



UNOCOM

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

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Statement of originality

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Deliverable abstract

The IDMP is a set of five different ISO standard specifications used to identify medicinal products that aims to ensure better safety to the patients at national or cross-border levels.

Starting from the CEF eHDSI Technical Specifications, the business requirements and the CDA Display tools as the base to guide the development of the specific technical specifications in order to support the implementation of the IDMP on the eHDSI infrastructure.

It intends to present the technical specifications, for the reference Portal integrated to Medicinal Product Database(s), that shall be considered to adopt the ISO IDMP standards among the national and cross-border systems, to ensure the interoperability of eP/eD & PS in the different Member States.

Keywords: eHDSI, Technical Specifications, Business Requirements, CDA display tool, interoperability.

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List of abbreviations

Abbreviation	Complete form
ACT-X	Activity, where 'X' is referred a sequential number
ADE	Adverse Drug Event
ATC	Anatomical Therapeutic Chemical Code
CDA	Clinical Document Architecture
CEF	Connecting Europe Facility
CVA	Cerebrovascular accident
eD	ePrescription
eHDSI	eHealth Digital Service Infrastructure
eHN	eHealth Network
EHR	Electronic Health Record
eP	eDispensation
MPD	Medicinal Product Dictionary
NCPeH	National Contact Point for eHealth
OTC	Over-the-counter
PhPID	Pharmaceutical Product Identifier
PS	Patience Summary
REQ	Requirement
TS	Technical Specification
WP	Work Packages

1 Executive summary

The development of the UNICOM project aims to support the implementation of several use cases including the development of Identification of Medicinal Products (IDMP) as a global and univocal identification of medicines for cross-border ePrescription and eDispensation.

The 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.

This task, starting from the CEF eHDSI Technical Specifications, will collect individual requirements and constraints from each country involved in the action to allow tailored definition of the eP and PS solutions. It has considered the business requirements already put in place in the UNICOM '*D5.1 - Business requirements for the adoption of IDMP in eHealth Services*', the eHDSI CDA Display Tool as a basis to guide the development of the specific technical specifications. This analysis has generated new requirements in line with their technical specifications in order to support the implementation of the IDMP on the eHDSI infrastructure.

This task will also provide the Requirement Specifications for the reference Portal integrated to Medicinal Product Database(s). This document is an input for WP6 - Implementation of the reference portal, which will be offered to Member States to aid their national implementations

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

2 Introduction

2.1 Background

Information in healthcare is enormously complex, covering many different types of data. This information needs to be aggregated and shared across different healthcare settings to 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 (PS) and ePrescription (eP). The generic services are the necessary implementation of data exchange at country level, the core services at EU level. These together enable the provision of Cross-Border eHealth Information Services (CBeHIS).

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

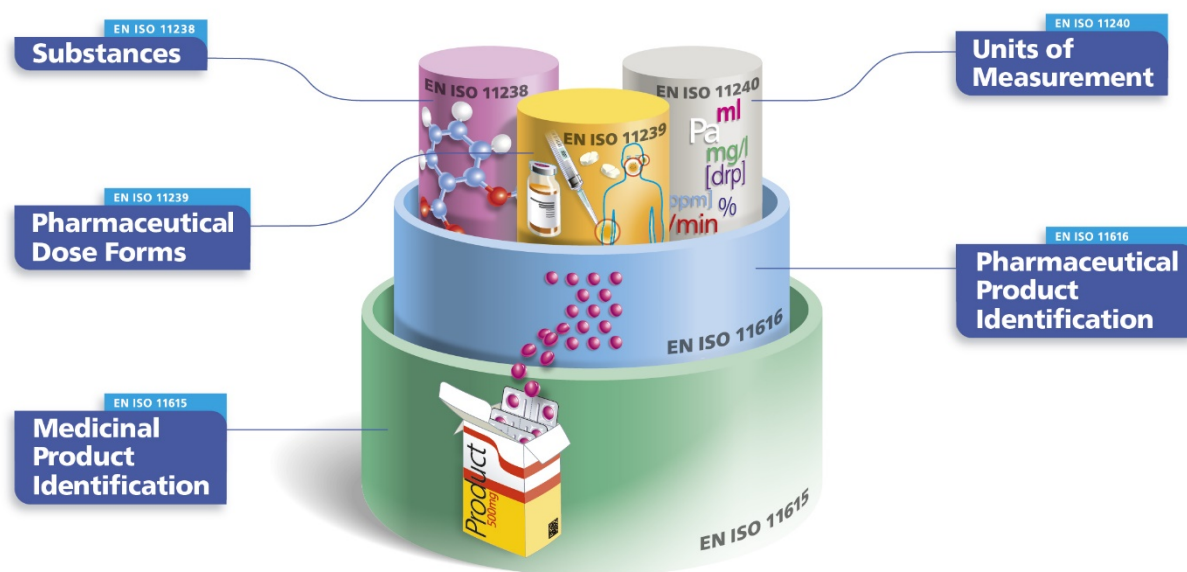


Figure 1: The 5 ISO standards used to identify medicinal products

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.

Specifically, Work Package (WP) 5 is tasked with the IDMP adoption in Member States eHealth services by coordinating the adoption of these standards at both national and cross-border levels. The focus is on ePrescription and Patient Summary 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.

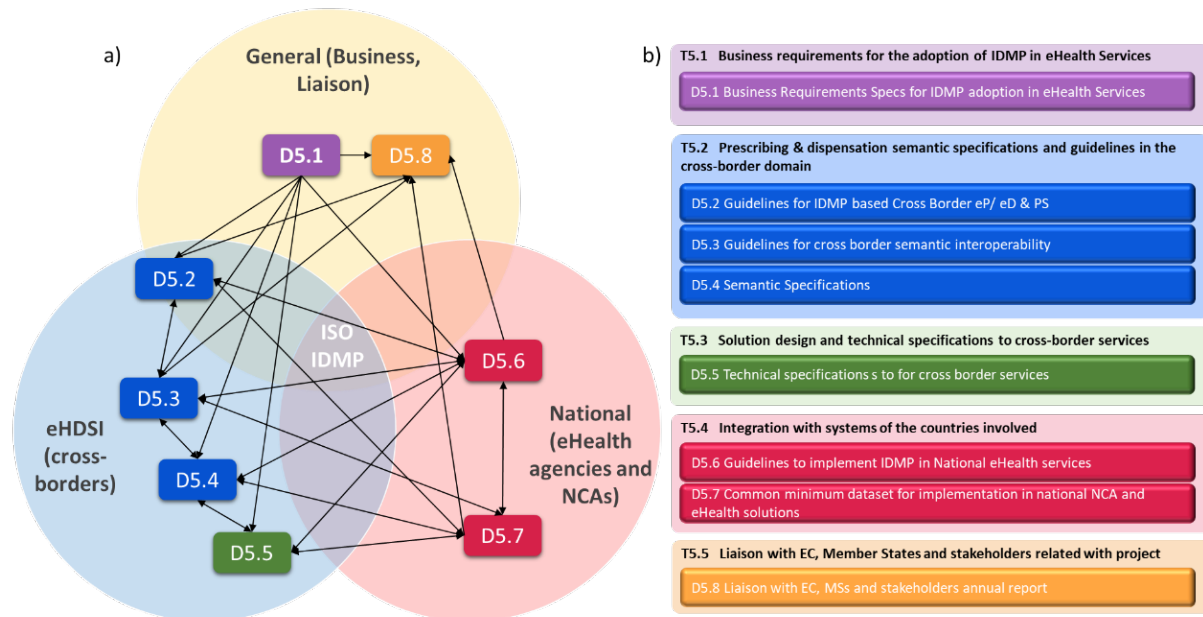


Figure 2: The WP5 deliverables relationship.

