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WP5 – IDMP adoption by eHealth Services

D5.3: Guidelines for cross-border semantic interoperability

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Deliverable abstract

The D5.3 - *Guidelines for cross-border semantic interoperability* intends to present the semantic components that should be considered for the adoption of the ISO IDMP standards among the national and cross-border systems. This ensures the semantic interoperability of eP/eD & PS in the different Member States. To fulfil this objective, the purpose of this document is to provide:

- A reference data model
- The data elements and their terminology bindings (master value sets).

An analysis of the semantic components from eHDSI is necessary to identify a proposed reference model and the first draft of the semantical data set to inform the implementation process.

Keywords: Semantic, eHDSI, IDMP, Interoperability, attributes.

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List of abbreviations

Abbreviation	Complete form
ATC	Anatomical Therapeutic Chemical Code
CBeHIS	Cross Border eHealth Information Services
CDA	Clinical Document Architecture
CEF	Connecting Europe Facility
CP	Change Proposal
EC	European Commission
eD	Electronic Dispensation
EDQM	European Directorate for the Quality of Medicines
eHDSI	Health Digital Service Infrastructure
eHN	eHealth Network
EMA	European Medicines Agency
eP	Electronic Prescription
EU	European Union
EU-SRS	European substance reference system
ID	Identification
IDMP	Identification of Medicinal Products
ISO	International Organisation for Standardisation
MVC	Master Value Set Catalogue
MPID	Medicinal Product Identifier
NCA	National Competent Agency
NCPeH	National Contact Points for eHealth
PCID	Packaged Medicinal Product Identifier
PhP	Pharmaceutical Product
PhPID	Pharmaceutical Product Identifier
PMS	Product Management Service
PPL	Pilot Product List
PS	Patient Summary
SMS	Substance Management Services
SPOR	Substance, Product, Organisation and Referential
STF	Semantic Task Force
UCUM	Unified Code for Units of Measure

Executive summary

The overarching objective of the UNICOM project is improved patient safety and better healthcare for all. It focuses on the implementation of the International Organization for Standardization (ISO) suite of IDMP (**ID**entification of **M**edicinal **P**roducts) standards. Work will involve further development, testing, implementation and diffusion of these standards for:

- regulatory purposes of national medicinal products authorities and the European Medicines Agency (EMA)
- global pharmacovigilance
- advancing cross-border digital health services, particularly ePrescription
- better healthcare for all, public health services, clinical research, big data analytics, artificial intelligence applications.

The WP5 focuses on the overall orchestration for the adoption of ISO IDMP in eHealth Services, at a national and cross-border level. Initially, the emphasis is on the ePrescription (eP) and Patient Summary (PS) use cases at a cross-border level. WP5 defines all requirements for the IDMP implementation and D5.3 sets the guidelines for sematic interoperability.

This document intends to present the semantic components to adopt the ISO IDMP standards among the national and cross-border systems, ensuring semantic interoperability in the different Member States. To fulfil this objective, the purpose of this document is to provide:

- A reference data model is needed for the adoption of IDMP in eP/eD.
  - Definition of a minimum semantic data set;
  - Mapping of IDMP-based codes at national and European level
  - Adoption of IDMP-based codes at CEF eHDSI level.
- The data model consists of the definition of data elements and their terminology bindings (master value sets).
- Additional guidelines for ensuring the consistency (across all actors and over time) of the model and its use.

A detailed analysis on both reference models and initial design identified a common semantic data set that should be used by the different stakeholders when adopting ISO IDMP.

1 Introduction and Background

1.1 Background

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

In 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). eHDSI sets up and starts deploying the core and generic services, as defined in the CEF, for Patient Summary and ePrescription. The generic services are the necessary implementation of data exchange at country level, the core services at EU level. These together enable the provision of Cross Border eHealth Information Services (CBeHIS).

Building on this, another EU initiative is the development of the UNICOM project. This work aims to support the implementation of specific use cases including the development of IDMP as a global and univocal identification of medicines for cross border ePrescription and eDispensation.

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

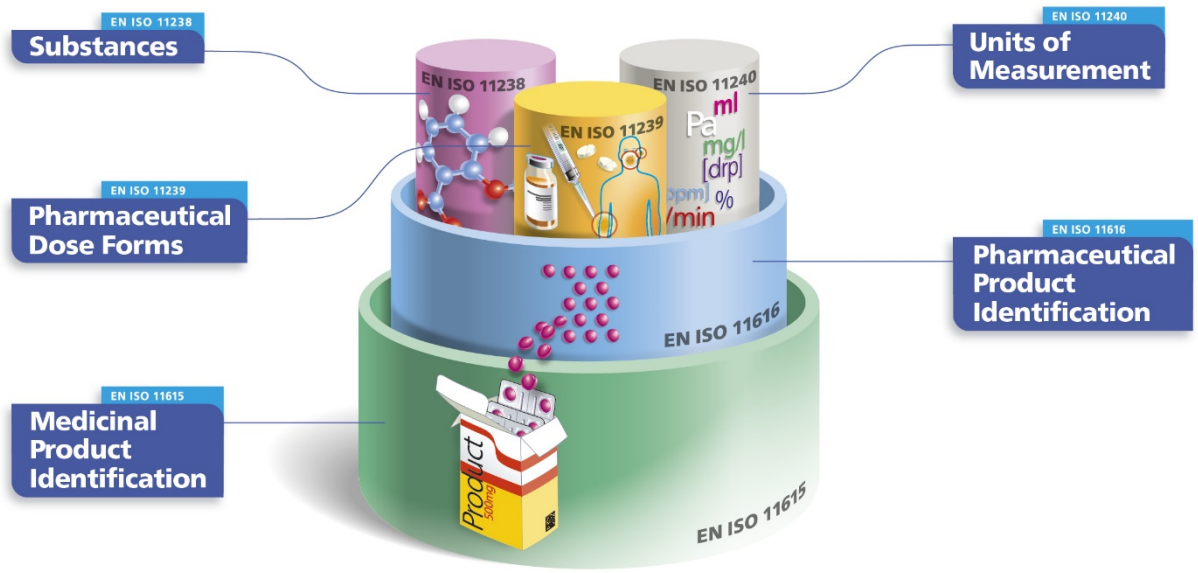

Figure 1: The 5 ISO standards used to identify medicinal products

To support the delivery of IDMP, the UNICOM project involves several Work Packages, each relating to different aspects of interoperability, business data and technology implementations (Figure 2).

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

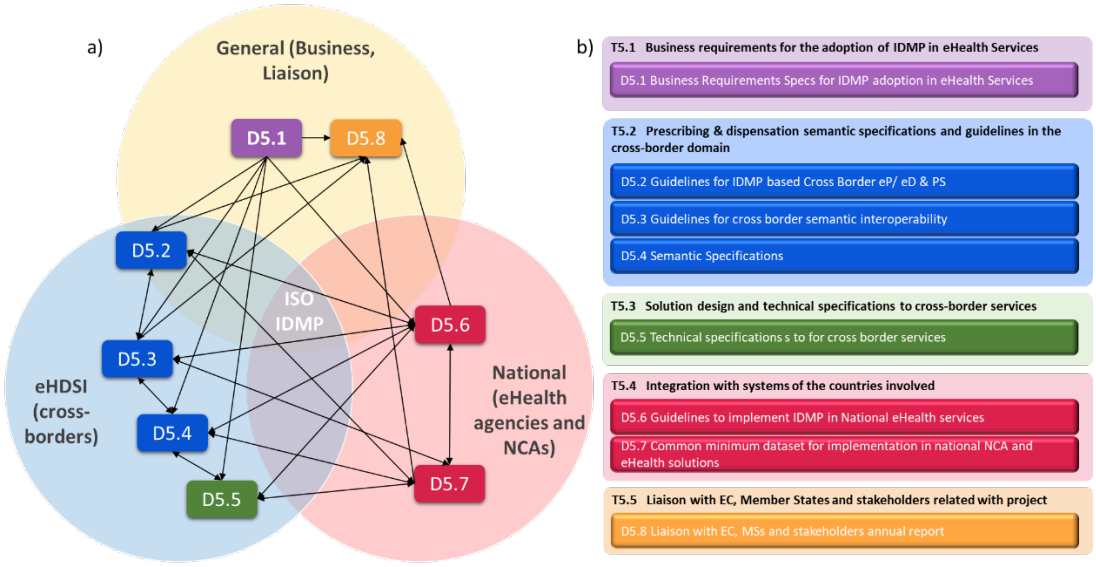

Figure 2: The WP5 deliverables relationship.
In a) the relationship between the different WP5 deliverables. B) the list of tasks and deliverables from WP5

The outputs of previous deliverables (D5.1 Business Requirements Specifications for IDMP adoption in eHealth Services and D5.2 Guidelines for IDMP based Cross Border eP/eD and PS) provided the basis for the definition of semantic components that should be considered to ensure the IDMP adoption among the different stakeholders. Building on this work, deliverable D5.3 is concerned with the development of guidelines for cross border semantic interoperability.

1.2 Introduction to D5.3

The complexity of identifying medicinal products among Member States in their ePrescription/eDispensation (eP/eD) & Patient Summary (PS) systems means it is essential to ensure the alignment of the elements, attributes to support the fully implementation of the IDMP standards.

Semantic interoperability is an important feature for the eHDSI services because it assures the exchange of health data at a computer processable level among the different Member States. Healthcare information needs to be expressed using interoperable syntax, while using code systems that represent the information of the eP/eD and PS that needs to be coded and translated. Moreover, semantic interoperability needs to address the issues associated with the usage of different terminologies and vocabularies between the different countries / regions. According to the Semantic Services Specifications[3], semantic interoperability needs common elements such as:

- A common data structure of eP/eD and PS to be exchanged;
- A commonly understood medical terminology based on value sets obtained from officially existing International code systems used in the eP/eD and PS (e.g., eHDSI MVC);
- A mean to access and maintain the content present in the eHDSI MVC that is transparent to the user (eHDSI Central Terminology Service and terminology access services interface).

