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Deliverable abstract

The Deliverable 5.1 (D5.1) presents an analysis about the CEF eHDSI eP/eD and PS Use Cases business requirements that were reviewed and updated to reflect current practices in the industry. To achieve this goal, a flow analysis was performed to provide an overview of the key aspects of the eP/eD and PS activities and to demonstrate how business value flows differ according to the different stakeholder perspectives. These maps were analysed to identify and improve the flow of information by identifying the necessary requirements to achieve a minimum dataset. The flow analysis was used as a platform to discuss, analyse, and identify the current challenges and business requirements that can impact the ISO IDMP implementation.

After analysing the business requirements, we proposed some initial recommendations in order to ensure the development of the project and facilitate the process of adoption ISO IDMP on the eHealth services.

Key words: ISO IDMP; Business Requirements; eHealth, ePrescription, Patient Summary, UNICOM

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TABLE OF CONTENTS

Deliverable abstract.....	3
List of abbreviations	7
Concepts and definitions	9
Executive summary	14
1 Introduction to the document.....	15
1.1 Background.....	17
1.2 Scope.....	18
2 UNICOM Vision to improve the CEF eHDSI Services	19
3 The need – standardization of the identification of Medicinal Products in EU	20
4 The opportunity – ISO IDMP	22
5 Legal and Policy Context	24
6 Use Cases	27
6.1 Analysis Methodology	27
6.2 ePrescription	29
6.3 Patient Summary.....	35
7 Business requirements Specifications for IDMP adoption in eHealth Services	39
7.1 The Business Requirements - approach.....	39
7.2 eHDSI Business requirements and UNICOM impact.....	40
7.3 Common Requirements Analysis	43
7.3.1 Dependencies / access streams.....	50
7.3.2 Summary of requirements:	52
7.3.3 Business analysis impact	54
7.3.4 Data Requirements	54
7.3.4.1. IDMP attributes in current cross-border eHealth services	54
7.4 Comparison of national eHealth Services (eP/eD & PS) and their respective legal base in EU countries.....	62
7.4.1 ePrescription / eDispensation.....	62
7.4.2 Patient Summary.....	70
7.4.3 Legal framework.....	74
8 Patient empowerment through UNICOM.....	76
9 Recommendations to adoption of ISO IDMP in EU	78
9.1 Organisational/Service	78
9.2 Functional	78
9.3 Semantic.....	78
9.4 Technical.....	78

Annexes	79
Annex 1 – Non-exhaustive list of elements to be included in medical prescriptions (Directive 2012/52/EU)	79
Annex 2 – eHDSI Requirements Catalogue	80
Annex 3 – Questionnaire D5.1	82
ePrescription services questions	83
Patient summary questions	90
Legal framework questions	96

LIST OF FIGURES

Figure 1: ISO IDMP suite of standards	16
Figure 2: eHealth actors	28
Figure 3: Value Stream Map of ePrescription between countries (Ireland and Portugal).....	30
Figure 4: Value Stream Map of Patient Summary. Ireland and Portugal are examples of countries participating in the exchange.	36
Figure 5: Generic process description for common requirements	43
Figure 6: eP solution among 17 European countries.	63
Figure 7: Use the eP a) on the Care settings and b) by the health professionals among the responders.....	63
Figure 8: Critical pieces of prescribing information required to dispense a prescription or provide substitution safely.....	65
Figure 9: Type of format for each product information attribute (X axis).....	66
Figure 10: Availability of the history medication regarding the actor.....	68
Figure 11: Information currently recorded about the dispensed medicines among the responder countries.	70
Figure 12: Patient summary solution among 14 European countries.	70
Figure 13. Use the PS a) on the Care settings and b) by the health professionals among the responders.....	71
Figure 14: Percentage of positive answers obtained from the questionnaire regarding the eP and PS legal framework.	75

LIST OF TABLES

Table 1: Main actions list on cross-border ePrescription.....	31
Table 2: Main actions list on cross-border Patient Summary.	35
Table 3: eHDSI Business requirements and UNICOM impact	40
Table 4: The summary of requirements	52
Table 5: Attributes for cross-border (from eHDSI), possible changes and impact of IDMP adoption.....	55
Table 6: The authentication mechanisms for eP services.	68
Table 7: Medicinal product information accessible using the PS service.	72
Table 8: The identification / authentication mechanisms for physicians and patients to access the PS services on national and cross-border levels.	73
Table 9: CEF eHDSI requirement catalogue.....	80

List of abbreviations

Abbreviation	Complete form
ADE	Adverse Drug Event
API	Active Pharmaceutical Ingredients
ATC	Anatomical Therapeutic Chemical Code
CEF	Connecting Europe Facility
CEN	European Committee for Standardization
eD	eDispensation
DSS	Decision Support System
EPF	European Patients' Forum
eHDSI	Health Digital Service Infrastructure
EHR	Electronic Health Record
EMA	European Medicines Agency
eP	ePrescription
epSOS	Smart Open Services for European Patients
EU	European Union
FDA	USA Federal Drug Agency
GDPR	General Data Protection Regulation
GP	General Practitioner
GS1	Global Standards One
HCPO	Healthcare Provider Organisation
HL7	Health Level Seven
HP	Health Professional
ICD-10	International Statistical Classification of Diseases and Related Health Problems, 10th revision
IDMP	Identification of Medicinal Products
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
LTF	Legal Task Force
MPD	Medicinal Product Dictionary
MS	Member State
MVC	Master Value Catalogue
NCA	National Competent Authority (for human medicines)
NCP	National Contact Point
NCPeH	National Contact Point eHealth
NIA	National Identification Authority
Ophelia	OPTimising HEalth LIterAcy
OTC	Over the Counter
PhP	Pharmaceutical Product
PhPID	Pharmaceutical Product identifier

PS	Patient Summary
SDO	Standards Developing Organisation
SPOR	Substance, Product, Organisation and Referential
SubID	Identification of the (active) substance
TBD	To be done
UNICOM	Up-scaling the global univocal identification of medicines
WP	Work Package
WHO	World Health Organisation

Concepts and definitions

This chapter intends to present the definition of the terms and the main concepts that are used on this document in order to ensure the correct understanding of the text. The source of all definitions used on the following table come from CEF eHDSI glossary³.

Concept	Definition
Active substance/ Active ingredient/ Active pharmaceutical ingredient	Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.
Actors	<ul style="list-style-type: none"> ▶ Actors may represent roles played by human users, external hardware, or other subjects. ▶ Actors do not necessarily represent specific physical entities but merely particular facets (i.e., "roles") of some entities that are relevant to the specification of its associated use cases. ▶ A single physical instance may play the role of several different actors and a given actor may be played by multiple different instances. ▶ Types of actors include: Users, database systems, clients and servers, cloud platforms, devices
Adverse Drug Event	A response to a medicinal product which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.
Allergen	A usually harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction. Example of allergens: pollen, dust mites, animal dander, mould, medications, insect venoms and various foods.
Attribute	A property or a characteristic of an entity. eHDSI use: Identity Management Specification
Available prescriptions	The prescriptions that can be retrieved for the patient in the act of dispensing (at that specific or particular moment). This implicitly means that it is a time valid prescription.
Brand name or Name of the medicinal product	The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorization holder.
Business actor	Business Actors perform business processes or functions in an organisation. Business Actors are humans working in departments, and business units. Business Actors may be individuals or groups such as healthcare professionals.
Connecting Europe Facility eHealth Digital Service Infrastructure	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. EU financial mechanism (based on call for proposals) that was launched by November 2015 and used by MS to support CBeHIS provision (preparation, deployment and operation of NCPeH - meaning generic services in CEF).
Clinical Information System	Solutions of Primary Care Centres, General Practitioner's for documentation and Prescription.
Coding System	A scheme for representing concepts using (usually) short concept identifiers to denote the concepts that are members of the system; defines a set of unique concept codes. Examples of coding systems are ICD-9, LOINC and SNOMED.
Concept	Unit of knowledge constructed through combining characteristics.