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

2.2 Introduction to D5.5

This task, starting from the CEF eHDSI Technical Specifications, will collect individual requirements and constraints from each country involved in the action to allow tailored definition of the eP and PS solutions.

If necessary, a CEF eHDSI Change Proposal will be drafted to address technical specifications and the Open National Contact Point (NCP) components and submitted to the eHDSI Change Management process. While preparing the Change Proposals, possibility of maintaining backward compatibility with the current solution will be carefully analysed.

This task will also provide the Requirement Specifications for the reference Portal integrated to Medicinal Product Database (MPD). This document is an input for WP6 - Implementation of the reference portal, which will be offered to Member States to aid their national implementations.

The technical specification for Cross-Border services uses the CEF eHDSI Technical Specifications as its starting point for collecting individual requirements and constraints from each Member State involved. A specification for a reference Portal, which is integrated into MPD(s), will also be generated as a part of D5.5 work. During this process, the need for changes to existing specifications may be identified and if so, draft CEF eHDSI Change Proposal(s) will be circulated for consideration.

2.3 Scope of the document

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

- Starting from the CEF eHDSI Technical Specifications
 - Collect individual requirements and constraints from each country involved in the action
- Relevant CEF eHDSI Change Proposal will be drafted and presented to the eHDSI Communities.
 - Address technical specifications and the OpenNCP components and functionalities.

- Provide the Requirement Specifications for the reference Portal integrated to Medicinal Product Database(s).
- The requirements specification will be used for the implementation of the reference CDA Display Tool in WP6 and may be reused by Member States in the national implementations.

3 eHDSI Technical Specifications review

3.1 Business and functional requirements

The business requirements for the adoption of IDMP in eHealth services was defined in deliverables “D5.1: Business requirements for the adoption of IDMP in eHealth Services”³ and “D5.2: Guidelines for IDMP-based Cross-Border ePrescription / eDispensation & Patient Summary”⁴ and intend to be a useful tool for contextualisation of the project and support the development of the UNICOM assets. It is focused on the cross-border domain at different dimensions: organisational / service, functional, semantic and technical.

This approach is needed to help Connecting Europe Facility eHealth Digital Service Infrastructure (CEF eHDSI) and the different countries on the adoption of the ISO IDMP, due to their different levels of maturity, allowing the participant countries and bodies to implement the ISO IDMP in a co-ordinated way.

This section generally describes the technical requirements based on the business requirement for the ePrescription and Patient Summary use cases. The main benefits of ISO IDMP adoption will be perceived on those scenarios. For more detailed information please read the documents D5.1³ and D5.2⁴.

3.1.1 Generic Activities and requirements

During the requirement analysis phase, several commonalities were found across the use cases. This section describes the activities and requirements that are common to eP and PS use cases. From each activity / requirement is presented the technical overview that should be considered to ensure the correct implementation of the ISO IDMP on the eHDSI infrastructure. With regards to the semantic transformation of data between countries, the NCPeH is responsible for semantic transformation and mapping to ensure the accuracy and integrity of semantic processing between Country A and Country B.

To ensure the alignment between the previous work on D5.1, the Business Requirements (Rx – where “x” represent the number) related with the Technical Specifications (TSx - where “x” represent the number) will have the same numbering.

ACT-01 (Activity 01). Country A generates a specific document type for their healthcare citizen

A clinical document is created according to the National procedure and submitted to the National / Regional infrastructure of Country A using internal workflows and includes different coding systems, including local codes.

³ https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D5.1_Business-Requirements-Specifications_Final_20210226.pdf

⁴ https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D5.2_Guidelines-for-IDMP-based-Cross-Border-eP-eD-PS_20210708.pdf

Requirements (REQ)

REQ-01. *A clinical document (i.e. a prescription, dispense, patient summary) SHALL follow the legal requirements in country A*

IDMP adoption should not require a different set of clinical processes or exceptions, or define a new process or legal change that would be incompatible with the existing legal and operational frameworks inside the countries.

IDMP enhancement comes after document creation, so it does not affect its creation and no technical change is needed.

REQ-02. *The clinical document SHALL contain relevant information for internal processing*

Adoption of IDMP should not force a reduction of the detail in which the products are identified in the documents that are issued.

REQ-03. *The clinical document SHOULD contain relevant information for cross-border processing*

When a document is created, it should contain enough information that somehow, through one or more steps of transcoding and cross-referencing, allow processing in a different country.

For example, when a product code is referred in a prescription, it is important that the prescription also indicates what type of code is that – whether a “generic” code, or a “branded product” code – this is important to allow any mapping and product discovery.

REQ-04. *The prescription / clinical document SHOULD be in a format that can be exposed in another IDMP-enabled country*

The exchange format needs to be compatible cross-country and any constraints on the document (for example terminology constraints) should be supportive of retrieval and display in the other country.

Technical Specifications (TS):

TS-01. *(ACT-01) Support for additional document types SHOULD be feasible with no or minimal effort. CDA is currently the chosen eHDSI format for usage and transport of eP, eD and PS.*

TS-02. *(REQ-02) Information currently present in the eHDSI exchange SHALL not be changed in any way. However, additional IDMP and non-IDMP attributes⁵ COULD be added.*

IDMP SHALL NOT affect current medicinal product information, it SHALL enhance it.

TS-03. *(REQ-03) There SHALL be additional validation(s) that document contains enough information for IDMP mapping / enhancement.*

Negative flows definitions SHALL be specified / reviewed, i.e., what should happen when document is not valid, i.e., does not contain enough information.

⁵ Non-IDMP attributes are referred on UNICOM 'D5.1 - Business requirements for the adoption of IDMP in eHealth Services'.

"In addition to the product identifiers, other attributes of the product that are relevant in the other stages SHOULD also have a conversion to a common language. Other attributes that may be useful to complete IDMP identifiers to perform medicinal products identification but are transactional data and are part of the document and not part of the product master data, SHOULD be converted in the clinical documents themselves and not mapped to product characteristics."

TS-04. (REQ-04) IDMP information SHALL enhance existing document by following existing HIT standard

It is important that the document is implemented in a common technical standard such as HL7 or IHE, to enable any analysis and mapping of the attributes.

HL7 CDA shall be used as HIT standard.

ACT-02. Make document available for cross-border access

Cross-border sharing of documents may require specific infrastructure and some data and metadata could be affected.

Requirements:

REQ-05. *There SHALL be a way to expose the documents normally used in one country for use in other countries*

The format of document should not only be compatible across countries, but also physically available in other countries. This may mean a technical conversion, an architectural bridge (for example between push or pull models) etc.

Technical Specifications:

The eHDSI exchange is already in place and it is operational, thus IDMP does not affect transportation level and no technical change was identified.

ACT-03. Positive identification of patient

Normally, patient identification is operational inside the country or the health system. For a patient to receive care in another country, obtaining the patient's data is necessary, which requires the positive identification of that patient in another country.

Requirements:

No new requirement is expected from UNICOM in this step.

Technical Specifications:

The eHDSI exchange is already in place and IDMP does not affect patient / citizen identification.

ACT-04. Request available / active prescriptions / Patient Summaries / Adverse Drug Event (ADE) / other clinical. document from another country

After the successful identification of the patient, the mechanism for requesting a clinical document should be defined: it could be done by polling for information in Country B from the Country A National Contact Point or from a central hub, or in another way.

The request stage is followed with a response, which provides information held in Country depending any additional information that is needed for the specific business activity.