To ensure the correct identification of Medicinal Products among the Member States, the minimal common elements, in an IDMP compliant format, must be defined and used by all different actors.

[3] EC, DG for Health and Food Safety. eHealth DSI. *Patient Summary and ePrescription – Semantic Services Specification*. DG Sante, CEF eHDSI, Doc version 2.1.0, 01/06/2017.

1.3 Scope of the document

This document intends to present the semantic components and applicable guidelines that shall be considered to adopt the ISO IDMP standards among the national and cross-border systems, ensuring the semantic interoperability of eP/eD & PS in the different Member States. To achieve this objective, we identified the key needs that will apply in this adoption by the Member States:

- A reference data model is needed for the adoption of IDMP in eP/eD. UNICOM defines a reference model (with this analysis), which should be persisted and used to guide Member States in the process of mapping IDMP to their reality. While each Member State will likely have their model, we recommend that Member States have a formal process to do this mapping between their model and this reference model. This will allow consistency, time savings, and enable progress monitoring.
- The data model consists of the definition of data elements and their terminology bindings (master value sets). These value sets have a lifecycle and their own governance, which requires attention by all stakeholders involved. For example: "dose forms" are mastered in EDQM, but a "dose form ontology" is not.

Within the first need – a reference data model and corresponding terminologies - two main workstreams were defined:

- Definition of a minimum semantic data set;
- Mapping of IDMP-based codes at national and European level
- Adoption of IDMP-based codes at CEF eHDSI level.

2 Minimum semantic data set specification

This deliverable aims at supporting Member States and CEF eHDSI to achieve a minimum level of semantic interoperability considering the adoption of ISO IDMP standards for the exchange of eP/eD and PS. For this, a list of attributes and identifiers were analysed based on:

- EMA Implementation Guide version 2.1[4];
- eHDSI requirements catalogue[5];
- Output from deliverables D5.1 and D5.2.

During the analysis, the following considerations were considered:

- Which data can National Competent Authorities (NCAs) provide?
- How to ensure the alignment between NCAs, eHealth agencies and eHDSI?
- How to develop a solution that is implemented and compliant to SPOR considering UNICOM and SPOR / ISO IDMP implementation timeline?

These points are critical to understand the minimum attributes that need to be defined for the pilot predicted in WP7. Thus, the list of minimum attributes should be based on data that are already in use and in what the NCAs are able to provide, while being compliant with SPOR.

Currently, ISO IDMP is still being implemented: identifiers such as Medicinal Product Identifier (MPID), Packaged Medicinal Product Identifier (PCID) and Pharmaceutical Product Identifier (PhPID) are not yet fully available. The information regarding the mechanism on the generation of these identifiers is not fully clarified, and this process is out of UNICOM scope. Nonetheless, considering the current state of play, structured and coded attributes are essential for the development of this minimal attribute list (for more details consult the section 4.2). Moreover, the information on the mechanism and supervision of the ISO IDMP identifiers generation and respective maintenance will be important to further understand how this will be adopted in the later phase of implementation.

[4] EMA. 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. 24 June 2021. EMA/285848/2020. https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-organization-standardization-iso_en-0.pdf

[5] https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/1.+eHDSI+Requirements+Catalogue

In deliverable D5.2, some key attributes were already identified as important improvements for exchange of eHealth services. For these services to be provided at cross-border level, this minimal data set of attributes and identifiers should be defined soon to support the development of the eHDSI Change Proposal (Annex 1:) and Pilot Product List (PPL). It is fundamental that these changes incorporate the main recommendations outlined in D5.1, D5.2 and D5.3 to ensure that the new eHDSI deployment wave (wave 6) facilitates the specifications as identified by UNICOM before the project pilot is operational (for more details consult the section 4.2).

2.1 Use Cases: EU-SRS and dependency points

EU-SRS (European substance reference system) provides scientifically sound descriptions of substances used in medicinal products in the EU by applying regulatory standards for the identification of medicinal substances in accordance with the ISO IDMP standards. This is a core central element for the identification of medicinal products.

While Substance Management Services (SMS) is considered “simplified” substance data, with reduced ISO IDMP fields, EU-SRS contains a comprehensive ISO IDMP substance data (extended number of fields). In other words, the EU-SRS database will support identification of structurally diverse substances as SMS is not equipped to capture the level of detail that is required for that.

During the process of implementation, SMS will be synchronised with EU-SRS database and a SMS user interface will be delivered.

The Product Management Service (PMS) and SMS will manage respectively the product and substance domains of SPOR master data in pharmaceutical regulatory process.

PMS will allow harmonised data and definitions to uniquely identify a medicinal product based on regulated information (e.g. marketing authorisation, packaging and medicinal information). Upon a successful submission of a product data to PMS, the system will generate a set of unique identifiers: i) PMS identifiers (ID), ii) MPID and iii) PCID. While only one PMS ID and MPID can be generated per medicinal product single entry, multiple PCID can be generated based on the authorised packaged medicinal product. Unlike MPID and PCID, the PMS ID remains unchanged during the medicinal product lifecycle.[4]

While UNICOM develops guidelines to facilitate the adoption of ISO IDMP to support the exchange of eHealth services, it will not create a new implementation guide. However, it will follow the SPOR/EMA implementation guides as they are developed, in order to add the IDMP-compliant data generated in the project. Therefore, UNICOM will have a dependency on the information generated in these implementation guides, such as;

a) information on how ISO IDMP identifiers will be generated,

b) how will these be kept over time and

c) the timeline for their implementation at the national / regional and EMA-level.

2.2 D5.2 use cases

The use cases documented in the deliverable 5.2 (Figure 3) explains how IDMP can be consistently used to meet the data requirements described in IDMP standard and in this work package:

The first key aspect is that the product information that is used in ePrescription (and eDispensation) consists of

- **Product Identifiers**
- **Product Attributes**

Product Identifiers can be of 2 types:

- **IDMP identifiers** (PhPID, MPID, PCID)
  - These identifiers are meant for interoperability and are considered core to any implementation. The semantics of these identifiers are defined by the ISO standards and the actual values are defined by and/or available through SPOR.
- **Non-IDMP identifiers**, e.g. national product or trade item identifiers
  - These identifiers, namely the national product identifiers or cluster codes, are those that are used in clinical practice either in a national prescription, or when dispensing. The national requirements rely on these existing codes. It is not expected that these codes will be replaced by IDMP identifiers in the short term. But they are defined formally and can be expected to be the starting point for a clinical flow, which needs to be transcoded into IDMP.

Product Attributes can also be split into:

- **IDMP attributes** (e.g. strength, substance, dose form, unit of presentation, etc.)
  - These attributes form part of a product definition. In the context of UNICOM scope, these attributes can complement (or in some cases replace) the product identifiers. The semantics of these identifiers are defined by the ISO standards and the actual values can be:
    - defined by and/or available through SPOR, for a cross-border usage – e.g. ATC classification, or IDMP dose form.
    - nationally or locally defined values, e.g. national codes for dose forms

    The IDMP identifier structure expects a biunivocal correspondence between an identifier and a combination of attribute values. For example, depending on the algorithm and level used, a single PhPID would correspond to one and only one combination of values of Substance, Strength and Dose Form.

- **National or local product definitions** may rely on non-IDMP attributes, i.e. attributes that are not defined by IDMP. If these attributes are required to define an equivalent product outside of the original jurisdiction, they would need to be identified and an approach to align/map the IDMP/non-IDMP attributes agreed. Currently, no such attributes have been identified.

It is essential that data has a commonly understood meaning between both countries so that it can be used with confidence. It is important that any unique set of attributes should not match 2 valid identifiers unless these identifiers are absolutely interchangeable. The uniqueness of this matching between identifiers and attributes is called “biunivocal correspondence” and has been highlighted as a gap and potentially a barrier to univocal identification.

To mitigate any risk, the IDMP generation algorithms should always ensure, preserve, and maintain the biunivocal correspondence between identifiers and the attributes that are unique to that identifier.

This approach of managing algorithms requires data quality initiatives to be put in place to ensure the successful compliance with the above.

With these recommendations in place, the articulation between the different data sets (IDMP, SPOR, EU and national databases and clinical systems) can be presented as follows:

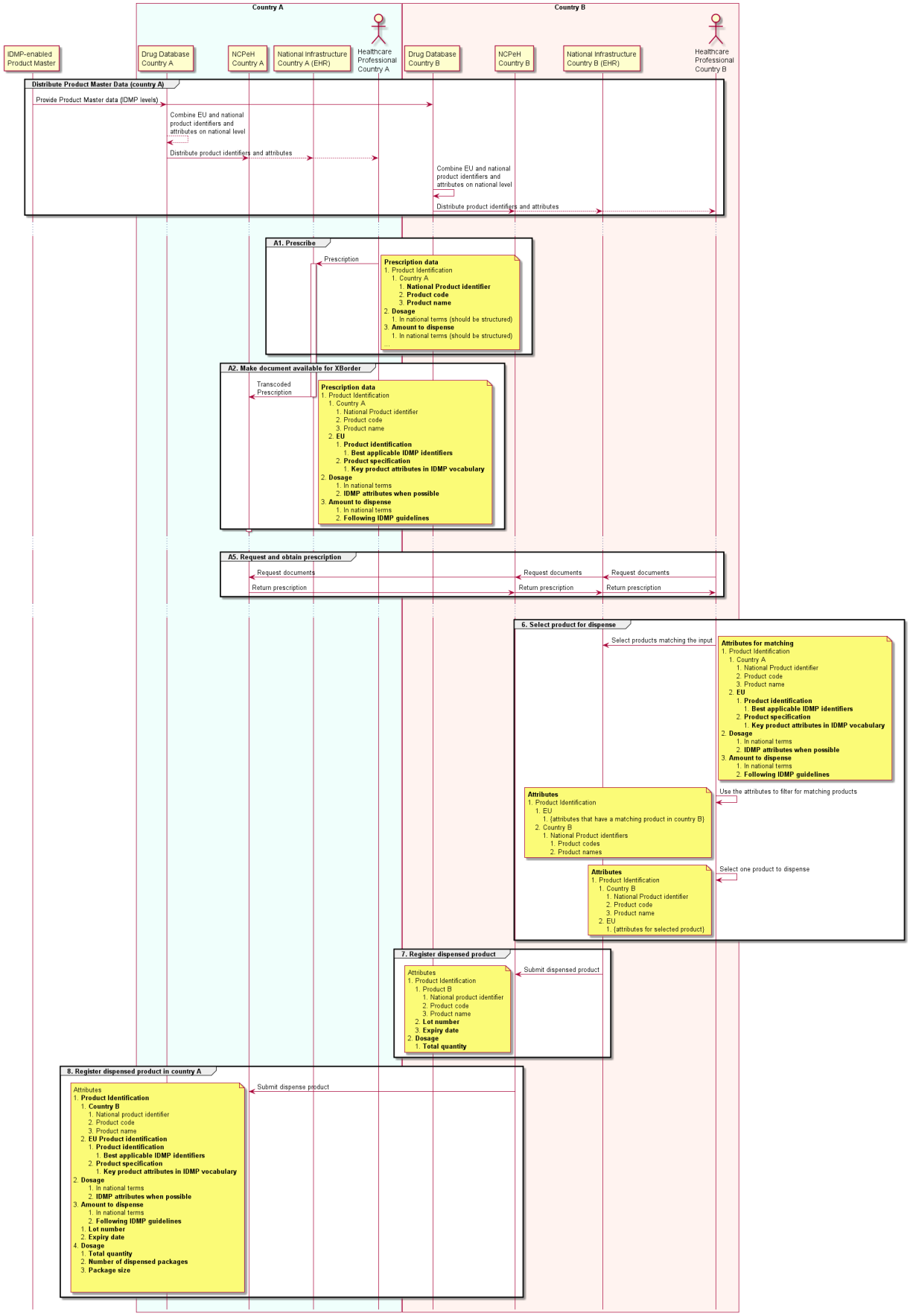

Figure 3: Generic ePrescription/eDispensation use case.

*There is a requirement for each Member State to identify/analyse how the compliant IDMP data relates to the eHDSI data sets, mapping the IDMP-based codes and their local codes – for attributes and identifiers.

2.3 Analysis of SPOR model vs eP and PS

In order to analyse the data models between SPOR and eHDSI systems for IDMP compatibility, it is interesting to study the information flows between the main UNICOM stakeholders across the development lifecycle from EMA SPOR downstream to MS and cross border. The following diagram (Figure 4) provides a simplified overview of such a possible flow, including the key data flows, and some indication of possible "ownership" or "source" of the data:

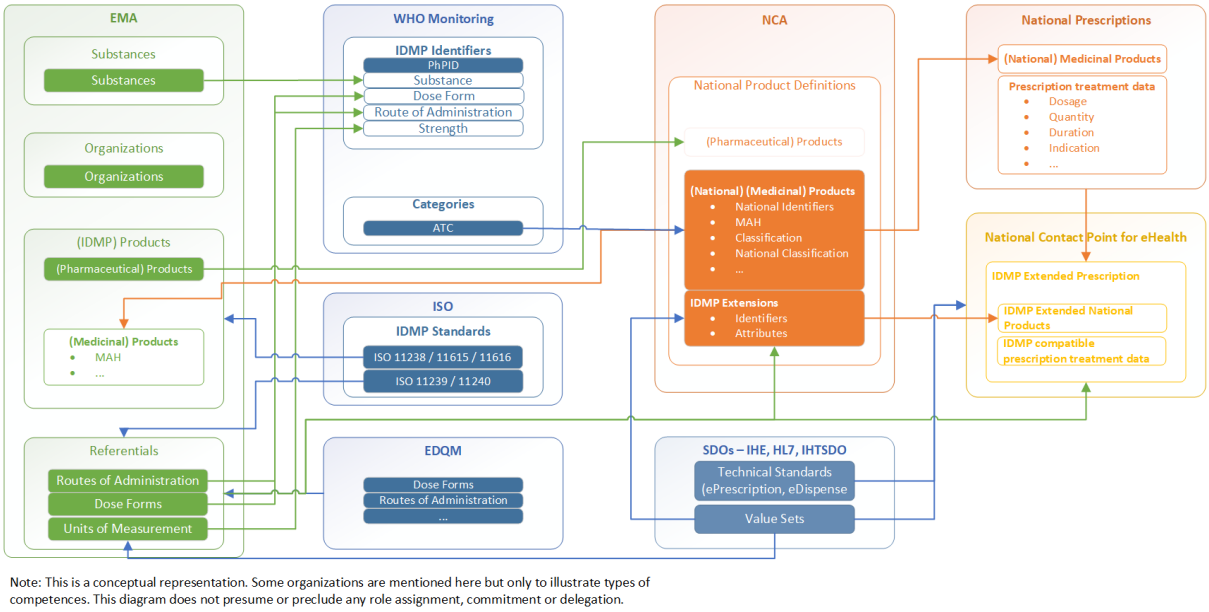

Figure 4: Suggested information flow between the main UNICOM Stakeholders.

This diagram (Figure 4) shows different "types" of data sets such as product definitions, reference data, prescription data, etc. where such data plays an essential role in several sections of the flow.

Highlights include:

- SPOR curates and maintains the reference data, which can originate from EDQM or other sources.
- The central regulator EMA acts as a custodian for IDMP-compliant product information, as per the models and requirements specified by ISO.
- A central entity would maintain global identifiers and classifications – e.g. the WHO UMC maintains the ATC Classification codes, and may also maintain unique PhPID values.
- Member States can maintain their nationally registered products, including the current national product definitions, and eventually the IDMP needed attributes (they can also migrate some of their data to IDMP attributes and identifiers, but this is not presumed or enforced)
- The ePrescription systems use this data – national data for national data flows, and IDMP-compatible data for cross-border flows.
- SDOs provide technical standards, reference implementations, testing, etc. to ensure that the technical data exchange is standardised.

The Figure 4 also highlights the differences in information sets – each part may have different information sets, according to the purposes of using that information.

While UNICOM D5.1 revealed the requirements for such data flows, UNICOM D5.2 analysed the data elements in prescriptions compared to IDMP, looking at different scenarios that justified the need for UNICOM to support different possibilities of identifying products.

In short, this analysis results in the same conclusion that UNICOM product data can be different.

This product information (and other information) is created, maintained, used in different cycles.

This justifies the definition and maintenance of these different data needs and models – namely for an IDMP product in the regulators, which was already known, but also for “IDMP-compatible” product data models at prescription and dispense, for example.

2.4 Match National coding into IDMP based coding and vice-versa

Product data exchange

1. From an EU perspective, the product master data is defined according to IDMP standard data definitions and the SPOR value sets. This requires a complex mechanism of data exchange that UNICOM project can validate but it is up to manufacturers and regulators (central and national). This data will be available in a central or distributed system.
2. The UNICOM product definitions (based on IDMP) are then exchanged with the national drug databases (can be a bidirectional communication). From this moment, the national drug databases contain the UNICOM IDMP attributes in addition to the national product identifiers and attributes used locally.
3. The Member States’ databases, enriched with the UNICOM dataset, can be used for transcoding of medicinal product information where needed – to the NCA of each country, and optionally to the eHealth infrastructure and even clinical systems in each country.

Clinical data exchange

1. When a prescriber prescribes one product, they would do it initially using the national identifiers and/or attributes, respecting the legislation of their own Member State. This is typically a product identifier, combined with treatment data that is relevant for dispensing, such as the posology and amount to dispense.
2. When a request to exchange the prescription with another country is received, there is a requirement for commonly understood meaning of the prescription details so that it can be dispensed with confidence, (irrespective of how the information is exchanged). In this sense, there is a transcoding activity:
    a. "Transform” the national product identifier to a cross-border identifier if there is a biunivocal (1:1) match.
        i. For example, if the prescription is done on a “generic” level and if the Member States definition of “generic” corresponds exactly to the level of granularity of Pharmaceutical Product, then the national product identifier can be matched with a Pharmaceutical Product Identifier.
    b. If there is no 1:1 correspondence between the identifiers, the national product identifier should be "decomposed” into its attributes.
        i. For example, a VMPP identifier does not correspond to any IDMP level, but it is commonly used. In this case, the VMPP identifier must be decomposed into the attributes that define it – substance, strength, dose form, and package amount.
    c. Any additional attributes in the prescription that belong to the UNICOM prescription dataset are used in the transcoding.
    d. Finally, all the national identifiers and attributes listed above are transcoded to their UNICOM equivalent
        i. and identifiers are gathered when possible. For example, given a substance, strength, and dose form, it is possible to gather a PhPID.
    e. This transcoded prescription is deemed cross-border compatible, regardless of the level of granularity chosen by the different Member States, and abides by the IDMP rules, providing a mechanism to dispense safely without discarding the intent of the original prescription.

2.5 Guidelines for Adoption by Member States

This effort of transcoding and translating highlighted several potential conflicting requirements:

1. The adoption of IDMP which implies a given model, defined outside the Member State – whether it's the Regulatory product definitions, or the ePrescription and eDispensation – which may conflict with the Member States definitions.
2. The need to preserve the compatibility with the national regulations and product definitions
3. The use of Value Sets that are commonly recognised, in replacement of or in addition to the nationally defined Value Sets.