³ <https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Glossary#eHDSIGlossary-C>

Concept	Definition
Connecting Europe Facility	A key EU funding instrument supporting the development of high performing, sustainable and efficiently interconnected trans-European networks in the fields of transport, energy and digital services (telecom).
Dispensed Medicine	The medicine given to a patient as indicated in the prescription ordered by a prescriber.
Dispenser	Healthcare professional who provides the order of a prescription. The professional person must be authorized to do so.
Pharmaceutical Dose Form	The physical manifestation (“entity”) that contains the active and/or inactive ingredients that deliver a dose of the medicinal product. The key defining characteristics of the Dose Form can be the state of matter, delivery method, release characteristics and the administration site or route for which the product is formulated. A term for the physical characteristics of a drug product - e.g., tablet, capsule or solution - which contains the drug substance and almost invariably other ingredients, such as excipient, fillers, flavours, preservatives or emulsifiers. The form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorization holder/manufacturer/distributor (e.g. tablets, syrup).
e-Dispensing/ eDispensation	The act of electronically retrieving a prescription and giving the medicine to the patient. Once the medicine has been dispensed, a report on the items dispensed is sent to the prescribing Member State in a structured format.
Electronic Health Record	<p>A comprehensive, structured set of clinical, demographic, environmental and social data information in electronic form, documenting the Health Care given to a single individual.</p> <p>Comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes.</p> <p>A comprehensive, structured set of clinical, demographic, environmental and social data information in electronic form, documenting the Health Care given to a single individual.</p>
Electronic Health Record System	System for recording, retrieving and manipulating information in electronic health records.
European Medicines Agency	A decentralised agency of the European Union (EU). It began operating in 1995. The Agency is responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.
ePrescription	<p>A medicinal prescription issued and transmitted electronically. The concept of the ePrescription service is understood as the ordering of a prescription in software, the electronic transmission of that prescription from the Prescription provider to a Dispense provider, the electronic dispensing of the medicine and the electronic transmission of the dispensed medicine information from the dispenser provider to the prescription provider.</p> <p>The ePrescription service is made up of electronic prescribing and electronic dispensing:</p> <p>ePrescribing is defined as prescribing of medicines in software by a health care professional legally authorized to do so, for dispensing once it has been electronically transmitted, at the pharmacy.</p> <p>eDispensing is defined as the act of electronically retrieving a prescription and giving out the medicine to the patient as indicated in the corresponding ePrescription. Once the medicine is dispensed, the dispenser shall report via software the information about the dispensed medicine(s).</p>
General Practitioner	A physician who provides primary care. A general practitioner treats acute and chronic illnesses and provides preventive care and health education for all ages and both sexes.
Generic medicinal product	Shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product had been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives or an active substance shall be considered to be the same active substance, unless they differ significantly in

Concept	Definition
	properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy or the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriated detailed guidelines.
Guideline	A suggested way of compliance when doing something. It is visible to those using or supporting the use of a particular service, but there are no sanctions if it is not followed.
Healthcare	Health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.
Health Professional	A doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment; In some documents, the acronym HCP is used. Doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC . This means that a Health Care Professional is a person who delivers health care or care products professionally to any individual in need of health care services, in order to prevent, relieve or treat a medical problem. A Health Care Professional must be related to at least one HCPO.
Hospital Information System	Implemented Solutions in Hospitals for documentation, accounting, etc. HIS delivers PS, eP for eHealth DSI.
Identifier	Non-empty set of attribute values that uniquely characterize an entity in a specific domain of applicability.
Medical (Health) Record	A systematic documentation of a patient's medical history and care. The term 'Medical record' is used both for the physical folder for each individual patient and for the body of information which comprises the total of each patient's health history. Medical records are highly personal documents and there are many ethical and legal issues surrounding them such as the degree of third-party access and appropriate storage and disposal. Although medical records are traditionally compiled and stored by healthcare providers (HP) personal health records maintained by individual patients have become more popular in recent years.
Medication Summary	All prescribed medicine which period of time indicated for the treatment has not yet expired, whether they have been dispensed or not. It is a synonymous of current medication. It contains the following information of each one: active ingredient, strength, posology (number of units per intake, frequency of intakes (per day/month or week) and duration of treatment) and onset date of treatment. At least, a list of current prescriptions with the following information of each one: brand name, active ingredient, pharmaceutical dose form, strength, package size, posology, onset date of treatment and end date of treatment.
Medicinal Prescription	Any medicinal dispensation issued by a professional person qualified to do so.
Medicinal Product	Any substance or combination of substances that may be administered to human beings (or animals) for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions. NOTE 1: A medicinal product may contain one or more manufactured items and one or more pharmaceutical products. NOTE 2: In certain jurisdictions a medicinal product may also be defined as any substance or combination of substances

Concept	Definition
	which may be used to make a medical diagnosis. NOTE 3: Adapted from ENV 13607 and ENV 12610.
Medicinal Product Dictionary	A systematic and accurate listing, description and identification of medicinal products designed to support the use (prescription, dispensing and administration of medications) in clinical care or other purposes (adapted from ISO 19256)
Medicinal Product Package/ Package Type	Delivery unit of a medicinal product in an outer container.
Medicine	(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human or veterinary beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. For UNICOM scope, only medicinal products for human use will be considered.
Master Value Sets Catalogue	A collection of terms used within certain parts of the eHDSI pivot documents (either parts describing the patient demographics or the clinical problems for example) based on standardised code system such as ICD-10, SNOMED CT, ATC classification, EDQM Standard Terms, and UCUM.
Original prescription	The minimum data set defined but as prescribed in the origin country (e.g. the brand name of country A that it will probably be different than the one dispensed in country B).
Patient Summary	An identifiable “data set of essential and understandable health information” that is made available “at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care”; it can also be defined at a high level as: “the minimum set of information need to assure Health Care Coordination and the continuity of care”.
Pharmaceutical Product	Qualitative and quantitative composition of a medicinal product in the dose form approved for administration in line with the regulated product information
Posology	Instruction on number of units per intake, frequency of intakes (per day/month or week) and duration of treatment.
Prescriber	Health Care Professional who issues a prescription.
Prescription	A prescription for a medicinal product or a medical device issued by a member of a regulated health profession within the meaning of Article 3 (1) (a) of Directive 2005/36/EC, who is legally entitled to do so in the Member State in which the prescription is issued.
Route of administration	Indicates the part of the body through or into which, or the way in which, the medicinal product is intended to be introduced. In some cases, a medicinal product can be intended for more than one route and/or method of administration.
Substance	Any matter irrespective of origin which may be: human, e.g. human blood and human blood products; animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products; vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts; chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.
System actor	System Actors also known as technical actors include the non-human actors, for instance information system or provides conveying information across borders.
Time valid prescription	It is the time during which the prescription can be dispensed (see Terminology in section 11). E.g. In Andalusia the time validity means that the patient can withdraw the medicine from the pharmacy until the date of the end of treatment while in other countries, like the UK, the patient can withdraw the medicine up to a maximum number of days from the date of issue, e.g. 6 months.

Concept	Definition
Valid prescription	An "official" prescription, i.e., a prescription made fulfilling the legislation and the procedures defined in that country.

Executive summary

The UNICOM project intends to facilitate the overall implementation of the ISO IDMP (Identification of Medicinal Products) standards that provide the basis for the global identification of medicinal products. ISO IDMP is composed by five ISO standards, which together, describe a standard data model for the proper identification and description of medicinal products and related concepts.

Currently the Medicinal/Pharmaceutical products are described in a wide variety of forms and records among the countries. By this, the proposed work intends to support and facilitate the further development of ISO IDMP standards, its adaptation to the various (new) requirements which have or will arise, as well as to promote the successful implementation of ISO IDMP standards across countries, to allow the univocal identification of medicinal products across the European Union and globally. There are many significant predictable benefits to the application of ISO IDMP that will invariably impact many domains, particularly through improved and safe semantic interoperability across language and other aspects related to data and information, such as the regulatory field, the clinical context and pharmacovigilance applications. Also, the ISO IDMP implementation will bring impacts to the commercial/ non-commercial entities regarding their global competitive advantage. Therefore, the application of ISO IDMP is fundamental to contribute to the safe prescription and dispensation of medicines, in all its involving environment.

This WP5 concerns the overall orchestration to adopt ISO IDMP in eHealth Services, at national and cross-border levels, with a focus on cross-border on ePrescription (eP) and Patient Summary (PS) use cases at cross-border level. It will be also driven by the state of IDMP adoption in EU eHealth services, including the significant challenges to be faced, current rates of adoption, public policy status and principal adoption methods.