Requirements:

REQ-06. *Product groups / classification SHOULD be identifiable in another country*

The identification of products may depend on product or categories – for this reason categories should be translatable and transportable to another country.

For example, ATC is a common global classification and can be easily identified in another country. However, matters like Legal status of supply, or the notion of “protected substances” may differ and it is important that these classifications can be understood across borders.

Technical Specifications:

TS-05. (REQ-06) IDMP information SHALL be added to document(s) before or during the pivoting in the NCPeH.

TS-06. (REQ-06) Central IDMP registry SHALL be used or local IDMP registries SHALL be in-sync with.

ACT-05. Obtain specific active ePrescription / Patient Summary / ADE / other clinical document from another country

It is possible to disclose all information or just a subset (depending on access rules) to the health professional in Country B.

For a Patient Summary, getting all the clinical information may be necessary for a better judgement and choice of treatment options for the health professional in Country B while for the prescription list, the dispenser will only have access to the prescription item indicated by the patient and, the dispenser makes a judgement whether it is safe to dispense this item without sight to all other prescriptions.

Similarly, the healthcare provider in Country B will need to make a judgement call on the treatment options available without full disclosed information to provide safe medical health care.

Requirements:

REQ-07. Products from one country SHALL be visible in another country, following access control rules

This broad business requirement implies that upon consultation, a healthcare practitioner shall be able to see that a given document includes products (for example a prescription) unless there are rules preventing this.

In other words, when a product is mentioned in a document, this shall be visible to the healthcare practitioner consulting the document from another country, depending on access control rules (derived from privacy concerns etc.).

The eHDSI exchange is already in place and access rules are already defined. “Hiding”⁶ specific medication in the exchanged document is not supported and retrieving specific eP is already bound to access rules. IDMP does not affect this.

No technical change is needed.

REQ-08. Product Classifications of products from one country SHALL be visible in another country

⁶ It is not supported by the eHDSI, it is a process that comes from the Member States. So, if any medication is “hiding” it is done in the Member State before the information is shared with the eHDSI systems.

In order to determine which products and which documents are relevant to retrieve, it is important that product classifications are also visible.

For example, if there is an emergency treatment for a Cerebrovascular accident (CVA), it is important to understand what blood-related medication the patient is also taking. Or in some cases, it is important to understand that drugs are considered protected substances in some countries.

The eHDSI supports the discovery and retrieval of documents based on metadata about document. Some metadata describes the content of the document, but not in such low-level detail – it is possible to discover documents that are of type prescription, but it is not possible to discover documents of type prescription for specific medication.

This requirement also somewhat introduces immense complexity expecting that each EU Member State maintains product descriptions of other Member States, e.g., to be aware if some product is a protected substance.

It might be useful to explore possibility that Product Master Data's data model contains such information.

No technical change is needed for this requirement.

Technical Specifications:

The eHDSI exchange is already in place and this function is already supported.

ACT-06. Select and dispense

ACT-06.1 Match and translate attributes and identifiers

After the clinical document is received in Country B, the next step is to bring the information that is issued in Country A in a form that the professional in Country B can understand given their purpose and context.

In the scenario of a prescription / dispensation, this means getting medicinal product information and all its prescribing details in a structure that is compatible with Country B, which includes vocabulary concept matching.

This is the core of UNICOM and where IDMP can add value – the identification of a product across borders.

Requirements:

REQ-09. *Products specified in one country SHALL be identifiable in another country*

A healthcare practitioner in country B shall be able to understand what product was meant in country A. This does not mean that the original code must be understood but there SHALL be a way to convert the specified product-related information into something that can be understood in another country.

For example, if the prescription contains the code 10000034, it is unlikely that this code is understood in country B, but it is important to understand that this refers to Fusidic Acid, 250 mg tablets – by expressing the relevant attributes (substance, dose form and strength).

REQ-10. *There must be a standardised technical format and infrastructure to exchange the information*

This is handled by the infrastructure and standard for data exchange and CDA is the chosen eHDSI format for usage and transport of eP, eD and PS.

Other alternatives can be considered if this requirement is respected: a standardised format and infrastructure are essential.

In practice, this requirement means that there is a common cross-border standard format for sending the information.

REQ-11. *The attributes used to identify the product shall be commonly identified to be understood across countries*

This requirement is about the semantic interoperability – before the content is understood, it is necessary that the language in which the content is expressed is also understood.

For example, when country A specifies “quantity” it is essential to know what this means – quantity to administer each time, quantity to dispense... or “indication” – is this the authorised indication for the product, or the reason for prescribing (which can differ from authorised indications, in the case of off-label use).

Another relevant example is the Product Code – when a prescription from country A specifies a product by its code, it is essential for country B to understand what type of code is being referred (a national code, a IDMP code, etc...).

REQ-12. *It SHALL be possible to translate products identifiers and / or attributes from one country to the other*

Systems in Country B, upon receiving a set of codes and attributes describing a product must be able to use convert those attributes to the national reality.

In most cases just one or several product codes are not sufficient to define the equivalence of products, for this reason the translation SHALL be done by attribute matching, not only by 1:1 mapping of codes.

REQ-13. *There SHALL be common product identifiers when possible*

This is governance requirement for local authority when performs mapping of local products to IDMP. No technical specification is needed.

REQ-14. *The attributes for Products SHALL follow a common language*

The common language does not have to include only the codes, but the attributes that are used to describe the product.

Besides the common codes – which are ensured by IDMP identifiers – the attributes should also use common codes and a common grammar where codes are not possible.

For example, substance codes, or dose form codes, or strength expressed in a common grammar, with quantities expressed in a standard form, and using standard, encoded units.

No technical specification is required as this is a governance requirement for local authority when performs mapping of local products to IDMP.

Technical Specifications:

TS-07. *(REQ-09) Pivoted and translated document SHALL contain IDMP information to enable processing by the dispenser using local or central IDMP registry.*

TS-08. (REQ-11) *Pivoted and translated document SHALL contain IDMP information.*

IDMP information SHALL follow existing or define new attributes using HL7 CDA, i.e., attributes in the CDA SHALL be coded using common terminology.

TS-09. (REQ-12) *IDMP registry, either local or central, SHALL support local mapping and translation.*

ACT-06.2 Find corresponding products (may include substitution)

After the clinical document retrieval is necessary select the corresponding medicinal product or a substitution for dispensation using product identifiers or a selection based on the prescription attributes. Grouping and substitution are important to find equivalent therapeutic treatment.

In order to perform a safe medicinal product selection or substitution, in principle it is needed to know all current treatment and allergies. Selection and substitution constraints should be expressed clearly, as well as product groups.

Requirements:

REQ-15 *Products groupings SHOULD be expressed intentionally (group is defined by listing the criteria for inclusion in the group) or extensionally the group is defined by listing all the products in the group) – using a common vocabulary when possible*

The common language does not have to include only the codes, but actually the attributes that are used to describe the product.

Besides the common codes – which are ensured by IDMP identifiers – the attributes should also use common codes and a common grammar where codes are not possible.

For example, substance codes, or dose form codes, or strength expressed in a common grammar, with quantities expressed in a standard form, and using standard, encoded units.

REQ-16 *Substitution rules SHOULD be expressed intentionally using a common vocabulary when possible*

If a product can be substituted within a group, there needs to be a mechanism to identify which products are in a group, and this mechanism should use the same common vocabulary as needed (to express rules that can be understood) or the product groups must indicate explicitly which products are in the group, to allow a lookup).