There is a need for a central model that addresses the common data needs between

- Regulatory and clinical scenarios
- Central and national medicinal product information systems

It is important to understand the variance between Member States because

a) some Member States have an established ePrescription infrastructure and a solid, legal definition of Product levels,

b) while other Member States, with no legacy systems in place, can mirror the IDMP model more easily.

UNICOM recommendations, presented as guidelines, can be used by the Member State interested in adopting the IDMP approach to implementation. It is important to emphasise that these are only guidelines and should not be considered as absolute requirements.

Guideline (1):

Each Member State should identify a reference data model for the Medicinal Products, in the different levels required in the country and considering cross-border use. This data model should:

- Consider the use cases identified in UNICOM:

  Regulatory exchange of master product information

  Prescribed product identification

  Dispensed product information

  Product in a Patient Summary

- Be expressed formally,

- Identify the data elements that are to be used

- Where required or appropriate, identify the data rules, including the value sets that are required or advised.

And consequently,

Guideline (2):

UNICOM provides a common data model which accommodates the needs of the different contexts; Member States should take this model presented by UNICOM and use it as a reference or pivot in their own mapping efforts.

UNICOM provide their model and method for use by Member States who are presented with mapping challenges as a result of their own specific data model and requirements.

The Value Sets is of key importance. Member States are expected to be the “owners” of some value sets, but also use other Value Sets that are obtained from an external source and owned /published by an external authority.

Guideline (3):

UNICOM will identify a collection of the Value Sets that are required for semantic interoperability (including necessary changes and clarifications). These Value Sets originate from the SPOR and from the Master Value Catalogue. There should be an agreed process for Member States to take this collection of Value Sets and use it in their own specifications, making the necessary provisions and adaptations.

Obviously, each change may have an impact in the interest of preserving current and future interoperability, it is important that Member States capture any such variations in a way that they can be monitored by the Member State.

This approach also assists in monitoring how close a Member State is to a “pure” IDMP adoption. It is anticipated that countries without a dominant predefined model, or a mapping to national concepts, will engage in this monitoring exercise (especially in Member States where the required / legacy models must be preserved).

Guideline (4):

The mapping from the UNICOM IDMP model to the Member States’ data models should be formally documented and matches and variations clearly identified.

- matches are important to identify the impact of eventual upstream modifications – when a value set from SPOR is changed, or a definition is updated, or a data element is changed…

- variations are important to capture in documentation, and an analysis required to see if there is any functional impact in such situations.

This implies that Member States keep track of their mapping and models. This is an important guideline. More detailed guidelines may be presented, but Member States should have some formal documentation of their data models.

Guideline (5):

The Value Sets mentioned in the UNICOM central product models (regulatory and clinical) should have clear governance. Specifically, it must be known, for each Value Set:

- Who is the owning entity;

- Status;

- Master Location/primary source;

- Versions and version management,

- The associated change and release process.

This effort should be taken by the different responsible authorities; UNICOM will identify the gaps in such governance, and the different stakeholders should address these gaps, where necessary.

With this governance established and the gaps addressed, the Member States can acquire the appropriate Value Sets for their implementations. Like UNICOM, Member States should retain a managed, curated collection of Value Sets.

Guideline (6):

The Value Sets mentioned in the UNICOM central product models (regulatory and clinical) should have clear governance. Specifically, it must be known:

- Who is the owning entity
- Master Location/primary source,
- Status,
- Versions and version management,
- What is the associated change and release process.

This effort should be taken by the different responsible authorities; UNICOM will identify the gaps in such governance, and the different stakeholders should address these gaps where necessary.

While Member States are expected to have some variations to the IDMP data model and to the model defined in UNICOM, it is important that these variations are understood so that an impact analysis can inform future developments.

Guideline (7):

Member States should follow a process to capture and document their models including adherence or variation to the UNICOM pivot models. The adherence is not mandatory but the consequences for any variation should be considered.

2.6 Using PhPID and other identifiers to identify equivalent medicinal products

The use of IDMP identifiers (PhPID, MPID and PCID) can impact eHealth services in different ways depending on whether the service is eP, eD or PS. Identifiers in national and cross border scenarios, highlighted below, intend to assign those identifiers to best-fit each respective service while at the same time identifying any limitations and advantages.

- **PhPID**

Depending on the level of detail provided in the drug verbatim and/or contextual information, the most accurate PhPID level should be coded. The information that is needed to code more precise levels of PhPID may be known from the drug verbatim or may be extracted from the contextual information such as country. The PhPID standard, uniquely associates medicinal products with the same or similar pharmaceutical composition, based on the substance, strength, reference strength and dosage form data elements. However, PhPID does not convey all the information to identify the dispensed product as a packed medicinal product.

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's wherever possible will enhance the translating and transcoding of medicinal product information to assure the correct identification and thus the safe and accurate dispensation.

- **MPID**

The MPID is not as specific as PCID in product level identification and as a result there are limitations in coding the free text drug verbatim to MPID level.

According to the ISO IDMP 11615 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 more 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 MP code segment.

In a national context, it can be used to define specific brand product in the eP, however the identification of the generic medicines on eD is challenging. At a cross-border level, the MPID should be avoided, because this identifier is specific to the country of registration,

For both contexts (national and cross-border), MPID may be used in both the eD report and PS document, to indicate more accurately the product that was dispensed (eD) or used by the patient (PS).

- **PCID**

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 PCID is a further refinement of product specification when compared to the MPID (the PCID just increases on the 'package description') it has the same implications as MPID and the usage on the eHealth services should be considered with the same remarks as MPID.

3 How to map IDMP to CEF eHDSI

The Deliverable D5.2 highlighted the need to harmonise the current eHDSI data sets used for the Patient Summary, ePrescription and eDispensation[6] supporting the different use cases. Figure 5 is an excerpt from the current eHDSI eP model.

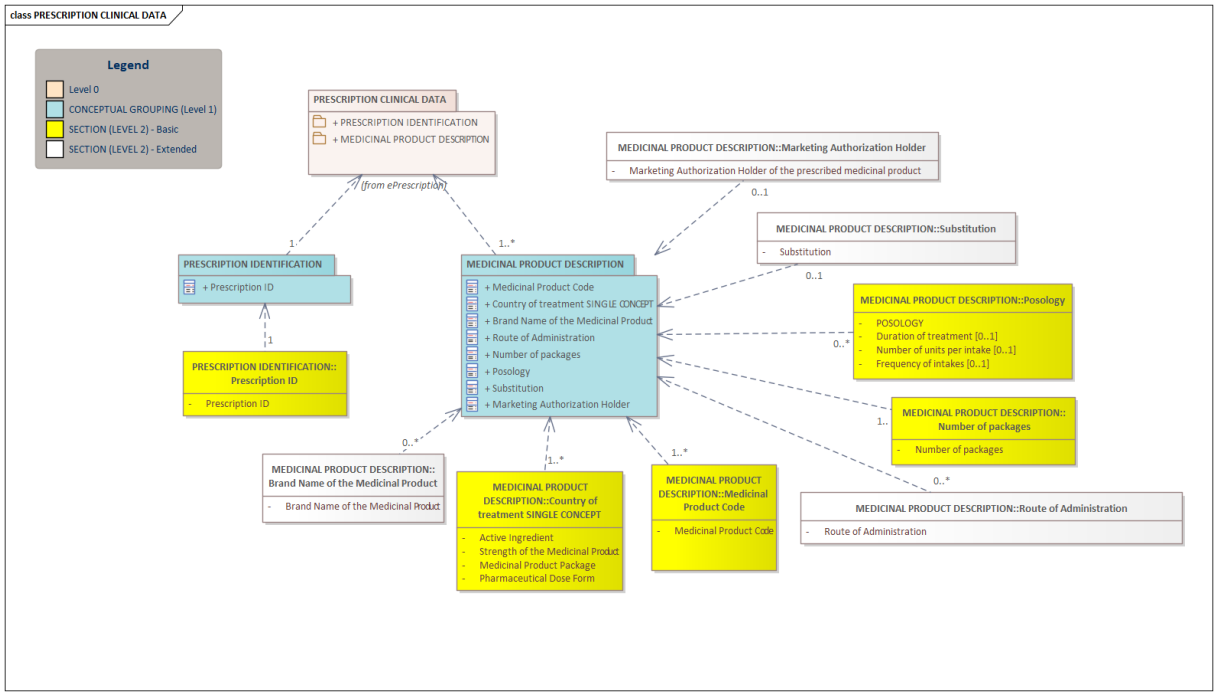

Figure 5: Current eHDSI ePrescription data set: medicinal product

Following this dataset and harmonising with other existing models (HL7 FHIR medication-related resources), a suggested “To be” product model was designed and expressed as a HL7 FHIR Logical Model. This is presented in Figure 6 below.

[6] More information can be found on the following websites:
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
https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/05.01.+Create+the+eHDSI+Patient+Summary+content.