The CEF eHDSI eP/eD and PS Use Cases were reviewed and updated to reflect current practices in the industry. The first step was to perform a flow analysis (similar to a value stream map) to provide an overview of the key aspects of the eP/eD and PS activities, and to demonstrate how business value flows differ according to the different stakeholder perspectives. These maps were analysed to identify and improve the flow of information by identifying the necessary requirements to achieve a minimum dataset. Some additional data, provided by ISO IDMP, may be offered as an extended dataset to ensure the safe identification and dispensation of medicines to the citizen and to help support high quality cross-border care for emergency or unplanned care events. These requirements define the scope and guidelines development to achieve the following objectives:

- ▶ Support the implementation of the ISO IDMP in interoperable eHealth Services;
- ▶ Define the business and functional requirements for the ISO IDMP adoption;
- ▶ Elaborate a structured functional and business analysis of the impact from the UNICOM project, and validate it in a relevant unplanned care/emergency situation.

The flow analysis was used as a platform to discuss, analyse, and identify the current challenges and business requirements. This work was instrumental in designing a bespoke questionnaire where the current situation of eP and PS in different European countries was gathered. The resulting knowledge will allow a deep analysis and new business requirements may come out of this process.

After analysing the business requirements, we propose some initial recommendations in order to ensure the development of the project and facilitate the process of adoption ISO IDMP on the eHealth services. This is the first version of the deliverable 5.1 that will be updated on the end of the project to include more concrete and direct recommendations according to the results achieved by the development of the UNICOM project.

1 Introduction to the document

The UNICOM project intends to facilitate the overall implementation of the ISO IDMP (Identification of Medicinal Products) standards that provide the basis for the global identification of medicinal products. Its implementation allows for the improvement of the identification of medicinal products on cross-border healthcare, including the ePrescriptions dispensation, Patient Summary consultation, and other clinical documents including medicinal products information.

ISO IDMP is illustrated in Figure 1 and is composed by the following five ISO standards, which together, describe a standard data model for the proper identification and description of medicinal products and related concepts:

1. Identification of medicinal products and packages - ISO 11615⁴

Establishes key definitions and concepts and describes data elements and their structural relationships, which are required for the unique identification and the detailed description of Medicinal Products. A Medicinal Product corresponds to a specific authorised product in the market. Therefore, one medicinal product is associated with one Market Authorisation Holder, who is responsible for its commercialisation. This standard defines the data elements, constraints and relationships associated with a Medicinal Product.

2. Identification of pharmaceutical products - ISO 11616⁵

One of the key concepts of IDMP is the Pharmaceutical Product, which describes the qualitative and quantitative composition of a medicinal product in a given dose form. This concept defined in ISO11616 provides specific information relevant to the identification of a Medicinal Product or group of Medicinal from the specific Market Authorisation Holder. It defines the data elements, structures and relationships that are required for the exchange of regulatory information, in order to identify pharmaceutical products. Each Pharmaceutical Product concept has a Pharmaceutical Product Identifier (PhPID). This standard defines that a Pharmaceutical Product can be defined at 4 levels, each including the following information, and corresponding to a different identifier:

- ▶ **Level 1:** Substance(s) term (ISO 11238)
- ▶ **Level 2:** Substance term(s) + strength + reference strength (ISO 11238, ISO 11240)
- ▶ **Level 3:** Substance term(s) + dosage form (ISO 11238, ISO 11239)
- ▶ **Level 4:** Substance(s) term + strength + reference strength + dosage form (ISO 11238, ISO 11239, ISO 11240))

3. Identification of the (active) substance(s) - ISO 11238⁶

Provides an information model to define and identify substances within medicinal products or substances used for medicinal purposes, including dietary supplements, foods and cosmetics.

4. Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239⁷

Defines standard structures and relationships between the data elements required for the exchange of information, which uniquely and with certainty, identify pharmaceutical dose

⁴ <https://www.iso.org/standard/70150.html>

⁵ <https://www.iso.org/standard/70044.html>

⁶ <https://www.iso.org/obp/ui/#iso:std:iso:11238:ed-2:v1:en>

⁷ <https://www.iso.org/standard/55032.html>

forms, units of presentation, routes of administration and packaging items related to medicinal products. Includes:

- ▶ A mechanism for the association of translations of a single concept into different languages.
- ▶ A mechanism for the versioning of the concepts in order to track their evolution.
- ▶ The rules to allow regional authorities to map existing regional terms to the terms created using ISO 11239:2012 in a harmonized and meaningful way.

5. Units of measurement (UCUM) - ISO 11240⁸

Specifies rules for the usage and coded representation of units of measurement for the purpose of exchanging information about quantitative medicinal product characteristics that require units of measurement (e.g. strength) in the human medicine domain; Also:

- ▶ Establishes requirements for units in order to provide traceability to international metrological standards;
- ▶ Provides rules for the standardized and machine-readable documentation of quantitative composition and strength of medicinal products, specifically in the context of medicinal product identification;
- ▶ Defines the requirements for the representation of units of measurement in coded form;
- ▶ Provides structures and rules for mapping between different unit vocabularies and language translations to support the implementation of ISO 11240:2012, taking into account that existing systems, dictionaries and repositories use a variety of terms and codes for the representation of units.

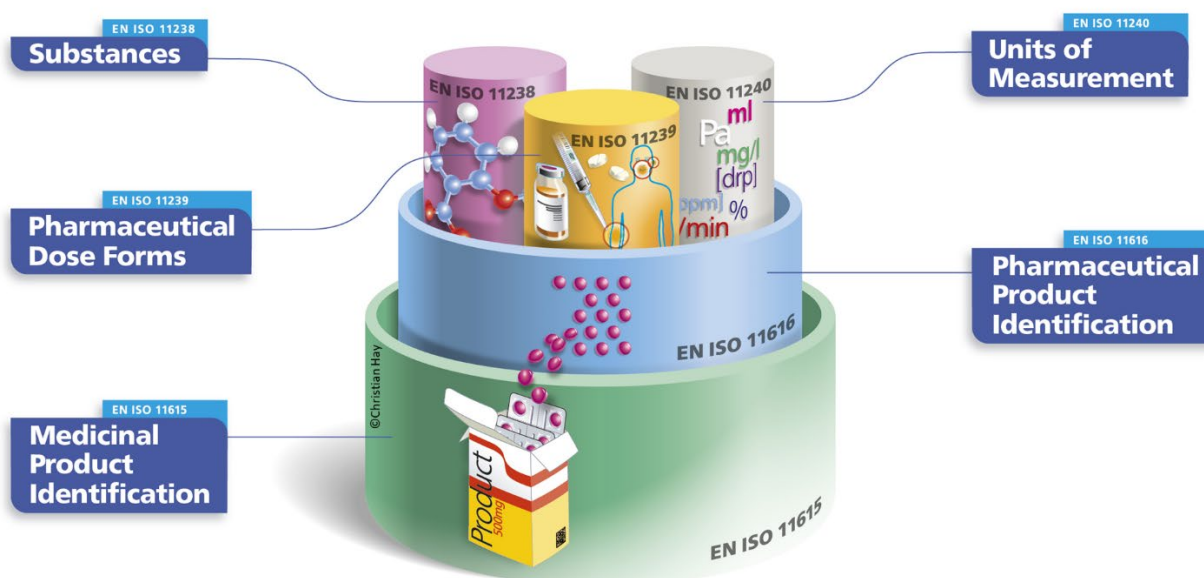


Figure 1: ISO IDMP suite of standards

The fundamental aim of the ISO IDMP set of standards is the safe identification, of medicinal products among the European Countries. It covers many aspects of the medicinal products description, such as: medicinal product name, active pharmaceutical ingredient (API), pharmaceutical product (route of administration, strength), marketing authorisation, clinical particulars, and packaging. The data model defined in IDMP establishes definitions and

⁸ <https://www.iso.org/standard/55033.html>

concepts to describe data elements and their structural relationships of products that are required for the identification of medicinal products. The achievement of a unique standard for medicinal products identification in Europe sets the scene for Member States to use an interoperable identification system, with the same parameters, and will increase the safety of ePrescriptions/eDispensations (eP/eD) in national and cross-border scenarios.