Technical Specifications:

TS-10 (ACT-06.2/REQ-15) *The medication SHALL be found, in order of preference*

The order should be:

- IDMP identifiers and attributes
- grouping and classification
- prescription attributes

TS-11 (ACT-06.2/REQ-16) *The result of querying SHALL contain an exact match or a substitution*

The substitution is locally specific, e.g., IDMP product in country A is grouped in the "fooA" group, but in country B, it is grouped in the "fooB" group, which does not necessarily contain the same IDMP products as group "fooA".

TS-12 (REQ-15, REQ-16) IDMP registry SHALL support grouping and collect and provide grouping criteria to be used during querying, as well as description of grouping decision.

Intentional grouping is not implementable without further specification and description – intentional grouping may produce countless groups – implementor needs to understand limits in order to implement sufficient solution.

ACT-07. Report Dispensed Product

This is equivalent to the creation of a new clinical document which SHALL be transported / converted from country B and SHALL be valid in country A. The same mechanisms and requirements should apply here.

Implicit requirement: The mechanism to identify a product across borders should be reusable. For example, identifying a prescribed and a dispensed product should follow the same mechanism. The key differences would be in terms of granularity (for example describing a dispensed product will require more precision – more attributes – than a prescription for a generic medication).

Technical Specifications:

TS-13 (ACT-07) The dispensation flow SHALL be the same as prescription flow, but in the opposite direction.

Granularity differences between eP and eD SHALL be considered in the dispensation flow.

3.1.2 Dependencies / access streams

For the business requirements listed above to be implementable and operational, there are a few dependencies that had previously not been identified or enforced, and are part of the UNICOM vision:

ACT-08. Set access permission rules getting ePrescriptions / Patient Summaries / ADEs / other clinical documents from another country

Accessing a patient's information for care in another country means the disclosure of a patient's health data to professionals in another country. This must respect GDPR privacy rules and other relevant regulations, which means the mechanisms for permitting access must be defined in advance – either through role-based access rules or consent-dependent permission. – (Any specific requirements on this will be produced by WP 13 or others as adequate).

Technical Specifications:

n/a – eHDSI exchange is already in place and this function is already supported.

Activity A.9. Make Medicinal Product Dictionaries (MPDs) and clinical systems aligned to common language (IDMP)

For a correct exchange and “conversion” of product identification between 2 countries (as in the case for ePrescription / eDispensation), the MPDs of at least one of the countries SHALL contain the IDMP set of attributes or identifiers for the products. In practice, this means that each country must have this, because each country may play the role of Country A or Country B.

The extent of this common set of attributes and identifiers will depend on the choices taken in this UNICOM project. This means that, besides any local identifiers, defining and describing attributes, the national MPD SHALL also contain a “common language” translation of some of the attributes.

Requirements:

REQ-17 *A minimum set of IDMP attributes and identifiers SHALL be synchronised for all products across all Member States*

This is a critical and mandatory dependency – When an IDMP-enabled description of medicinal products is available e.g., in the central regulator, it must be synchronised across countries wherever needed.

REQ-18 *For this synchronization and governance of attributes, there SHOULD be a common standard to exchange detailed product master data*

This exchange of product master data will include not only IDMP attributes and identifiers, but also identifiers of other levels outside of IDMP (such as those used in the countries’ operational and legal settings).

REQ-19 *The exchange of IDMP attributes SHALL be appended to the current descriptions of the products on a national level*

This articulation between IDMP concepts and identifiers and the local concepts and identifiers is the pivotal point for IDMP to be operational without imposing on legal frameworks and clinical practices.

For example, there is no need to require that prescriptions in country A are done in a way compatible with PhPIDs Level 4 (basically supporting only “generic” prescriptions), because the MPD in the country can establish the correspondence between one national product concept and the necessary IDMP attributes and identifiers.

The product “common language” attributes are defined according to IDMP and this synchronisation can take place in the National Contact Point or central regulatory actors – and even be extended to individual EHRs.

There SHALL be a transport and synchronisation exchange of product master data.

Finally, after the important functional requirements are met with the possibility of transcoding the content between countries, the practical adoption of IDMP services may depend on additional services, for example:

- ▶ A lookup service that allows to check the “IDMP expression” of a product, which enables IDMP-centric product search (e.g., for substitution).
- ▶ A lookup service for checking a product’s characteristics in a different language or specific context (e.g., a patient from Greece can scan the barcode of an Over-the-counter (OTC) in Finland and see the relevant characteristics of the product in their language).

These requirements can be studied when their need emerges.

A final recommendation (not a mandatory business requirement, but applicable for those cases that are outside of the current scope of eHDSI) is that the scope of application of IDMP is expected to grow, therefore:

REQ-20 *The designed solution should be ready to accommodate a growth in complexity of the products or of the workflow, instead of being limited to the use case originally planned.*

n/a – definition / explanation of possible growth is needed

Technical Specifications:

TS-14. (ACT-09) Local IDMP registry with maintained mappings to local medication database(s) SHALL be utilised.

TS-15. (REQ-17) IDMP registry SHALL be either centrally managed and either exposed to or shared with local instances, or there SHALL be mechanism for federated government

TS-16. (REQ-18) IDMP registry SHALL be exposed using common HIT standard for either local-to-central or peer-to-peer sync

TS-17. (REQ-19) Local medicinal product registry SHALL be enhanced with IDMP, or there SHALL be mapping mechanism between local MP registry and IDMP registry.

3.2 CDA Display Tool Specification

MyHealth@EU in fact uses a document-based representation for the services currently supported: ePrescription / eDispensation and Patient Summary. Documents are adopting the HL7 CDA R2 standard for their physical representation⁷.

The CDA display tool represents all the clinical information required to issue the eP/eD and PS on the eHDSI. In this regard, this deliverable will only focus on the analysis and presentation of the CDA display tool specifications related to the medicinal products identification that may be impacted by the implementation of the ISO IDMP on eHDSI infrastructure. Any CDA Display tool specifications not referred in this document are out of UNICOM's scope.

The CDA Display tool analysis and its relationship with the Master Value Catalogue (MVC) are shown below. In order to facilitate the analysis, only the fields and information blocks related to medicinal products identification will be described in this document. The full CDA tool specifications⁷ is available in the eHDSI website under prior authorisation, and was the basis used for the aforesaid analysis.

3.2.1 ePrescription

This chapter intends to present the ePrescription / eDispensation and Patient Summary specifications related to the CDA Display tool.

3.2.1.1. ePrescription Item

The eP item is the substance for which a prescription is created.

The substance and the corresponding ATC code are displayed in the title of a surrounding block (Figure 3, Table 1). The block consists of three major parts:

- Medicinal product, with information about the prescribed medication.
- Prescription details, with information about the prescription itself.
- Dispensation details, with information about the dispensation.

⁷ For more information, please visit the following website:

https://webgate.ec.europa.eu/fpfs/wikis/display/EHDSI/CDA+Display+Tool+Specification?preview=/888399099/888399100/eHDSI_CDA_Display_Tool_Specifications_v2.2.0.pdf

Note: the access to this document needs to be requested to eHDSI management.



Figure 3: ePrescription Block

Table 1: ePrescription CDA Mapping

Values	XPath ⁸	Translation in CDA ⁹	VS ¹⁰
Substance Name	consumable/manufacturedProduct/manufacturedMaterial/asSpecializedKind/generalizedMedicineClass/code/@code	NA	
ATC Code	consumable/manufacturedProduct/manufacturedMaterial/asSpecializedKind/generalizedMedicineClass/name(Only if consumable /manufacturedProduct/manufacturedMaterial/asSpecializedKind/generalizedMedicineClass/code /@codeSystem='2.16.840.1.113883.6.73')	NA	

Requirements:

No new requirements are needed

⁸ XPath:

- a. NO means that this info cannot be get from the CDA.
- b. The XPaths here provided are reported just for exemplification. Alternatives and more specific rules may however be applied (e.g. filter per template ID instead of for code...) to better identifying the concept to be displayed.