Product	I	0..*	Element	Product **Prod-1:** Either a Product code or a name (or both) shall be provided
code	S	0..*	BackboneElement	Product code set
productCode		0..*	CodeableConcept	Product code
packagedProductCode		0..*	Codeable	Packaged Medicinal Product code
medicinalProductCode		0..*	CodeableConcept	Medicinal Product code
pharmaceuticalProductCode		0..*	CodeableConcept	Pharmaceutical Product code
PCID		0..1	CodeableConcept	IDMP PCID
MPID		0..1	CodeableConcept	IDMP MPID
PhPID	S	0..*	CodeableConcept	IDMP PhPID
name		0..*	BackboneElement	Product Name
type		0..1	CodeableConcept	type
name		0..1	string	name
composition	S I	0..*	BackboneElement	Composition **Prod-12:** Either the structured information or the textual description (or both) shall be provided
ingredient	I	0..*	BackboneElement	Ingredient **Prod-13:** Either a substance code or a name (or both) shall be provided
substanceName		0..1	string	Substance name
substanceCode		0..*	CodeableConcept	Substance code **Binding:** http://hl7.eu/fhir/ig/unicom/ValueSet/SubstanceCode (preferred)
ingredientRole		0..1	CodeableConcept	Ingredient role
substanceQuantity		0..1	Ratio	Substance quantity
description		0..1	string	Textual Composition
classification		0..*	BackboneElement	Classification
code		0..*	CodeableConcept	Classification code
ATCcode		0..*	CodeableConcept	ATC code
doseForm		0..*	BackboneElement	Dose form
type		0..1	CodeableConcept	Form type
formCode		0..*	CodeableConcept	Form code **Binding:** http://hl7.eu/fhir/ig/unicom/ValueSet/edqm-doseForm (preferred)
route		0..*	CodeableConcept	Route of Administration **Binding:** http://hl7.eu/fhir/ig/unicom/ValueSet/edqm-route (preferred)
identifier		0..*	BackboneElement	Product Identifier
uniqueIdentifier		0..1	Identifier	Unique Identifier
dataCarrierIdentifier		0..*	Identifier	Data Carrier Identifier
lotNumber		0..1	string	Lot number
marketingAuthorization		0..*	BackboneElement	Marketing Authorisation
manufacturer		0..*	SimpleOrganization	Manufacturer
package		0..*	BackboneElement	Package
description		0..1	string	Package description
packageStructure		0..*	BackboneElement	Package Structure
containerType		0..*	CodeableConcept	Container type (1st level) **Binding:** http://hl7.eu/fhir/ig/unicom/ValueSet/edqm-package (preferred)
capacityQuantity		0..1	Quantity	Container Capacity (1st level)
container		0..*	BackboneElement	Container (2nd level)

Figure 6: "To be" product model as defined in UNICOM D5.2 (HL7 FHIR Logical Model)

As this proposed model is developed, an analysis of the eHDSI specifications is necessary to identify any gaps that would require further harmonisation and possible changes to the eHDSI specifications.

Figure 7 and Figure 8 illustrate a suggested reorganisation of the information model; these suggestions have been designed in a way to ensure that these models stay in alignment with the current eHDSI CDA implementation.

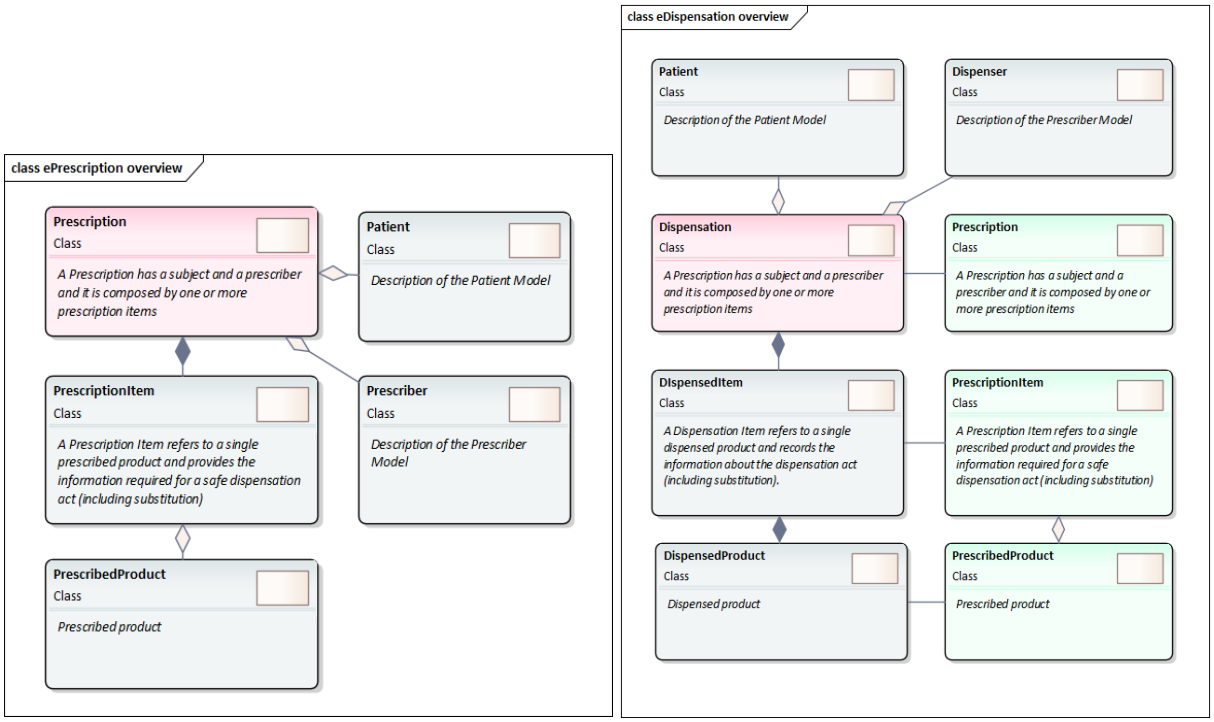

Figure 7: ePrescription / eDispensation overview

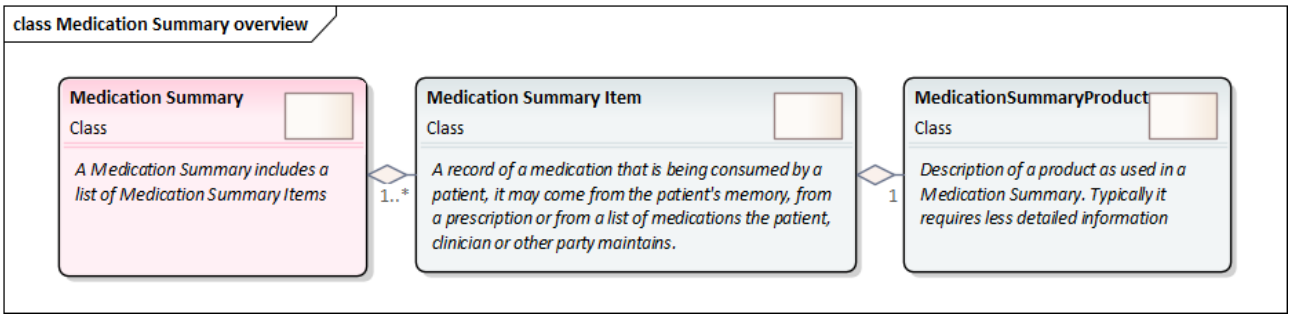

Figure 8: Patient Summary (medication section) overview

The following subsection describes a common model for eP, eD and PS, using a common abstraction for the Prescribed, Dispensed and the product used in the medication section of the Patient Summary. A mapping between the IDMP identifiers, attributes and a revised proposed product model as well as the results of a gap analysis on the current eHDSI model are provided.

3.1 Common models for eP/eD & PS

This section presents a common model for the eHealth Services (eP/eD & PS) in a general view (Figure 9). Some gaps identified in the current eHDSI model are highlighted and discussed below.

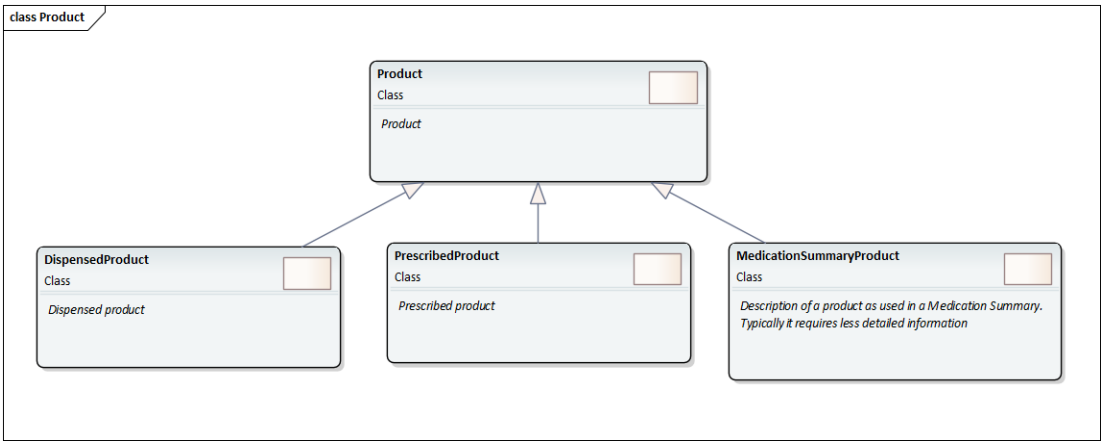

Figure 9: Suggested eHDSI Common Product Model

The following schema (Figure 10) summarises the content currently selected from the SPOR spreadsheet of attributes. The relationship between Medicinal Product (MP) and Packaged Medicinal Product (PC) follows the structure used in the spreadsheet: where the MP model is used as the foundation for all the other models of information (including PCs). This differs from an alternative relationship that could be reasonably expected, where the models are separate - the Package Product is a package for one or more Medicinal Products. The Package Item class has been removed by the very last version of the selected SPOR elements but left in this schema as a placeholder.