In order to adopt the ISO IDMP in eHealth Services, at national and cross-border levels, it became necessary to elaborate the Business requirements for the adoption of IDMP in eHealth Services that intend to be a useful tool for contextualisation of the project and support the development of the UNICOM assets. This approach is needed in order 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 coordinated way.

This document elicits the Business Requirements for the adoption at national level and the implementation at cross-border level, which can then be used for extensions of the current CEF eHDSI assets. It focuses on the description of the state of IDMP adoption in EU eHealth services, including the significant challenges to be faced, current rates of adoption, public policy status and principal adoption methods will be provided, and will be produced, focusing on the cross-border domain by different levels: service, functional, semantic and technical.

1.1 Background

In the past years, some important projects and initiatives have been developed in order to achieve a uniform identification of medicinal products and, at the same time an interoperable electronic system of prescription and dispensation of medicines, including the national and cross-border contexts.

One of the most important European projects that was the basis for the deployment of the ePrescription/eDispensation and the communication of medication related information (within the Patient Summary) for a citizen while abroad, on a cross-border context of interoperability is epSOS⁹. These project activities contributed to the development of the EC Directive 2011/24 on cross-border Health Services. Medicinal Products are described by adopting structured and coded concepts to allow an unambiguous identification. Currently the eHealth Digital Service Infrastructure (eHDSI) is operating and expanding the cross-border eP/eD and PS services. These services would clearly benefit from fully and unequivocal identification of the medicinal products among the different countries.

Another important project is openMedicine¹⁰. It evaluated the application of IDMP concepts to cross-border care and aimed to reach a wider consensus in order to univocally identify and describe unambiguously a medicine, resulting in the delivery of the appropriate medicinal product to a patient at the retail or community pharmacy level in line with national regulations. This project was aligned with the main regulatory agencies and SDOs (Standard developing Organizations), such as EMA, USA FDA (Federal Drug Agency), WHO, ISO, CEN, GS1, HL7, IHE and others. This cooperation has brought the exchange of expertise between those organizations, and the results of these activities have improved the sharing of knowledge and clarified the path for standardization of the identification of medicinal products.

One of the initiatives is SPOR – a project for data management that addresses four dimensions (Substance, Products, Organization and Referential) for identification of pharmaceutical products, for human and veterinary uses. This project is managed by European Medicines Agency (EMA) the EU Network Data Board, and intends to support the implementation of the

⁹ <https://cordis.europa.eu/project/id/224991>

¹⁰ www.open-medicine.eu

compliant ISO IDMP on the National Competent Agencies (NCAs) by providing a common master data set. SPOR will allow the evolution of the EMA Article 57 Database¹¹ for Pharmacovigilance and of the procedure to create, maintain and consult medicine information.

In order to ensure the continuity and applicability of these initiatives and projects, the UNICOM project intends to use the relevant information produced by the related projects to facilitate the adoption of ISO IDMP in the cross-border context and encourage the adoption in the national context where needed.

1.2 Scope

The Business Requirements for the adoption at national level and at cross-border level of the IDMP, as extensions of the current Connecting Europe Facility eHealth Digital Service Infrastructure (CEF eHDSI) assets, will focus on the cross-border domain at different dimensions: organisational/service, functional, semantic and technical.

The key focus will be put on the ePrescription (eP) and Patient Summary (PS) use cases at cross-border level, acknowledging that other use cases are supported. It will be also driven by the state of IDMP adoption in EU eHealth services, including the significant challenges to be faced, current rates of adoption, public policy status and principal adoption methods.

¹¹ <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/data-medicines-iso-idmp-standards/public-data-article-57-database>

2 UNICOM Vision to improve the CEF eHDSI Services

The focus of the WP5 will be on the improvement of the eHealth services (eP/eD & PS use cases) aligned with the CEF eHDSI current services by adopting ISO IDMP Standards.

Interoperability across national / international digital health services and regulatory systems needs to be achieved to allow reliable information about any specific medicinal product and the related pharmaceutical product(s) to flow wherever it is needed. The information must be accessible, independently of the alphabet or language used by the sending or receiving actors.

By this, the overall vision of the proposed work is **to support and facilitate the further development, adaptation to the various (new) requirements which have or will arise, as well as the successful implementation of ISO IDMP standards and accompanying data models, terminologies, coding systems, value sets etc.** allowing the univocal identification of medicinal products across the European Union and globally.

In this context, the intention of the UNICOM is based on the following ambitions:

- ▶ A cross-border mobility of European patients, through the ePrescription and Patient Summary improvement, in line with the eHealth Network Guidelines, in order to support a safer Dispensation, and enabling the exchange of information related to medicinal products, not limited to Patient Summary consultation and Adverse Drug Event (ADE) reporting, in the country of origin and across borders.
- ▶ Improve patient safety, by enabling countries' drug databases to support ISO IDMP implementation, and allowing trustworthy and simplified exchange of medicinal product information.

3 The need – standardization of the identification of Medicinal Products in EU

This chapter describes why the standardization of the identification of medicines in EU is a global need, namely why it is important to simplify the exchange of information between stakeholders and enhance the interoperability of systems in the European medicines regulatory network and internationally.

Therefore, this point will include how current medicinal products are identified within the EU and the issues experienced by eP systems nationally and cross-border. It also will explain the need for the standardization for the identification of medicinal products to achieve the safest level of eP/eD.

So, the implementation of ISO IDMP using a harmonized approach, to identifying and describing a medicinal product, was critical to ensure a reliable cross-border identification of medicines and to facilitate exchange of medicinal product information across jurisdictions, in support of improved patient safety.

Medicinal/Pharmaceutical products and substances are described in a wide variety of forms and records like patient summaries, medication histories, prescription documents, (electronic) patient and medical records, vaccination documents and others; precise information is indispensable in these contexts too. Due to this variable approach to the identification of medicinal products, the ADE reports could face a serious problem on the correct identification of the medicinal product leading to a potentially incorrect report. For that reason, the ADE reporting needs to be handled in a seamless way, focusing on the active substance primarily, regardless of the medicinal product prescribed and dispensed to the patient at home or abroad.

This ambitious work faces some challenges:

- ▶ Each country has several different concepts of granularity of “Medicinal Product”, and these concepts are often deeply embedded in the legal and operational models of the countries.
- ▶ Even when the concepts match, the rules and expectation for prescription are inconsistent – for example the rules for dispensation (e.g. narcotics and Over The Counter (OTC) classification) vary across the countries.
- ▶ Across the different countries, a medicinal product can have different names, and/or variations in strength or package size;
- ▶ In an emergency, the unavailability of a specific product that requires replacement can be an issue
- ▶ Not every medicinal product is available in each country because there may not be a need or market for that particular medicine in every MS or due to the market launch strategies of marketing authorisation holders,
- ▶ The same medicinal product name can be, sometimes, identifying a different product in another country;
- ▶ Problems when the eDispensations, returned to the country of affiliation of the patient, referring to a medicinal product dispensed that is not available or registered in the patient’s country of origin.

However, standardization of data by itself is not enough to achieve the proposed identification of medicinal products in a standard way. Naturally, because of different policies in each country regarding medicinal products - i.e. medicinal/pharmaceutical products having different names, variation in dosage and package size etc.

In summary:

- ▶ The goal of the ePrescription is to maximise the probability of dispensing the correct medicinal product at national level and cross-border.
- ▶ The ePrescription frequently refers to a PhPID among which the pharmacist shall select the medicine to be dispensed.
- ▶ Univocal identification of a Medicinal Product is a requirement when no substitution is allowed, either by the prescriber or by Country of Treatment laws.
- ▶ The eDispensation shall univocally identify the dispensed Pharmaceutical Product, although it may happen that such medicine is not available in the Country of Affiliation.
- ▶ Pharmacovigilance require the univocal identification of the administered Medicinal Product, to correlate it with the reported ADE.

On the next chapter *the opportunity* will be explored how the UNICOM could support and improve these issues. However, it is important to understand that this project has a limited scope, and along with this document, we will focus only on what the UNICOM can perform.

4 The opportunity – ISO IDMP

In this chapter we intend to present how the UNICOM project can improve the current identification of medicinal products among Europe. Our focus will be on the eHealth Services managed by CEF eHDSI. It is important to highlight that UNICOM cannot solve all associated issues linked with identification of medicinal products. However, it can improve the current medicinal products identification.