⁹ Translation in CDA

- a. NO means that the translated information to be displayed cannot be get from the CDA.
- b. Y (YES) means that the translated information to be displayed shall be retrieved from the CDA.
- c. NA means that no translations are applicable for this info (e.g. date).

¹⁰ VS (valorised only if “Translation in CDA” not “Y” or “NA”)

- a. NO means that this concept is not included in the current MVC.
- b. Information provided as textual note.

3.2.1.2. Medicinal product

The medicinal product block (Figure 4,

Table 2) collects all the information related to the prescribed medication.

The information appears as a list of medicines allowed to be dispensed.

For each medicine one row with the following fields in sequence:

“Active ingredient”, “Strength”, “Package size” or “posology”, “dose form” (“Brand Name”)

Example

1. KETOPROFENE 2.5[mg] / 100[g] 50[g] GEL (LASONIL C.M.*GEL 50 G 2,5%)
2. IBUPROFENE 200[mg] per unit 100 unit(s) GEL (ADVIL IST.L.GELS*100CPS PVC)

From this page it shall be possible to select a medicine and open the related details.

The page sketch above provided does not put in evidence controls needed to navigate the pages, since it will be most likely a portal feature, implementers need however to take them in account.

In order to assure the navigation also for external portals “without the need of retrieving again the whole eP document” – as requested by this specification – it has been proposed to adopt a single dynamic page where navigation between the different views – in accordance with the workflow described in the chapter 2.1 – is internal to that page.

In case of missing information, the field is left empty (even when not allowed by the specs).

Example (no active ingredient)

2.5[mg] / 100[g] 50[g] GEL (LASONIL C.M.*GEL 50 G 2,5%)

In case of null flavored value information the nullflavor description is shown. Example (no strength denominator)

IBUPROFENE 200[mg] per unit / No Information 100 unit(s) GEL (ADVIL IST.L.GELS*100CPS PVC)

In case of uncoded element [with reference to text] (“Active Ingredient”) (e.g. <value xsi:type="CD" > <originalText><reference value="#link-1"/> </originalText></value>) the not-translated referenced text will be shown

Active ingredient 200[mg] per unit 100 unit(s) (ADVIL IST.L.GELS*100CPS PVC)

If the “Active ingredient” is a coded field, such as SMS, it can be automatically translated. However, if it is a free text field, it cannot and should never be translated. If the reference is missing, this indicates a no value case and the field is left empty.

Medicinal product									
Active Ingredient	<table border="1"> <thead> <tr> <th>Code System</th> <th>Code</th> <th>Name</th> <th>Strength</th> </tr> </thead> <tbody> <tr> <td>ATC</td> <td>A10AE04</td> <td>Insulin glargine</td> <td>100 international unit / 1 milliliter</td> </tr> </tbody> </table>	Code System	Code	Name	Strength	ATC	A10AE04	Insulin glargine	100 international unit / 1 milliliter
Code System	Code	Name	Strength						
ATC	A10AE04	Insulin glargine	100 international unit / 1 milliliter						
Brand Name	LANTUS								
Strength	100 U/ml								
Package Size	10 milliliter								
Dose Form	Solution for injection								
Route of Administration	Subcutaneous use								

Figure 4: Medicinal Product Block¹¹

¹¹ This figure shows specific attributes and does not represent all fields. The complete information can be found on the

Table 2. Same is applicable to other examples below.

Table 2: Medicinal Product CDA Mapping

Values	XPath	Translation in CDA	VS
Active Ingredient – Code System	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/code/@codeSystem	Y	
Active Ingredient - Code	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/ingredient/code/@code	Y	
Active Ingredient - Name	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/ingredient/name	NA	
Active Ingredient – Strength Value	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/ingredient/quantity/@value	NA	
Active Ingredient – Strength Value (Unit)	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/ingredient/quantity/@unit	Y	
Brand Name	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/name	NA	
Marketing Authorization Holder	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/marketingAuthorizationHolder/name	NA	
Strength	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/ingredient/desc	NA	
Package Size Value	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/asContent/containerPackagedMedicine/capacityQuantity/@value	NA	
Package Size Unit	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/asContent/containerPackagedMedicine/capacityQuantity/@unit	Y	
Dose Form	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/formCode	Y	
Route of administration	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/routeCode/@code	Y	

Requirements:

REQ-21 The clinical document **MUST** support the use of IDMP codes in the medicinal product attributes. The system **SHALL** specify what is each IDMP code.

REQ-22 The Active Substance Code **MUST** be universally understood and enable translation and conversion.

REQ-23 *The Strength Unit SHOULD be universally understood and enable translation and conversion.*

REQ-24 *The Package Size Unit SHOULD be universally understood and enable translation and conversion.*

REQ-25 *The Dose form SHOULD be universally understood and enable translation and conversion.*

REQ-26 *A code for Route of Administration SHOULD be universally understood and enable translation and conversion.*

Technical Specifications:

TS-18 (REQ-21) *A system code exclusive for IDMP SHOULD exist to relate correctly with the active ingredient and signalise that the CDA document is IDMP compliant.*

TS-19 (REQ-22) *A code for Active Substance MUST exist for IDMP to correctly identify and signalise that the substance is correctly identified and MUST be available in the SPOR databases*

TS-20 (REQ-23) *A code for Strength Unit SHOULD exist and SHOULD be available in the SPOR databases to standardise units and measures.*

TS-21 (REQ-24) *A code for Package Size Unit SHOULD exist and SHOULD be available in the SPOR databases to standardise units and measures.*

TS-22 (REQ-25) *A code for Dose form SHOULD exist and SHOULD be available in the SPOR databases to standardise units and measures.*

TS-23 (REQ-26) *A code for Route of Administration SHOULD exist and SHOULD be available in the SPOR databases to standardise units and measures.*

3.2.1.3. Prescription Details

This part provides detailed information about the prescription (Figure 5: Prescription Details Block, Table 4: Prescription Detail CDA Mapping).

By default, the substitute check box is not marked; The Dispensed Product, the Dispensed Package Size and the Dispensed Number of packages are prefilled with the values specified in the prescription. (in the example “Lantus”, “10 millilitre” and “5”).

If the brand name substitution is not permitted in the prescription, the brand name may be modified / adjusted in absolutely clear cases when it is known that the exact same medicinal product as prescribed (same manufacturer and exactly the same composition) is available in Country B under a slightly different name. This decision is made by the pharmacist, and no general rule is given, as this is case-specific. If the substitute check box is marked, a medicinal product produced by a different manufacturer may be dispensed. Dispensed Package size and Dispensed Number of packages may be modified irrespective of the value of the substitution checkbox as indicated on the prescription. The value of the

Dispensed Number of packages can be modified, but not the value unit, which is based on the unit defined in the prescription.

Data described here are derived from the section Medications Summary 1.3.6.1.4.1.12559.11.10.1.3.1.2.3 (LOINC code 10160-0).

As general rule, the same approach defined for the other sections for handling missing, null flavored values, and uncoded information have to be applied: in practice if not else specified in case of missing values nothing needs to be displayed; if nullflavored the nullflavor description shall be displayed.