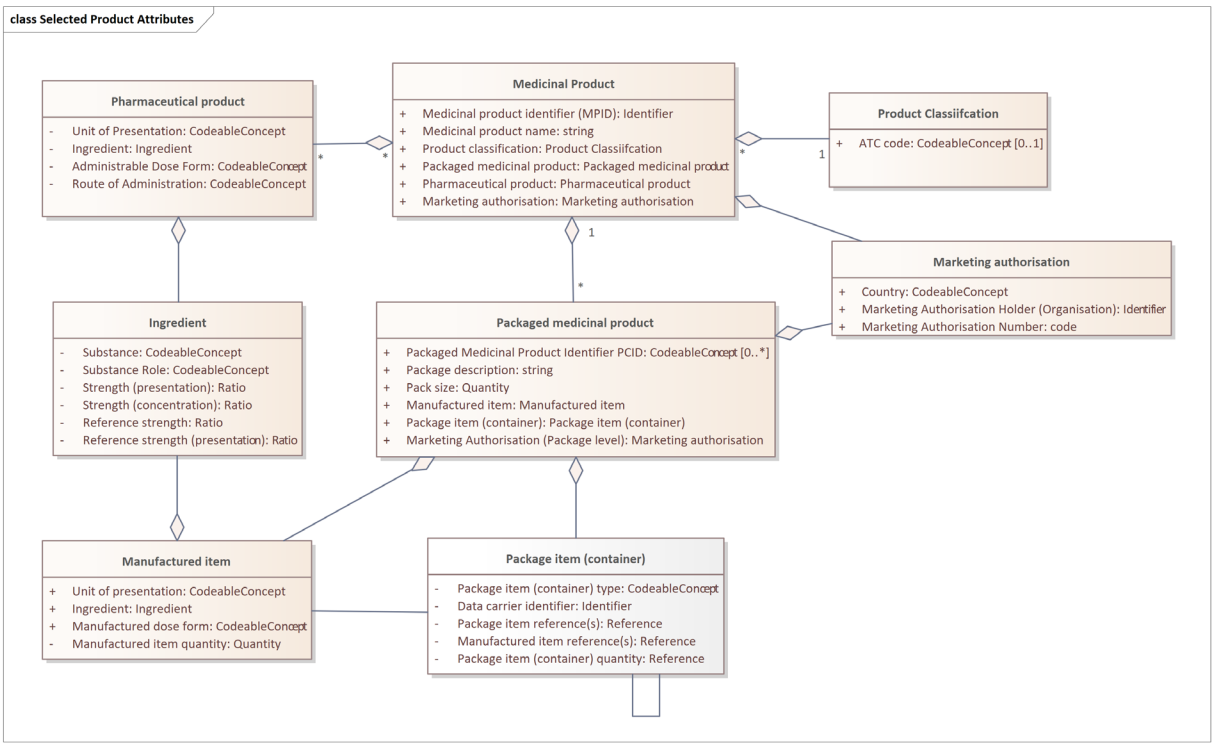

Figure 10: SPOR selected attributes

For each class of information, a formal mapping to the agreed model has been completed and the result is summarised in a correspondence matrix below. In Figure 11 the results for both Medicinal Product classes are shown for illustration purposes, and the matrix is reported for all the others.

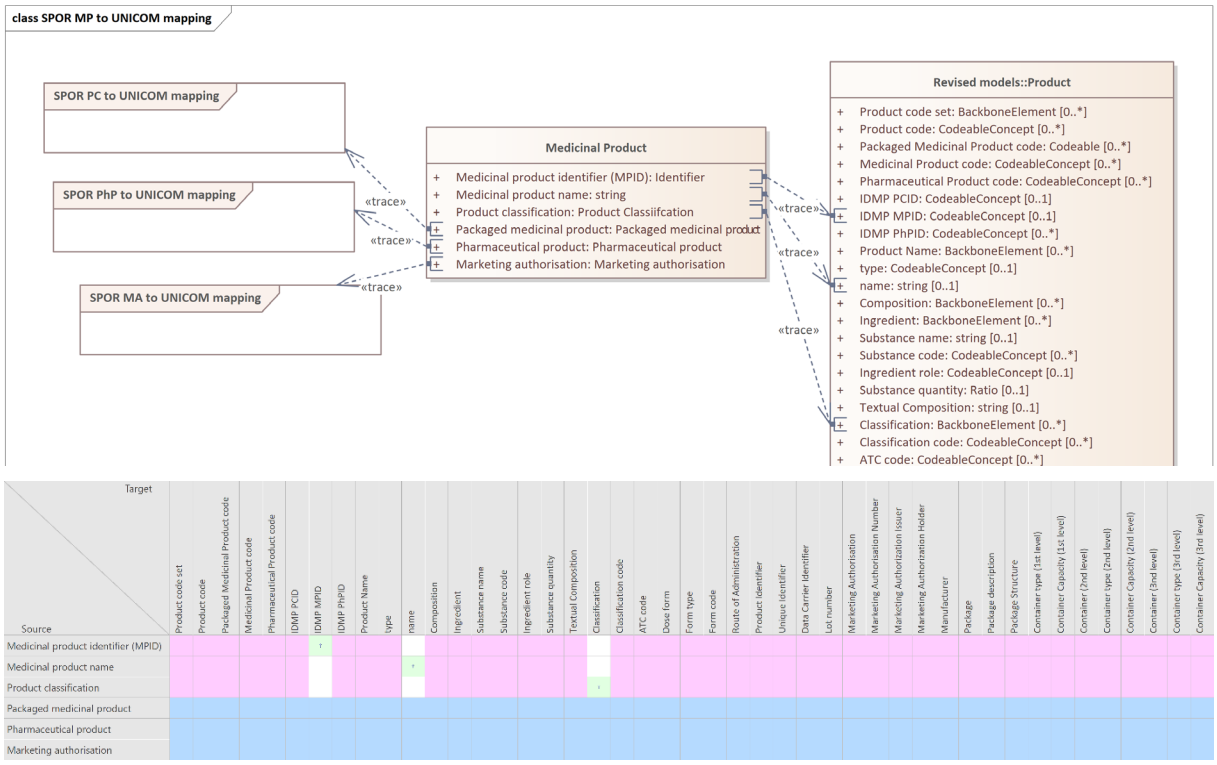

Figure 11: SPOR Medicinal Product selected attributes mapping

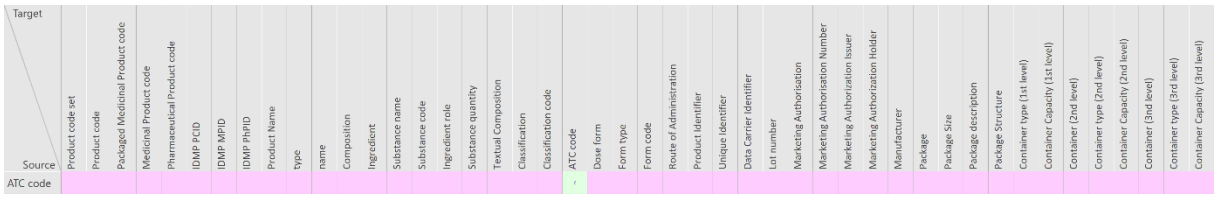

Figure 12: SPOR Classification (ATC) selected attributes mapping

All the selected attributes have been mapped into the target model and some gaps have been identified and are highlighted below.

Gaps with eHDSI data set:

1. The ATC classification is missing in the current data set even if already implemented by the eHDSI specifications as distinct information (as a product identifier) (Figure 12).

The mapping details about the Packaged medicinal product, Pharmaceutical product and Marketing authorisation are described hereafter (Figure 13).

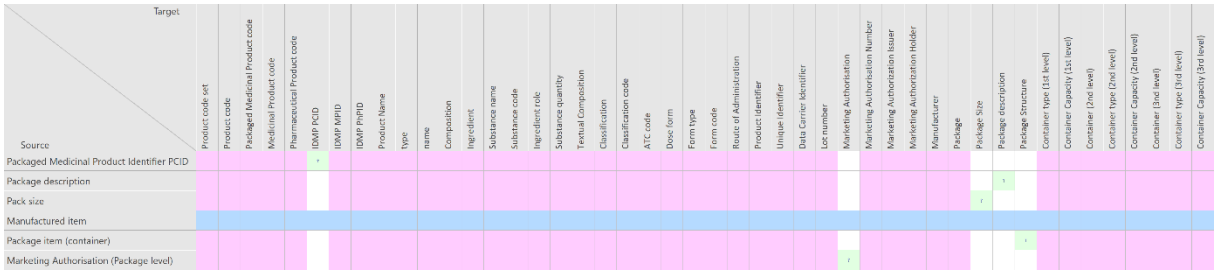

Figure 13: SPOR Packaged Medicinal Product selected attributes mapping

2. A package size element has been added to the model, whereas the manufactured item has not yet been included.

A more detailed assessment should confirm whether this level of detail is necessary or not.

For future consideration:
The role of the manufactured item should be analysed, and its impact verified.

3. The definition of the eHDSI element “Medicinal Product Package” is constrained to only the size of the package when a more explicit indication of the structured data to be captured for the package could be provided. In the data set information about the package, package size, description, potentially also package item, might be summarised in the element “Medicinal Product Package”.

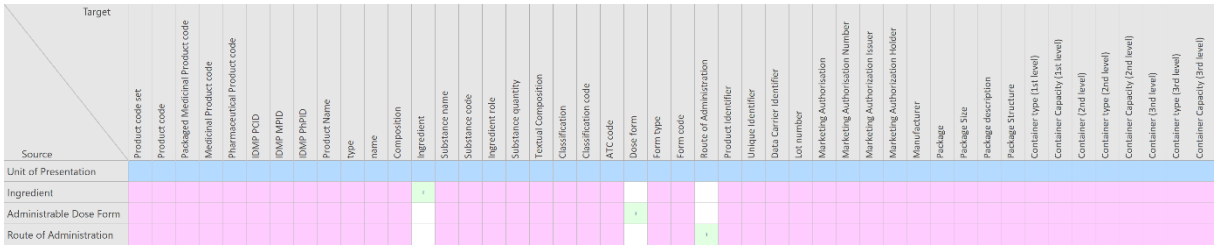

Figure 14: SPOR Pharmaceutical Product selected attributes mapping

4. The unit of presentation is not captured as distinct information in the current model (Figure 14).

For future consideration:
Further analysis is needed to understand if it is valuable to include as a separate element, or if it is used only as a unit for the strength (presentation)

5. Similarly, to unit of presentation above (i.e. missing in the data set), the various types of dose forms could be described with only the Pharmaceutical Dose Form element.