The consistent and effective implementation of ISO IDMP is also an ambition of health professionals, national health system organisations and all the stakeholders, by enabling and facilitating the safe identification of medicinal and pharmaceutical products for regulatory compliance, clinical usage and pharmacovigilance improvement, thereby substantially improving patient safety.

There are many significant predictable benefits, impacting many domains, to the application of IDMP, particularly through improved and safe semantic interoperability across language and other aspects related to data and information, such as the regulatory field, the clinical context and pharmacovigilance applications. Also, we cannot ignore that the ISO IDMP implementation will bring impacts to the commercial/ non-commercial entities regarding their global competitive advantage. e. g. some pharmaceutical industries can register the same medicinal products on a country using different units of presentation/dose form, to avoid the substitution/selection for a generic medicinal product.

Considering the implementation of the ISO IDMP on the eHealth Services, it is possible to split it into four main levels (service, functional, semantic and technical) in order to facilitate the comprehension about what the project can bring in each level:

► Organisational/Service

At the organizational level, the implementation of the ISO IDMP will contribute to make MP-related data available, easily identifiable, and accessible at the cross-border level. Therefore, it has the potential to increase the safe communication and exchange of MP-related data in all steps of the medicine life cycle, including clinical trials, marketing authorisation and pharmacovigilance. In addition, it can contribute to reinforce activities concerning the promotion of awareness and information about the benefits of ePrescription services and PS data exchange at cross-border level. Furthermore, it can contribute to help foster the interoperability of technical systems among producers and supplier of ICT, institutions, insures and other relevant stakeholders.

► Functional

At the functional level, the implementation of the ISO IDMP can support the right interpretation of MP-related data, namely in the right identification of the medicinal product, and thus contribute to increase the safety not only in the dispensation process of a medicine, but also in the health care treatment of a patient in a cross-border situation.

► Semantic

It is this level where the implementation of the ISO IDMP can have more impact. On this field it is defined the computational languages and how the different systems can communicate between them without loss of information. To facilitate this communication, it is common to use codification standards where an information can be coded, improving the communication, and avoiding issues when the messaging is being exchanged between systems from different languages.

The identification of medicinal products uses codes, defined both at national and European level, but following different approaches. Market registration is handled differently: this makes it difficult to use these identifiers. Since epSOS, it was adopted the description of medicine

attributes, by using structured datasets and international code systems, however the lack of fully structured and coded information led to the adoption of extensive use of narrative descriptions. These issues led to the difficulty of identifying medicine to be dispensed.

The adoption of the ISO IDMP on the eHealth systems can support the correct identification of the medicinal products through their attributes and ensure a correct dispensation of the medicines.

► Technical

At the technical level, the ISO IDMP, complying with CEF specifications, can contribute to improve the security of MP-related data communication. In addition, the ISO IDMP implementation will indirectly contribute to advance infrastructures linking systems and services, such as interconnection services, data integration services, and data presentation.

Considering the exposed, it is possible to improve the current eHealth services with the adoption of the ISO IDMP. It can ensure a univocal medicinal product identification across the EU, in all European Union languages, regardless of the drug names in national markets.

5 Legal and Policy Context

In this chapter, the Legal and Policy Context that is relevant to the UNICOM project is described.

Healthcare records are becoming increasingly digitized in EU member states; offering an opportunity to provide the electronic exchange of the most up to date and relevant information to support citizens travelling from country A (the patient's country of affiliation) and is seen in another Member State Country B (country of treatment). This level of Interoperability requires a high level of cooperation between different member states and will present many different types of challenges. It requires among the other needs harmonisation of ownership, access rights, privacy, confidentiality and system security to strengthen the trust and confidence between all stakeholders, specifically patients and health professionals.

The adoption of general guidelines for the electronic exchange of supporting data for citizens who are travelling inside Europe is necessary to guarantee the rights of citizens to obtain the healthcare citizen in cross-border settings and in a way that ensures the highest standards of protection of personal data and confidentiality.

It is important to have an analysis on guidance and governance issues, but also the assessment of impacts based on risks, costs benefits analysis to be anticipated for IDMP application domains and stakeholders. Additional burden on personal data protection related to the introduction of IDMP should be considered.

So, in the framework of the UNICOM project, it is important to consider the following regulations:

- ▶ **Commission Recommendation 2008/594/EC¹² of 2nd July 2008 on cross-border interoperability of electronic health record systems**

The Commission Recommendation nr. 2008/594/EC, says that the Electronic Health Record systems have the potential to achieve greater quality and security in health information than the traditional forms of health records. Interoperability of electronic health record systems should make access easier and enhance the quality and safety of patient care throughout the Community by providing patients and health professionals with relevant and up-to-date information while ensuring the highest standards of protection of personal data and confidentiality. Enhancing cross-border cooperation in the domain of eHealth requires cooperation between providers, purchasers, and regulators of healthcare services in different countries. At the same time any measure relating to interoperability need not necessarily lead to the harmonization of laws and regulations of the organization and delivery of healthcare in countries.

- ▶ **Regulation (EU) 2016/679¹³ of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)**

It is important to ensure compliance with regulation (EU) 2016/679 concerning the protection of natural persons with regard to the processing of personal data and on the free movement of such data, e.g. how GDPR applies to the UNICOM systems, as extensions of CEF services, and the additional governance structures that need to be put in place to ensure that GDPR and other national legal requirements are met, and specific data protection and cybersecurity

¹² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008H0594&from=EN>

¹³ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>

challenges as they may arise in the context of the piloting of patient facing applications, how to govern any uses of personal data collected within the pilots, and also - with a view to later scaling them up as commercial products - how to ensure that future patient facing applications and services are fully compliant and that the cross-border operation of eP/eD & PS services does not pose additional risks to privacy.

► **Cross-border directive 2011/24/EU¹⁴ of 9th March 2011 on the application of patients' rights in cross-border healthcare**

The electronic prescription and dispensing of medications can have different use cases on different organizational scales, and each scale presents a different organization of the process. So the Member States in the eHealth Network, created in application of Art. 14 "eHealth" of Dir.2011/24/EU, have adopted some clauses to the general guidelines for the electronic exchange of health data under cross-border directive 2011/24/EU to support exchange of ePrescription and eDispensation data, and Patient Summary, through the electronic exchange of supporting data for citizens who are travelling inside Europe, where a patient from Country A (the patient's country of affiliation) is seen in another Member State Country B (the country of treatment)

This directive aims to guarantee and facilitate patient mobility and the free provision of healthcare services, by allowing the access to safe, high-quality cross-border healthcare and to promote healthcare-related cooperation between member States, while maintaining each State's independent authority to organize and provide healthcare services:

- The interoperability of eHealth solutions should be achieved whilst respecting national regulations on the provision of healthcare services adopted in order to protect the patient.
- The patient is reimbursed by the Member State of affiliation for at least the amount reimbursed for identical care provided in the State of residence, insofar as the treatment received abroad is covered by that State's healthcare system. Medicines may be reimbursed according to Country specific rules and procedures.
- Cross-border prescriptions for medications or medical devices: the patient's home country must provide follow-up care of equal quality, regardless of where treatment was initially provided. It is important to consider the Article 11 regarding the Recognition of prescriptions issued in another Member State.

► **Directive 2012/52/EU¹⁵ of 20th December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State**

This Directive lays down measures for the uniform implementation of Article 11(1) of Directive 2011/24/EU concerning the recognition of medical prescriptions issued in another Member State. It shall apply to prescriptions, as defined in point (k) of Article 3 of Directive 2011/24/EU, which are issued further to a request of a patient who intends to use them in another Member State. The Member States shall ensure that prescriptions contain the minimum data set defined (Annex 1). The minimum set of information to consider a prescription as a valid one is indicated: substances (using INN terminology), strength, dose form is among the others. They are included in the dataset indicated in the eHN Guidelines.