Table 3: Medicine Item prescribed

Active ingredient	Strength	Dose form	Units per intake	Frequency of intakes	Route of Administration	Onset Date	End Date
Hydrokortizón (A01AC03)	50 [mg] per unit	Injekcia	50 [mg]	1 [d]	Gel	14/08/2011	09/05/2011

Table 3: Medicine Item prescribed shows an example of how the medicine information should be displayed.

If the “Active ingredient” is a coded field, such as SMS, it can be automatically translated. However, if it is a free text field, it cannot and should never be translated. If the reference is missing, this indicates a no value case and the field is left empty.

Section is Missing

Medications Summary non presente !

No info scenario (substanceAdministration.code@code is “182849000” or “408350003” or “182904002”)

If the substanceAdministration.code@code is “182849000” or “408350003” or “182904002” only the related displayName shall be displayed.

History of pharmacotherapeutic drugs is unknown

No info scenario (just a nullflavored entry is present).

This is not consistent with current eHDSI specifications; however, for the robustness of the solution this use case could be “easily” dealt showing just the nullflavor description.

(this could be reuse for other sections)

Prescription details	
Onset Date	2020-05-22
End Date	2020-06-22
Units per intake	1
Frequency of Intakes	5 ml per day
Number of packages	3
Instructions to patient	For the treatment of diabetes Used as needed
Advise to the dispenser	Diabetes patient
Is substitution of brand name allowed?	No

Figure 5: Prescription Details Block

Table 4: Prescription Detail CDA Mapping

Values	XPath	Translation in CDA	VS
Units per Intake value	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/doseQuantity/low@value entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/doseQuantity/high@value	NA	
Units per intake unit	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/doseQuantity/low@unit entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/doseQuantity/high@unit	NA	
Frequency of intake	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/effectiveTime[2]	NA	
Number of packages	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/entryRelationship[@typeCode='COMP']/supply[@moodCode='RQO']/quantity/@value	NA	
Substitution code	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/entryRelationship[@typeCode='SUBJ'][@inversionInd='true']/observation[@classCode='OBS']/[code/@code='SUBST' and code/@codeSystem='2.16.840.1.113883.5.6']/value/@code	NA	

Requirements:

REQ-27 If the reference for the active ingredient code is missing then the cell **MUST** be left empty

Technical Specifications:

TS-24 (REQ-27) If the Active Ingredient is not present, the clinical document field **SHOULD** be empty and a textual box **SHOULD** exhibit the message: "Medications Summary not Present".

Number of units per Intake

This information is expressed as a Physical Quantity range. Hereafter is specified how it is expected to be shown in different use cases (Table 5):

Table 5: Intake Units Display

Low	Low Unit	High	High Unit	Display
50	mg	50	mg	50 [mg]
50	1	50	1	50 unit(s)
50	mg	(no information)	mg	50[mg] -
(no information)		60	mg	- 60 [mg]
50	mg	60	mg	50 [mg] – 60 [mg]
50	mg	Missing		50 [mg] -
Missing		Missing		-

Requirements:

REQ-28 The number of units per intake *SHOULD* be universally understood and *SHOULD* enable translation and conversion.

Technical Specifications:

TS-25 (REQ-28) The Number of Units per intake *SHOULD* be informed using the IDMP code for that attribute and *MUST* be present in the SPOR databases.

Frequency of Intake

As described in the specification this information is provided through the second effectiveTime attribute of the substanceAdministration class. (entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/effectiveTime[2]).

This element may be given a value (valorised) using several time related data types:

- **TS** (effectiveTime, e.g. specific point of time – date)
- **IVL_TS** (dosage period, e.g. From initial date to final date)
- **PIVL_TS** (frequency of intake, e.g. One pill in each 8 hours)
- **EIVL_TS** (event-based time interval, e.g. with meals, between meals, before breakfast, before sleep)
- **SXPR_TS** (Parenthetic Set of Time Expressions –. This type is designed for cases when the frequency varies over time).

The descriptions above do not cover all the conceivable attribute combinations for time-related data types provided by the standard; rather, it attempts to represent the most prevalent examples encountered in exchanged CDAs. In addition, this information can also be provided in an unstructured format.

Requirements:

REQ-29 The Frequency of units per intake **SHOULD** be universally understandable and **SHOULD** enable translation and conversion.

Technical Specifications:

TS-26 (REQ-29) The Frequency units per intake **SHOULD** be informed using the IDMP code for that attribute and **MUST** be present in the SPOR databases.

3.2.1.4. Dispensation Details

For Dispensation Display Block (Figure 6: Dispensation Details Block, Table 6: Dispensation CDA Mapping) should inform the real medicine dispensed, if a substitution was made, and information about the package.

Dispensation details

Substitute * Mark the checkbox if brand name (when allowed) has been substituted or package size has been changed

Dispensed Product

Dispensed Package size milliliter

Dispensed Number of packages

* If substitution of brand name is marked as not allowed, pharmacists may still consider dispensing the national equivalent even though the brand name might be slightly different.
This is a known situation: the same pharmaceutical company is marketing the same medicinal product in different countries with slightly different names due to marketing reasons.
If the pharmacist is certain that this is the case, the systems allows the input of the new brand name.

Dispense

Figure 6: Dispensation Details Block

Table 6: Dispensation CDA Mapping

Values	XPath	Translation in CDA	VS
Dispensed Product	-	NA	
Dispensed Package Size	-	NA	
Dispensed Number of packages	-	NA	
Substitute	-	NA	

Requirements:

REQ-30 *The clinical document MUST inform whether a substitution was made.*

REQ-31 *If substitution was made, the Actual Dispense Medicinal Product information in the clinical document MUST be provided to unequivocally identify the actual dispensed product.*

Technical Specifications:

TS-27 (REQ-30) *The field 'isSubstitution' SHOULD be informed if 'true' or 'false' to inform that a Substitution was made or not.*

TS-28 (REQ-31) *If a substitution was made, the Actual Dispensed Medicinal Product information MUST be provided unequivocally in the Clinical Document.*

3.2.2 Patient Summary

Patient Summary details related to medicinal product information are similar as for the ePrescription, so the requirements and technical specifications outlined above can be considered for both services.

3.2.3 CDA Display tool and IDMP attributes mapping

In order to enrich the current eP/eD & PS services, the proposed IDMP data should be mapped to the CDA display tool. This mapping analysis was done on *D5.4 – Semantic Specifications*¹².

All the work done in the WP5 deliverables was planned to ensure internal alignment and cohesion of all information released in those documents. For further details on CDA and IDMP data mapping, please consult the D5.4.

4 Requirements and Technical Specifications

This section intends to present in a strict way all the specifications and requirements analysed and discussed through the document taking into consideration some parameters to classify it (Table 7, and Table 7) and provide valuable information on the implementation phases on the project.

The tables on sections 4.1 and 4.2 were analysed according to the following criteria:

- **Identification:** Each requirement and technical specification should be uniquely identified (i.e., number and description).
- **Priority:** The stakeholder should identify the priority of each requirement. This may be established through a consensus process among potential stakeholders. The defined criteria used for identifying the priority of each requirement / technical specification was defined as: . I
 - High: predicted for wave 6 of eHDSI;
 - Medium: predicted for wave 7 of eHDSI;
 - Low: others cases with lower priority.
- **Criticality:** The analyst, working with the stakeholder, should define the criticality of each requirement. Some requirements could have a low priority from the user's perspective, but

¹² D5.4 was not yet publicly accessible at the time of this deliverable submission. All WP5 deliverables will be made available on the following website: <https://unicom-project.eu/public-deliverables/>

nevertheless be essential for the success of the system.

