with this improvement, it is a good opportunity to consider the switch to the hl7 pharmacy profile in order to adhere to an HL7 standard and fix open issues in the current epSOS medication extensions.