¹⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024&from=EN>

¹⁵ https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=uriserv:OJ.L_.2012.356.01.0068.01.ENG

► **Regulation (EU) No 520/2012¹⁶ of 19th June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council**

This regulation stipulates that the implementation of “terminology set out in the ISO IDMP suite of standards” is binding for “Member States, marketing authorisation holders and the [European Medicines] Agency.” It concerns “internationally agreed terminology” applied “for the classification, retrieval, presentation, risk-benefit evaluation and assessment, electronic exchange and communication of pharmacovigilance and medicinal product information.” The implementation process is currently under way by EMA and the EU Medicines Regulatory Network.

Regarding the implementing IDMP by national eHealth Services Agencies, all solutions should comply with all legal requirements. All the teams should have a preventive proactive behaviour in this matter, searching for accurate information and continuous update on this subject to avoid any non-compliance with any laws.

¹⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0520&from=EN>

6 Use Cases

6.1 Analysis Methodology

This WP5 concerns the overall orchestration to adopt IDMP in eHealth Services, at national and cross-border levels, with a focus on cross-border on ePrescription (eP) and Patient Summary (PS). 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.

The eHDSI eP/eD and PS Use Cases were reviewed and updated to reflect current practices in the industry. The first step was to perform a flow analysis (similar to a value stream map), to provide an overview of the key aspects of the eP/D and PS activities and demonstrates how business value flows from different stakeholder perspectives.

The eP/D and PS maps are analysed to identify and improve the flow of information by identifying the necessary requirements to achieve a minimum dataset. Some additional data, provided by ISO IDMP, may be offered as an extended dataset to ensure the safe identification and dispensation of medicines to the citizen and to help support high quality cross-border care for emergency or unplanned care events, either in terms of:

- i) dispensing of medicines in a country, when the medicines has been prescribed in a different country, or
- ii) allowing that a Health Professional of a country can consult the Patient Summary of a patient seeking for healthcare either in occasional or in regular visit from other country

Identifying Actors (Figure 2) is one of the first steps in Use Case analysis. Each type of external entity with which the system must interact is represented by an Actor.

This work provides the platform to discuss how the UNICOM project can contribute to the univocal identification of medicines.

A high-level description of the use cases identifies the key activities, business and technical actors and supporting data flows for delivering of cross-border eP and PS.

This analysis allows a better identification not only of the areas where eHDSI services may be improved, but also the common dependencies in difference Member States, for example the need for common ePrescription and eDispensing services at national level, and how these services articulate with a common cross-border architecture provided by eHDSI.

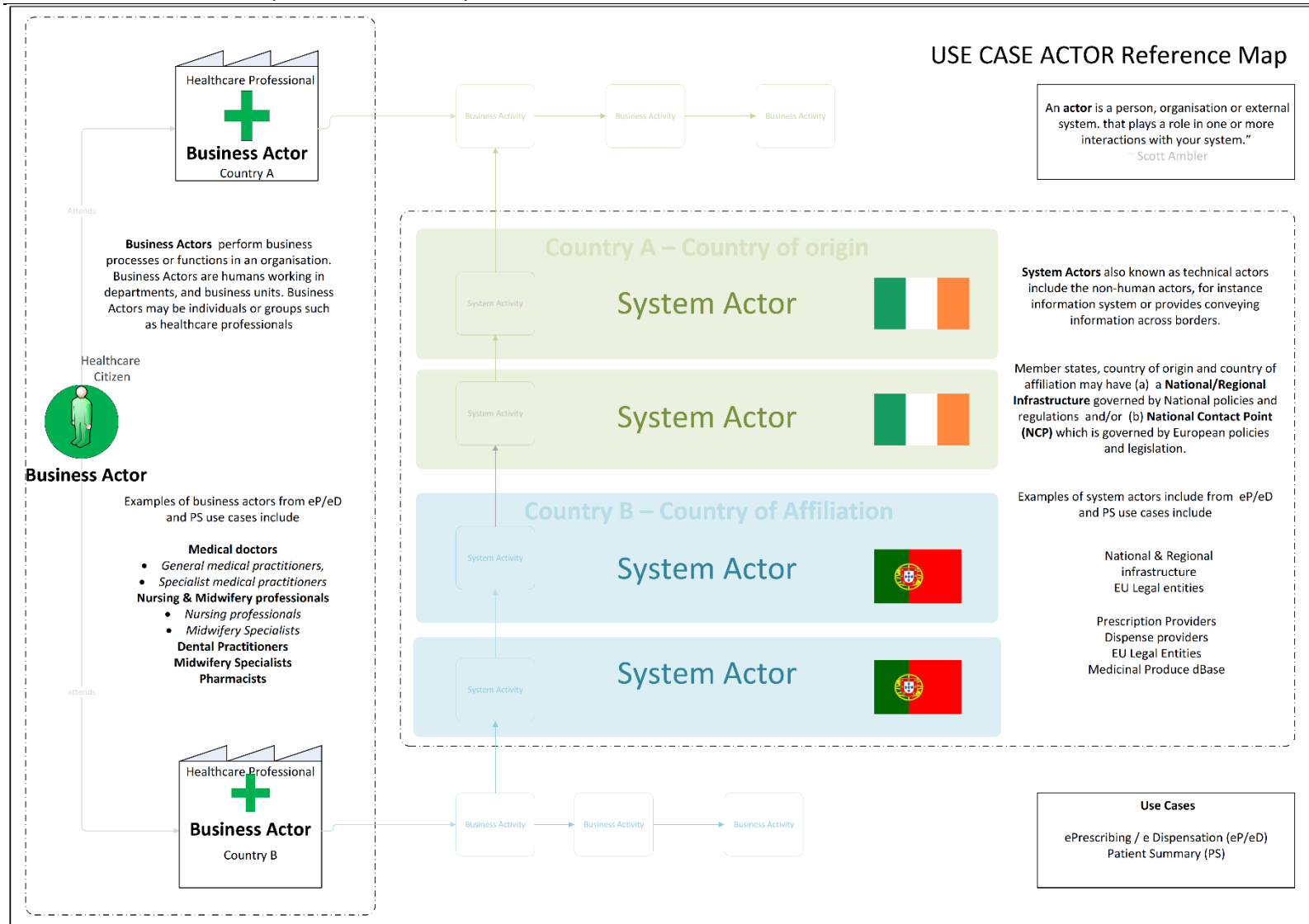


Figure 2: eHealth actors

6.2 ePrescription

The eHSDI ePrescription Use Case underpins the work of WP5 which includes in its scope the development of business requirements for the adoption of IDMP in eHealth services.

- ▶ ePrescription (and eDispensation) allows EU citizens to obtain their medication in a pharmacy located in another EU country, thanks to the online transfer of their electronic prescription from their country of residence where they are affiliated, to their country of travel.

A prescription, in addition to prescriber and patient information, must contain the information provided in EU legislation in Commission Implementing Directive 2012/52/EU (Annex 1). Data elements that identify and characterise the medicinal product include product name, clinical particulars, pharmaceutical product, pharmaceutical form, dosage and medicinal product packaging. These attributes are going to be enhanced and clarified by the use of IDMP.

Coding standards contribute to the unique identification and description of a medicinal product. This is necessary for the safe exchange of information across different stakeholder domains and avoids the risk of misidentification of the correct product.

Considering the eP flows between cross-border countries, it is possible to analyse different scenarios and the activities within.