- **Feasibility:** The stakeholder and analyst working together should identify the feasibility of including each particular requirement in the system and classify each requirement by types of feasibility appropriate to the system domain.
- **Risk:** Risk analysis techniques can be used to determine a grading for system requirements, considering their consequences or degree of risk avoidance. In this case, the risk was classified as High, Moderated or Low according to the analysis and the impact for each technical specification.
- **Source:** Each requirement should be further classified by a label that indicates the originator. There may be multiple sources that can all be considered creators of the requirement. It is useful to identify the creator(s) of each requirement so that if requirements are unclear, conflict, or need to be modified or deleted, it will be possible to identify the individual(s) or organisation(s) to be consulted. In this case, the main sources analysed were eHDSI, National Competent Authorities (national medicinal product databases), SPOR databases and IDMP sources.

4.1 Summary of Requirements

All the requirements described in this document are listed in this section (Table 7: Summary of Requirements), along with an analysis in terms of their priority and source considering the developments predicted in WP6 of UNICOM, as well as their alignment with eHDSI timeline.

The requirements from REQ-01 to REQ-20 comes from the *D5.1 – Business requirements for the adoption of IDMP in eHealth Services*¹³. The requirements starting at REQ-21 were developed in this work.

As mentioned, this analysis is intended to support WP6 in the development of solutions for the implementation of IDMP on eHDSI and Member States.

Table 7: Summary of Requirements

ID	Requirement description	Priority	Source
REQ-01	A clinical document (i.e. a prescription, dispense, patient summary) SHALL follow the legal requirements in country A	Low	NCA / eHDSI
REQ-02	The clinical document SHALL contain relevant information for internal processing	High	NCA / eHDSI
REQ-03	The clinical document SHOULD contain relevant information for cross-border processing	High	NCA / eHDSI
REQ-04	The prescription / clinical document SHOULD be in a format that can be exposed in another IDMP-enabled country	High	NCA / eHDSI
REQ-05	There SHALL be a way to expose the documents normally used in one country for use in other countries	Low	NCA / eHDSI
REQ-06	Product groups / classification SHOULD be identifiable in another country	High	NCA / eHDSI / IDMP

¹³ For more information, please visit: https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D5.1_Business-Requirements-Specifications_Final_20210226.pdf.

ID	Requirement description	Priority	Source
REQ-07	Products from one country SHALL be visible in another country, following access control rules	Low	NCA / eHDSI
REQ-08	Product Classifications of products from one country SHALL be visible in another country	High	NCA / eHDSI
REQ-09	Products specified in one country SHALL be identifiable in another country	High	NCA / eHDSI
REQ-10	There must be a standardised technical format and infrastructure to exchange the information	High	NCA / eHDSI
REQ-11	The attributes used to identify the product shall be commonly identified to be understood across countries	High	NCA / SPOR / eHDSI
REQ-12	It SHALL be possible to translate products identifiers and / or attributes from one country to the other	High	eHDSI
REQ-13	There SHALL be common product identifiers when possible	High	NCA / SPOR / eHDSI
REQ-14	The attributes for Products SHALL follow a common language	High	NCA / SPOR / SDOs / eHDSI
REQ-15	Products groupings SHOULD be expressed intentionally (group is defined by listing the criteria for inclusion in the group) or extensionally the group is defined by listing all the products in the group) – using a common vocabulary when possible	High	
REQ-16	Substitution rules SHOULD be expressed intentionally using a common vocabulary when possible	High	
REQ-17	A minimum set of IDMP attributes and identifiers SHALL be synchronised for all products across all member states	Medium	NCA / eHDSI / SPOR
REQ-18	For this synchronization and governance of attributes, there SHOULD be a common standard to exchange detailed product master data	High	NCA / SPOR / eHDSI / SDOs
REQ-19	The exchange of IDMP attributes SHALL be appended to the current descriptions of the products on a national level	High	NCA / eHDSI
REQ-20	The designed solution should be ready to accommodate a growth in complexity of the products or of the workflow, instead of being limited to the use case originally planned.	Low	NCA / eHDSI
REQ-21	The clinical document MUST support the use of IDMP codes in the medicinal product attributes. The system SHALL specify what is each IDMP code.	Low	NCA / eHDSI

ID	Requirement description	Priority	Source
REQ-22	The Active Substance Code MUST be universally understood and enable translation and conversion.	High	NCA / eHDSI
REQ-23	The Strength Unit SHOULD be universally understood enable translation and conversion.	High	NCA / eHDSI
REQ-24	The Package Size Unit SHOULD be universally understood enable translation and conversion.	High	NCA / eHDSI
REQ-25	The Dose form SHOULD be universally understood and enable translation and conversion.	High	NCA / eHDSI
REQ-26	A code for Route of Administration SHOULD be universally understood and enable translation and conversion.	High	NCA / eHDSI
REQ-27	If the reference for the active ingredient code is missing, then the cell MUST be left empty	Low	
REQ-28	The number of units per intake SHOULD be universally understood and SHOULD enable translation and conversion.	High	NCA / eHDSI
REQ-29	The Frequency of units per intake SHOULD be universally understandable and SHOULD enable translation and conversion.	High	NCA / eHDSI
REQ-30	The clinical document MUST inform whether a substitution was made.	Low	NCA / eHDSI
REQ-31	If substitution was made, the Actual Dispense Medicinal Product information in the clinical document MUST be provided to unequivocally identify the actual dispensed product.	Medium	NCA / eHDSI

4.2 Summary of Technical Specifications

In this section, all Technical Specifications are listed in Table 8: Summary of Technical Specifications, which were analysed with regards to their relevance, priority, criticality and risk, using the criteria described above.

This analysis is intended to support WP6 in the development of solutions for the implementation of IDMP on eHDSI and Member States.

Table 8: Summary of Technical Specifications

ID	Requirement description	Priority	Criticality	Feasibility	Risk	Source
TS-01	(ACT-01) Support for additional document types SHOULD be feasible with no or minimal effort. CDA is currently the chosen eHDSI format for usage and transport of eP, eD and PS.	Low	None	Out of UNICOM's scope	High Supporting unspecified document types might introduce unneeded complexity, as it can be done based only on assumptions.	eHDSI
TS-02	(REQ-02) Information currently present in the eHDSI exchange SHALL not be changed in any way. However, additional IDMP and non-IDMP attributes COULD be added.	High	Critical	Feasible IDMP enhancement SHALL come after document creation and before pivoting, so it does not affect document creation nor created content, it adds additional content	Moderate Location of business logic, its deployment and governance are not yet clear.	eHDSI
TS-03	(REQ-03) There SHALL be additional validation(s) that document contains enough information for IDMP mapping / enhancement.	High	Critical	Feasible Existing validation tools will be enhanced or component responsible for IDMP will perform validation	Low	IDMP
TS-04	(REQ-04) IDMP information SHALL enhance existing document by following existing HIT standard	High	Critical	Feasible Enhancement is implemented by additional CDA entries or entry attributes	Low	IDMP