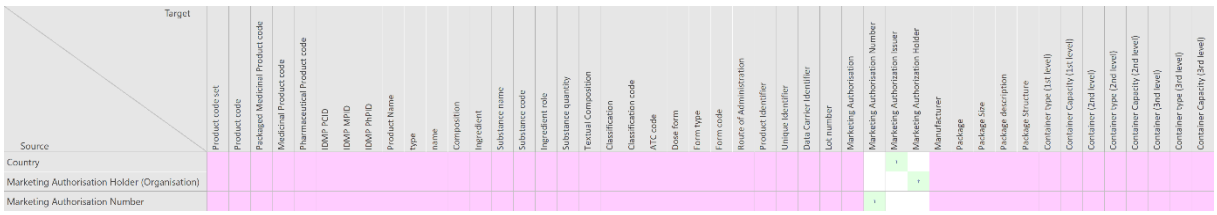

Figure 15: SPOR Marketing Authorisation selected attributes mapping

All attributes are mapped (the country is part of the information about the issuer).

6. The only information currently included is the Marketing Authorization Holder. Some Marketing Authorisation Numbers may be used as Product codes (see e.g. the Italian AIC)

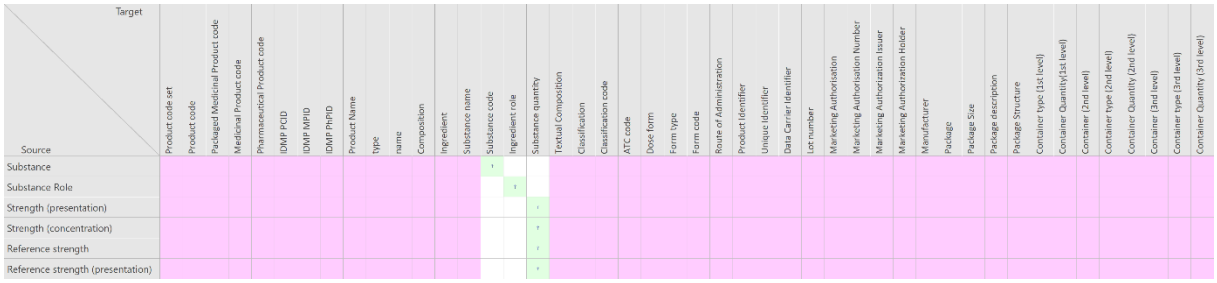

Figure 16: SPOR Ingredient selected attributes mapping

All the selected attributes are mapped into the revised model, the different kinds of strengths are supposed to be represented by using a combination of substance role, and substance quantity ratio.

For example, the substance role of a reference strength will be an active moiety; the denominator of the quantity ratio will be a measurable quantity (e.g. ml) while that of the presentation strength will be represented by a unit of presentation.

***Note**: considering that the current https://spor.ema.europa.eu/rmswi/#/lists/100000072050/terms value set doesn't distinguish the active moiety[7] the information about reference strength versus strength might be used to also fill the actual substance role.*

7. Missing substance role. To be further analysed if more than one kind of strengths should be conveyed.

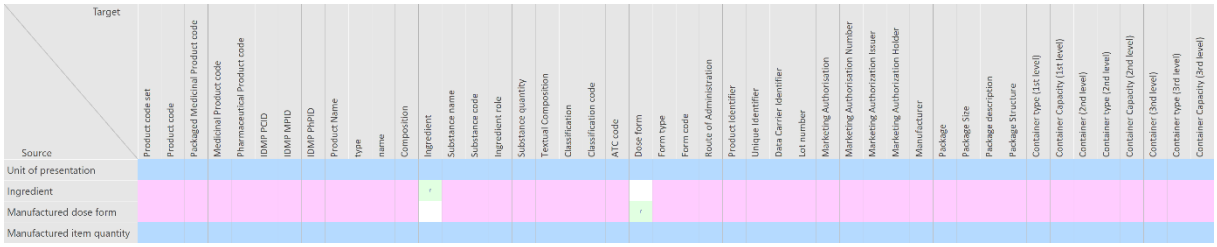

Figure 17: SPOR Manufactured Item selected attributes mapping

Further assessments to evaluate the effective need of representing the manufactured item in the product model as distinct information are required, as well as for the mapping of manufactured item details as ingredient, unit of presentation and dose form.

If the manufactured dose form could be represented as one of the product dose forms; further investigations should be done to understand if, and under which conditions, the manufactured item ingredients could represented by the product ingredient. No mapping is available instead for the unit of presentation.

[7] The current active values are: Active; Adjuvant; Excipient and Solvent / Diluent

***For future consideration*:** role of the manufactured item; if not included as distinct information, analyse the representation of some of the manufactured item's details such as ingredients and unit of presentation.

8. This gap depends on the final choice on the manufactured item representation. The current data set doesn't include the manufactured item, concerning the manufactured item details, the current data set includes a Pharmaceutical Dose Form described as it was a unit of presentation; an active ingredient not explicitly related to a manufactured item or a pharmaceutical product.

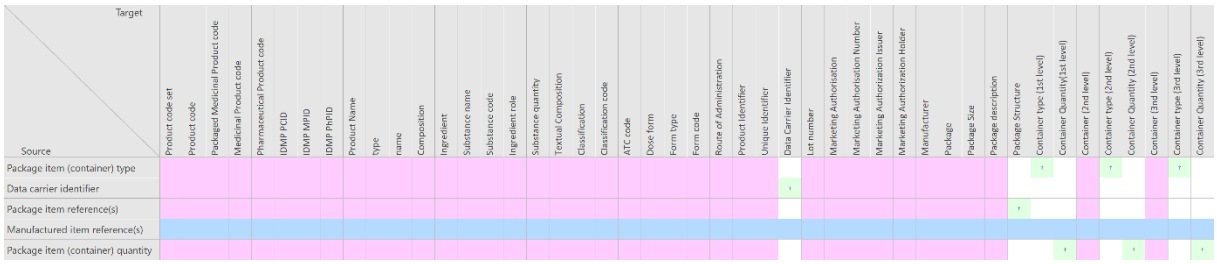

Figure 18: SPOR Package item (container) selected attributes mapping

Note: detailed information about packaged items (containers) has been removed by the very last version of the selected SPOR elements, however such a level of detailed description of the package is in any case already (partially) implemented in the eHDSI specifications and it has been always part of the discussed improvements since epSOS. Therefore, it has been left here as a placeholder.

The model has been updated as follows: the package item capacity Quantity has been substituted by the quantity element to better reflect the actual information to be conveyed.

Concerning the package details mapping, the structure of the package has been described by using a three-nesting level structure for each level the quantity and the type of container is provided. No references to the manufactured items are for the time instead given (see the consideration about the manufactured items above). Only the most outer data carrier identifier is for the time being included in the model as one of the possible product identifiers.

For future consideration: role of the Package item (container); references to the manufactured items; data carrier identifiers to be tracked. Even if we could consider that all package details are in principle mapped in the element "Medicinal Product Package", the definition of that element is currently constrained to the size of the package. A more explicit indication of the data to be captured for the package should be provided.

3.2 Definition of a minimal attribute list for the eHealth services

Some NCAs that work in collaboration with UNICOM were consulted to define the minimum attribute list, using the EMA implementation guide V2.1[4] as the reference. This exercise was essential to understand what attributes are already available, and which are planned.

The list of attributes was mapped to the existing eHDSI data set catalogue and this exercise showed that multiple attributes can be mapped to a single eHDSI data element. Depending on the eHDSI element there may be a single mapping to the EMA attribute list or to multiple EMA attributes (such as Class, Category, Sub-Category).

The correct identification of the attributes in use in different Member States is essential for the appropriate development of software connections in WP6 to ensure the transmission of information between the countries in cross-border context. UNICOM partners (eHDSI communities) working

collaboratively with internal partners (WPs 2, 3 and 4) conducted an analysis and the subsequent list of attributes was divided into three main priorities (There are different priorities among PS, eP and eD), defined as:

- Priority 1: the minimal attribute list for eHealth Services with IDMP compliant data are considered essential to issue the PS, eP and eD services (Table 1).
- Priority 2: attribute list for eHealth Services with IDMP compliant data with additional attributes for later deployments that can support the identification of the medicinal products and smart substitution (Table 2).
- Priority 3: maximum attribute list for eHealth Services with IDMP compliant data for later deployments. This includes attributes that are not yet implemented and are not required for the exchange of eP/eD and PS but can improve the data quality on the services (Table 3).

This minimal list of attributes is fundamental for UNICOM development, feeding into other work package deliverables i.e. WP5 and directly supporting the activities in WPs 6 (Software and extensions for CEF eHDSI) and 7 (Software and extensions for CEF eHDSI) including other relevant UNICOM WPs and the PPL task. This work must be kept aligned with eHDSI communities and EMA implementation framework.

A 'Change Proposal' (CP) on the 'CP-eHealthDSI-066: Align eHDSI with ISO IDMP' (Annex 1) was submitted by the eP Cluster on 8th Oct. to eHDSI Change Management. The initial draft of this CP was produced in 'D5.2 - Guidelines for IDMP-based Cross-Border eP/eD/PS' and is an intensive analysis on the current eHDSI Business Requirements considering the further implementation of the ISO IDMP on the eHDSI systems. Thereafter, the eP cluster, Semantic Task Force (STF) and other eHDSI communities provided feedback and the CP updated accordingly, in collaboration with UNICOM.

There are synergies between this CP and another CP which deals with the identification of complex packaging of medicines 'Medication Information representation improvements' produced by the eHDSI Architecture group. This alignment reinforces the importance of the adoption of the suggested changes to ensure a correct implementation of the ISO IDMP and support the correct identification of medicines.