UNICOM – D5.1: Business requirements for the adoption of IDMP in eHealth Services

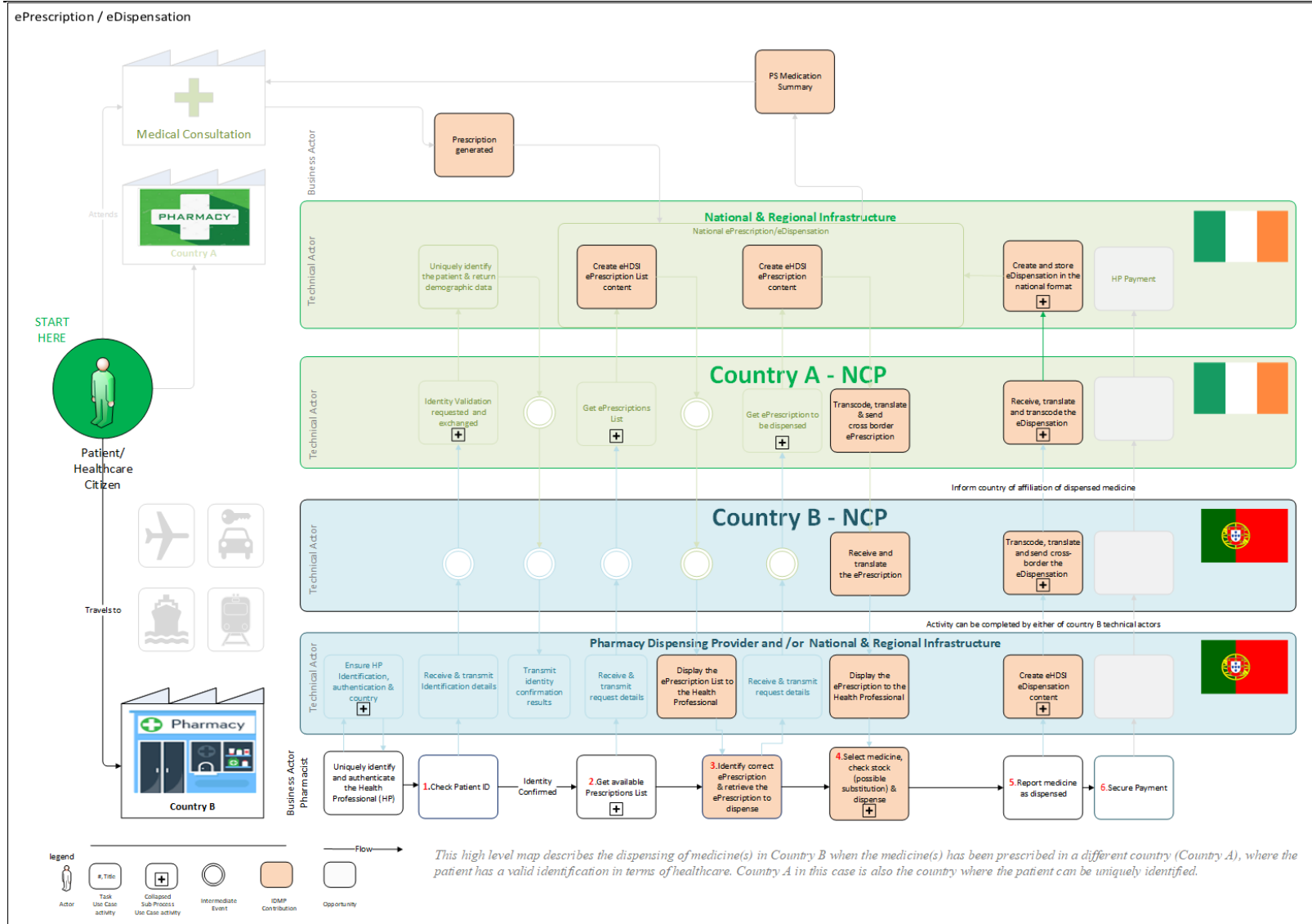


Figure 3: Value Stream Map of ePrescription between countries (Ireland and Portugal)

The Figure 3 represents the Value Stream Map for an ePrescription scenario. It identifies the different roles and responsibilities of both Countries in a cross-border exchange. In this, the highlighted (orange) boxes identify the sub-process where issues and constraints may be impacted from IDMP and should therefore be a target for UNICOM, that is, they show where the existing needs can be improved by the UNICOM project.

The Table 1 describes the key activities for the description of an eP Use case.

Table 1: Main actions list on cross-border ePrescription.

Action List – ePrescription
1 - Check Patient ID
2 - Get available prescription list
3 - Identify the correct prescription/ Retrieve the medicine to dispense
4 - Select medicine, check stock (possible substitution) and dispense
5 - Report medicine as dispensed
6 - Provide dispensed medicine to the patient (and secure payment)

Taking these steps and recognizing the need for other actions that are not in the value stream mapping, we can detail the steps and present some identified gaps. The main focus is how UNICOM can improve or build on existing flows, keeping in mind that UNICOM is focused on the product identification.

Concepts / definitions: in this description, the following concepts are referred to:

1. Country A - typically where prescription is written and stored (country of affiliation)
2. Country B – typically where the prescription is retrieved and dispensed (country of treatment)
3. National/Regional Infrastructure – corresponds to the “dispense provider” in eHDSI and executes the same activities in a cross-border setting.

PRE-CONDITIONS – CEF eHDSI (redeveloped)

4. The patient must have already been electronically prescribed a valid prescription, by an authorized prescriber in Country A.
5. The Health Professional in Country B is assumed to be legally authorized to dispense medicinal products and is identified and authenticated via agreed mechanisms in Country B.
6. In Country B, there has to be a mechanism to validate the identity of the patient and to handle patient GDPR related action (e.g. provision of consent where applicable) and the results to be made available at the pharmacy of country B
7. Dispenser in Country B requests available prescription list.
 - a. In order to obtain the needed information in Country B, the Prescription Provider in Country A must make available the prescriptions to be sent to another country upon their request. Which prescriptions are made available – that is a question that is still open and must be resolved:
 - b. Country A must have the necessary context information or parameters to determine which are the prescriptions that the patient can withdraw from the pharmacy at that specific moment.

8. Country A must provide, maintain and support a logical country node (NCPeH) supporting communication of the information identified in this section with Country B and vice versa (*Ensure traceability and auditability of the exchanged data¹⁷*)
9. Dispense Provider must be able to obtain or get prescriptions and to send the dispensed medicine information to Country A (*Make ePrescription available, 07. Handle Dispensation of the Prescription and Substitution*)
10. There is a chain of trust between system actors in this process (*Ensure Trust between countries*)
11. All technical actors (Non-Human Actors - Open NCP of both countries, National Infrastructure and the dispenser provider) involved in the process must be able to retrieve all the information describing the process and the data involved in it (such as the identification of the HP/dispenser, the identification of the patient, consent (where applicable), prescription list and details of the prescription required), all this information must be able to be traced and recovered.

1. Check Patient ID – CEF eHDSI (redeveloped)

1. A patient from Country A visits a pharmacy in Country B to get the medicine(s) already prescribed in Country A by an authorized prescriber.
2. The patient identifies himself to the health professional (HP) and offers a means of identification e.g. patient national identifier, patient demographics, passport.
3. The HP informs the patient about his/her data protection rights, explains the process, and confirms their identity.
4. If identity validation is still necessary, the HP requests permission (consent where applicable) to validate the patient identity via Country A infrastructure.
 - a. The HP/dispenser of Country B requests patient identity validation from Country A
 - ▶ Country A confirms and provides to Country B the (positive or negative) patient's identification confirmation.
 - ▶ Country B confirms and provides to the HP/dispenser the (positive or negative) patient's identification confirmation.

2. Get available prescription list

Once the identity of the patient is validated, the following steps are undertaken

1. HP/dispenser in Country B requests a list of 'Available' prescriptions from country A.
2. Technical actors from both Country A and B are involved in:
 - a. Processing of the requests.
 - b. Check patient consent has been provided (where applicable).
 - c. Get list of 'available' prescriptions and copies of the originals and provides this information to Country B in the agreed eHDSI format.
 - d. Transforming the eHDSI format into a suitable format for displaying in Country B. The prescription list should be understandable by the Country B pharmacist, to allow an easy selection of the eP to be dispensed.
 - e. Conveys the list of available prescriptions to the HP/dispenser
3. HP/dispenser reviews the prescription list. If no valid prescription is available, the use case is terminated.

¹⁷ Note: The Italic text refers to the CEF eHDSI Requirements Catalogue. Along of the text in eP and PS use cases you can find some requirements listed here. For more details visit:

<https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/1.+eHDSI+Requirements+Catalogue>

3. Identify the correct prescription/ Retrieve the medicine to dispense

The dispenser agrees with the patient which prescription is required (related to the medicine the patient requires). If no valid prescription is available, the use case is terminated.

1. The HP/dispenser raises a request for the selected prescription.
2. Technical actors from both Country A and B are involved in:
 - a. Processing of the requests
 - b. Get the prescription and copies of the originals if required and provides this information to Country B in the agreed eHDSI format.
 - c. Transforming the eHDSI format into a suitable format for dispensation in Country B. The prescription must be understandable in the Country B's official language, the content of the prescription has to comply with the usual practice in Country B (format and content, including coding mechanisms and displaying of information) and must contain at least the minimum (could be the maximum) data set.
 - d. Conveys the prescription (and copy) to the HP/dispenser
3. HP/dispenser reads the prescription details and confirms dispensation is possible.