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ID	Requirement description	Priority	Criticality	Feasibility	Risk	Source
TS-05	(REQ-06) IDMP information SHALL be added to document(s) before or during the pivoting in the NCPeH.	High	Critical	Feasible Exchange document is machine readable, so it is possible to "open" it and add IDMP information	Moderate Location of business logic, its deployment and governance are not yet clear. High Signed documents cannot be enhanced with the IDMP without destroying the signature, thus destroying the document authenticity	IDMP
TS-06	(REQ-06) Central IDMP registry SHALL be used or local IDMP registries SHALL be in-sync with.	High	Critical	Feasible	Moderate Central IDMP registry will be replaced by EMA's SPOR services in the future and there is no clear strategy describing possible federation and / or synchronization	IDMP
TS-07	(REQ-09) Pivoted and translated document SHALL contain IDMP information to enable processing by the dispenser using local or central IDMP registry	High	Critical	Feasible	Low	IDMP
TS-08	(REQ-11) Pivoted and translated document SHALL contain IDMP information.	High	Critical	Feasible	Low	IDMP
TS-09	(REQ-12) IDMP registry, either local or central, SHALL support local mapping and translation.	High	Critical	Feasible	Moderate There is not enough information to design the solution suitable out-of-the-box for all Member States, which means that the solution will be implemented using the lowest common denominator	IDMP

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ID	Requirement description	Priority	Criticality	Feasibility	Risk	Source
TS-10	(ACT-06.2) The medication SHALL be found, in order of preference, The order should be: ➤ IDMP identifiers and attributes ➤ grouping and classification ➤ prescription attributes	High	Critical	Feasible	High There are no clear rules (yet) how IDMP grouping and substitution should work	?
TS-11	(ACT-06.2/REQ-16) The result of querying SHALL contain an exact match or a substitution	High	Critical	Feasible	High There are no clear rules (yet) how IDMP grouping and substitution should work	?
TS-12	(REQ-15, REQ-16) IDMP registry SHALL support grouping and collect and provide grouping criteria to be used during querying as well as description of grouping decision.	High	Critical	Feasible	High There are no clear rules (yet) how IDMP grouping and substitution should work	?
TS-13	(ACT-07) The dispensation flow SHALL be the same as prescription flow, but in the opposite direction.	High	Critical	Feasible Enhancement is implemented by additional CDA entries or entry attributes	Low	?
TS-14	(ACT-09) Local IDMP registry with maintained mappings to local medication database(s) SHALL be utilised.	High	Critical	Feasible	Moderate There is not enough information about current Member States local registries to design a solution suitable out-of-the-box for all Member States, which means that the solution will be implemented using the lowest common denominator	IDMP
TS-15	(REQ-17) IDMP registry SHALL be either centrally managed and either exposed to or shared with local	Medium	Medium	Feasible	Low	IDMP

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ID	Requirement description	Priority	Criticality	Feasibility	Risk	Source
	instances, or there SHALL be mechanism for federated government					
TS-16	(REQ-18) IDMP registry SHALL be exposed using common HIT standard for either local-to-central or peer-to-peer sync	High	Critical	Feasible	Moderate There is only FHIR IG tackling IDMP interoperability through resources, but it is still in the making	IDMP
TS-17	(REQ-19) Local medicinal product registry SHALL be enhanced with IDMP, or there SHALL be mapping mechanism between local MP registry and IDMP registry.	High	Critical	Feasible	Moderate There is not enough information about current Member States local registries to design a solution suitable out-of-the-box for all Member States, which means that the solution will be implemented using the lowest common denominator	IDMP
TS-18	(REQ-21) A system code exclusive for IDMP SHOULD exist to relate correctly with the active ingredient and signalise that the CDA document is IDMP compliant.	Low	Critical	Feasible Requirement is actually saying that when code is used, the IDMP system shall be used as well	NA	
TS-19	(REQ-22) A code for Active Substance MUST exist for IDMP to correctly identify and signalise that the substance is correctly identified and MUST be available in the SPOR databases	High	Critical	Feasible	High Currently available SPOR databases are for referentials and organisations. Substances and Products are not available (https://spor.ema.europa.eu)	
TS-20	(REQ-23) A code for Strength Unit SHOULD exist and SHOULD be available in the SPOR databases to standardise units and measures.	High	Critical	Feasible	High Currently available SPOR databases are for referentials and organisations. Substances and	

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ID	Requirement description	Priority	Criticality	Feasibility	Risk	Source
					Products are not available (https://spor.ema.europa.eu)	
TS-21	(REQ-24) A code for Package Size Unit SHOULD exist and SHOULD be available in the SPOR databases to standardise units and measures.	High	Critical	Feasible	High Currently available SPOR databases are for referentials and organisations. Substances and Products are not available (https://spor.ema.europa.eu)	
TS-22	(REQ-25) A code for Dose form SHOULD exist and SHOULD be available in the SPOR databases to standardise units and measures.	High	Critical	Feasible	High Currently available SPOR databases are for referentials and organisations. Substances and Products are not available (https://spor.ema.europa.eu)	
TS-23	(REQ-26) A code for Route of Administration SHOULD exist and SHOULD be available in the SPOR databases to standardise units and measures.	High	Critical	Feasible	High Currently available SPOR databases are for referentials and organisations. Substances and Products are not available (https://spor.ema.europa.eu)	
TS-24	(REQ-27) If the Active Ingredient is not present, the clinical document field SHOULD be empty and a textual box SHOULD exhibit the message: "Medications Summary not Present".	Low	None	Out of UNICOM's scope	n/a	
TS-25	(REQ-28) The Number of Units per intake SHOULD be informed using the IDMP code for that attribute and MUST be present in the SPOR databases.	High	Critical	Feasible	High Currently available SPOR databases are for referentials and organisations. Substances and Products are not available (https://spor.ema.europa.eu)	

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ID	Requirement description	Priority	Criticality	Feasibility	Risk	Source
TS-26	(REQ-29) The Frequency units per intake SHOULD be informed using the IDMP code for that attribute and MUST be present in the SPOR databases.	High	Critical	Feasible	High Currently available SPOR databases are for referentials and organisations. Substances and Products are not available (https://spor.ema.europa.eu)	
TS-27	(REQ-30) The field 'isSubstitution' SHOULD be informed if 'true' or 'false' to inform that a Substitution was made or not.	Low	None	Out of UNICOM's scope	n/a	
TS-28	(REQ-31) If a substitution was made, the Actual Dispensed Medicinal Product information MUST be provided unequivocally in the Clinical Document.	Medium	Medium	Feasible	Moderate Central IDMP registry will be replaced by EMA's SPOR services in the future and there is no clear strategy describing possible federation and/or synchronization.	

5 Suggested changes to be proposed to eHDSI

Based on the information analysed in this document, it is possible to suggest some improvements to the current eHDSI systems in order to enhance the eP/eD & PS services and enable IDMP adoption. Table 9 shows all required changes related with each eHDSI business requirement.

Table 9: Proposed eHDSI changes

eHDSI Req. number	eHDSI eP/eD & PS Requirement	Proposed Changes
05.01	Create the eHDSI Patient Summary content	Enhance the document to add IDMP codes and IDMP-compliant attributes to Active substance, dose form and units of the dispensed medicine.
05.02	Transcode, translate and exchange cross-border the Patient Summary	Enhance the document to add IDMP codes to Active substance, dose form and units of the dispensed medicine.
06	Make ePrescription available to HP	Already in place no change is needed.
06.01	Create the eHDSI ePrescription content	Already in place no change is needed.
06.02	Transcode, translate and exchange cross-border the ePrescription	Enhance the document to add IDMP codes to Active substance, dose form and units of the dispensed medicine.
07	Handle Dispensation of medicine and substitution	Inform de dispensed medicine in IDMP code, inform in the code is Substitution as true
07.01	Create the eHDSI eDispensation content	Already in place no change is needed.
07.02	Transcode, translate and exchange cross-border the eDispensation	Enhance the document to add IDMP codes to Active substance, dose form and units of the dispensed medicine.
09	Ensure High quality information (structured, equivalent, understandable) is exchanged between countries	Enhance the document to add IDMP codes to Active substance, dose form and units of the dispensed medicine.