Table 1: Minimal attribute list for eHealth Services with IDMP compliant data (Priority 1).

eHDSI data elements[8]	eHealth Services*			Attributes from EMA IG Section V2.1 (2021-02)[4]						
	PS	eP	eD	#	Class	Category	Sub-category	Sub-sub-category	Sub-sub-sub-category	Sub-sub-sub-sub-category
Active Ingredient / Active ingredient ID (code)	R	R	R	6.4.	Medicinal Product	Pharmaceutical product	Ingredient			
				4.10.4.	Medicinal Product	Packaged medicinal product	Manufactured item	Ingredient		
				5.5.1.	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Substance	
ATC code	R	R	R	1.13.3.	Medicinal product	Product classification	ATC Code(s)			
Medicinal Product Code	O	O	R	1.2.	Medicinal Product	Medicinal product identifier (MPID)				
				4.1.	Medicinal Product	Packaged medicinal product	Packaged Medicinal Product Identifier PCID			
Marketing Authorization Holder of the prescribed medicinal product	O	O	O	2.8.	Medicinal Product	Marketing authorisation	Marketing Authorisation Holder (Organisation)			
Brand Name of the Medicinal Product	O	O	R	1.14.1.	Medicinal Product	Medicinal product name	Full name			
Medicinal Product Package	O	R	R	4.2.	Medicinal Product	Packaged medicinal product	Package description			
				4.3.	Medicinal Product	Packaged medicinal product	Pack size			
Number of packages	O	R	R	4.7.5.	Medicinal Product	Packaged medicinal product	Package item (container) quantity	Package item (container) quantity		

[8] The eHDSI data elements were evaluated from the eHDSI confluence page at:
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

eHDSI data elements[8]	eHealth Services*			Attributes from EMA IG Section V2.1 (2021-02)[4]						
	PS	eP	eD	#	Class	Category	Sub-category	Sub-sub-category	Sub-sub-sub-category	Sub-sub-sub-sub-category
Strength of the Medicinal Product	R	R	R	5.5.2.2.2.	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Strength	Strength (Presentation single value or low limit)
				5.5.2.3.2.	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Strength	Strength (Concentration single value or low limit)
				5.5.3.1.	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Reference strength	Reference Substance
				5.5.3.3.2.	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Reference strength	Reference strength (Presentation single value or low limit)
Pharmaceutical Dose Form	R	R	R	1.5.	Medicinal Product	(Authorised) pharmaceutical form				
				6.2.	Medicinal Product	Pharmaceutical product	Administrable Dose Form			
				4.10.3.	Medicinal Product	Packaged medicinal product	Manufactured item	Manufactured dose form		
Route of Administration	R	R	R	6.6.	Medicinal Product	Pharmaceutical product	Route of Administration			

*R – Required element; O – Optional element.

Table 2: Preferred attributes for further implementation (Priority 2).

Attributes from EMA IG Section V2.1 (2021-02) [4]						
#	**Class**	**Category**	**Sub-category**	**Sub-sub-category**	**Sub-sub-sub-category**	**Sub-sub-sub-sub-category**
4.7.1.	Medicinal Product	Packaged medicinal product	Package item (container)	Package item (container) type		
4.10.1	Medicinal Product	Packaged medicinal product	Manufactured item	Unit of presentation		
5.1	Medicinal Product	Pharmaceutical product	Ingredient	Ingredient role		
5.5.3.4.	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Strength	Reference strength (Concentration)
5.5.3.4.2.	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Strength	Reference strength (Concentration single value or low limit)
5.5.3.4.3	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Strength	Reference strength (Concentration high limit)
6.3	Medicinal Product	Pharmaceutical product	Unit of Presentation			

Table 3: "Maximum" attribute list for eHealth services (Priority 3)

Attributes from EMA IG Section V2.1 (2021-02) [4]						
#	Class	Category	Sub-category	Sub-sub-category	Sub-sub-sub-category	Sub-sub-sub-sub-category
1.6.	Medicinal Product	Combined pharmaceutical dose form				
2.2.	Medicinal Product	Marketing authorisation	Marketing Authorisation Number			
2.3.	Medicinal Product	Marketing authorisation	Country			
4.2.1.	Medicinal Product	Packaged medicinal product	Package description	Language		
4.4.	Medicinal Product	Packaged medicinal product	Packaged Medicinal Product Identifier PCID			
4.6.2.	Medicinal Product	Packaged medicinal product	Marketing Authorisation (Package level)	Marketing Authorisation Number (Package Level)		
4.6.3.	Medicinal Product	Packaged medicinal product	Marketing Authorisation (Package level)	Country		
4.7.2.	Medicinal Product	Packaged medicinal product	Package item (container)	Package item reference(s)		
4.7.3.	Medicinal Product	Packaged medicinal product	Package item (container)	Manufactured item reference(s)		
4.7.6.	Medicinal Product	Packaged medicinal product	Package item (container)	Data carrier identifier		
4.10.2.	Medicinal Product	Packaged medicinal product	Manufactured item	Manufactured item quantity		
5.5.2.1.	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Strength	Quantity Operator
5.5.2.2.3.	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Strength	Strength (Presentation high limit)
5.5.2.3.3.	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Strength	Strength (Concentration high limit)
5.5.3.3.3	Medicinal Product	Pharmaceutical product	Ingredient	Substance	Strength	Reference strength (Presentation high limit)

4 Summary of guidelines

This section presents the guidelines highlighted throughout of the document to improve the reader experience.

Guideline (1):

Each Member State should identify a reference data model for the Medicinal Products, in the different levels required in the country and considering cross-border use. This data model should:

- Consider the use cases identified in UNICOM:
    - Regulatory exchange of master product information
    - Prescribed product identification
    - Dispensed product information
    - Product in a Patient Summary
- Be expressed formally,
- Identify the data elements that are to be used
- Where required or appropriate, identify the data rules, including the value sets that are required or advised.

-

Guideline (2):

UNICOM provides a common data model which accommodates the needs of the different contexts; Member States should take this model presented by UNICOM and use it as a reference or pivot in their own mapping efforts.

-

Guideline (3):

UNICOM will identify a collection of the Value Sets that are required for semantic interoperability (including necessary changes and clarifications). These Value Sets originate from the SPOR and from the Master Value Catalogue. There should be an agreed process for Member States to take this collection of Value Sets and use it in their own specifications, making the necessary provisions and adaptations.

-

Guideline (4):

The mapping from the UNICOM IDMP model to the Member States' data models should be formally documented and matches and variations clearly identified.

- matches are important to identify the impact of eventual upstream modifications – when a value set from SPOR is changed, or a definition is updated, or a data element is changed…
- variations are important to capture in documentation, and an analysis required to see if there is any functional impact in such situations.

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Guideline (5):

The Value Sets mentioned in the UNICOM central product models (regulatory and clinical) should have clear governance. Specifically, it must be known, for each Value Set:

- Who is the owning entity;
- Status;

- Master Location/primary source;
- Versions and version management,
- The associated change and release process.

This effort should be taken by the different responsible authorities; UNICOM will identify the gaps in such governance, and the different stakeholders should address these gaps, where necessary.

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Guideline (6):

The Value Sets mentioned in the UNICOM central product models (regulatory and clinical) should have clear governance. Specifically, it must be known:

- Who is the owning entity
- Master Location/primary source,
- Status,
- Versions and version management,
- What is the associated change and release process.

This effort should be taken by the different responsible authorities; UNICOM will identify the gaps in such governance, and the different stakeholders should address these gaps where necessary.

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Guideline (7):

Member States should follow a process to capture and document their models including adherence or variation to the UNICOM pivot models. The adherence is not mandatory but the consequences for any variation should be considered.

5 Annexes

Annex 1: CP-eHealthDSI-066: Align eHDSI with ISO IDMP

The following change proposal about eHDSI business requirements was initially developed in the deliverable '*D5.2 - Guidelines for Cross-Border ePrescription / eDispensation'* and presented to the eHDSI eP cluster and Semantic Task Force (STF) to support the update and cocreation of this document.

The cooperation between eP cluster, STF and UNICOM towards the maturation of the document, has culminated on the submission of this document on 08 Oct. 2021 by eP cluster in conjunction with UNICOM.

This change proposal contains the analysis and suggestions for improvements on the current eHDSI business requirements and intends to support the further implementation of the ISO IDMP at eHDSI.

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 Member States, marketing authorisation holders and EMA to make use of the ISO IDMP standards. 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 based on 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 esther, 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 standardised 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 considered.

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 an 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 starting 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 must 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 consider 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

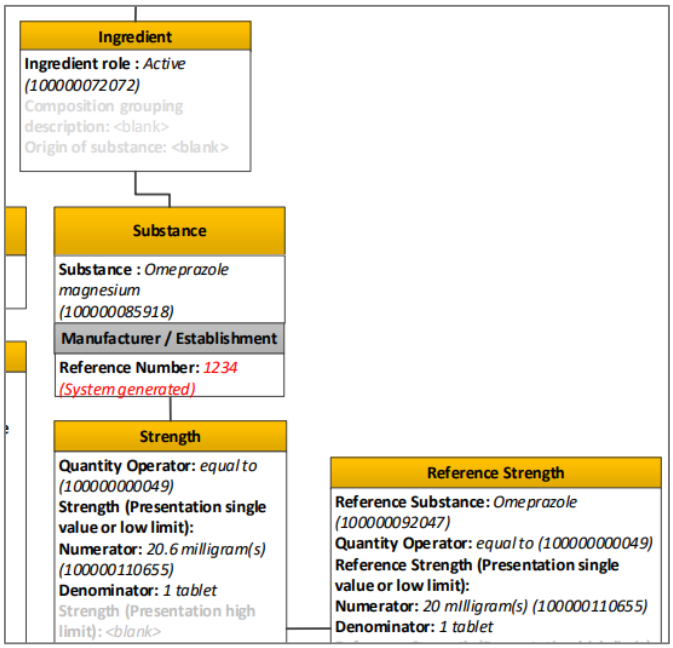
No impact at this point.

Ingredients and strengths

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 cross border 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 standardised, 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.