4. Select medicine, check stock (possible substitution) and dispense

1. The dispenser determines whether or not the exact medicine (as prescribed) can be dispensed.
 - a. If exact medicine is available, the dispenser proceeds with the dispensation procedure.
 - b. If the exact medicine is not available:
 - i. The dispenser confirms that a licenced equivalent (article 5 of Dir 2001/83/EC) is available to dispense. If not, an unlicensed product may be sourced.
 - ii. The dispenser advises the patient of the various options and agrees their preferred choice of medicine to be dispensed.
 - iii. If no substitution can be dispensed, or patient does not wish to avail of the options presented, patient is advised to seek a Health professional and the use case is terminated.
2. Medicine is selected, prepared and dispensed.

5. Report medicine as dispensed

Once the medication has been dispensed, it is necessary to register the dispensation information with Country A.

1. Technical actors from both Country A and B are involved in:
 - a. Electronically record dispensation information in Country B.
 - b. Country B informs Country A of dispensation (in the agreed eHDSI format).
 - c. Country A manages the dispensation information appropriately.
 - d. Country A sends the confirmation on the correctness of the eDispensation. To be noted that it is not requested to Country A to check the correctness of the dispensed medicine, because a medicine registered abroad could be not registered in Country A.
 - e. If Country A sends a negative feedback, the dispensation process must be restarted.

6. Provide dispensed medicine to patient and secure payment

The HP/dispenser gives the dispensed medicine to the patient, offering advice where necessary. The citizen/patient may be requested to pay for medication, however, payment reimbursement, if applicable, will differ from country to country.

6.3 Patient Summary

The Patient Summary (PS) is one of the main documents related to the provision of good patient care, and it is used to support better decision making and improve the quality of treatment. This document contains information about the patients' past medical events, vaccines, allergies and medicinal products prescribed.

- ▶ Patient Summary provides essential healthcare information (allergies, current medication, previous illness, surgeries, etc.) to the healthcare provider in another country ensuring the safer and better-quality treatment of the EU citizen. It is part of a larger collection of health data called electronic Health Record. The digital Patient Summary is meant to provide clinicians with essential information in their own language concerning the patient. This significantly reduces clinical risk in the event of a linguistic barrier. In the future, it is anticipated that the full Health Record will become available across the EU.

The PS is shared (with consent) between Health Professionals at a national/regional level and also cross-border in some EU countries. Since the PS contains information about prescribed medicinal products, it raises an interest for the UNICOM project and the eHealth Services at national and cross-border levels.

The eHDSI Patient Summary underpins the development of the PS and demonstrates the business and data flows between cross-border countries. It also describes various activities performed by different actors in order to realise safer treatment of a patient in Country B.

Considering the PS flows between cross-border countries, it is possible to analyse different scenarios and the activities within. The Table 2 describes the key activities for the description of the PS use.

The Figure 4 below, represents the Value Stream Map from PS use case. It identifies the different roles and responsibilities of both Countries in a cross-border exchange. Additionally, the pink boxes identify the issues and constraints that could be improved by UNICOM, that is, the existing needs that can be improved with the UNICOM project.

Table 2: Main actions list on cross-border Patient Summary.

Action List – Patient Summary
1 – Check Patient ID
2 – Consult Patient Summary of Country A
3 – Report treatment received
4 – Secure payment

UNICOM – D5.1: Business requirements for the adoption of IDMP in eHealth Services

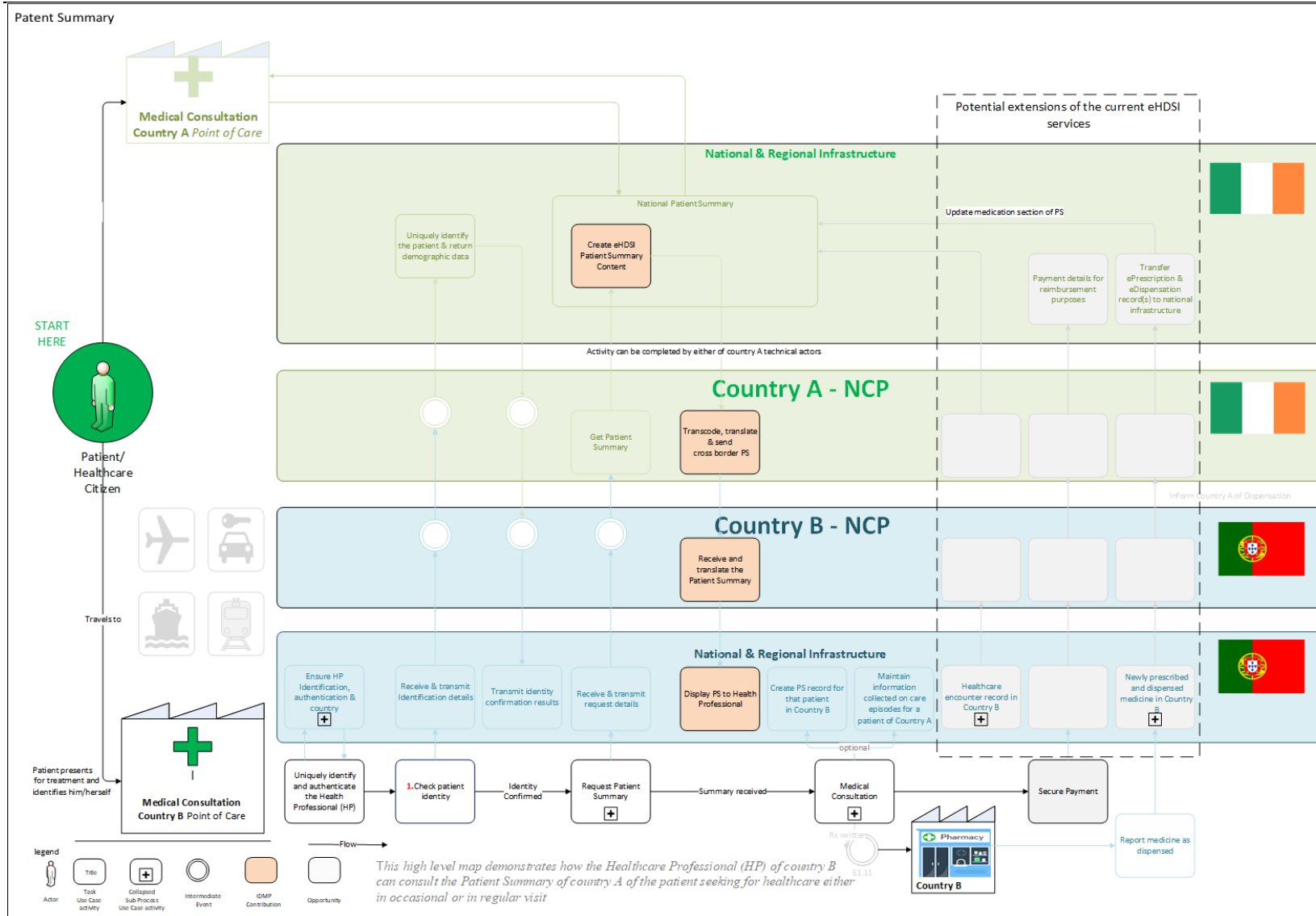


Figure 4: Value Stream Map of Patient Summary. Ireland and Portugal are examples of countries participating in the exchange.

PRE-CONDITIONS

1. Country A – country of affiliation (where PS is created).
2. Country B – country of treatment (where the PS is consulted)
3. Patient request for medical assistance in country B to a HP.
4. Possibility to retrieve the PS from Country A.
5. The Health Professional is a person legally authorized in country B to provide healthcare and is identified and authenticated in country B. A mechanism to validate the identity of the patient and to handle GDPR related patient actions (e.g. provision of consent where applicable) has to be available at the Point of Care of country B creating the validation request to country A.
6. The health Professional must be related to at least one Healthcare Provider Organisation (HCPO) or to a Health Authority.
7. Country B must provide, maintain and support an NCPeH supporting communication of information with country A and vice-versa.
8. There is a chain of trust between system actors in this process.
9. The HP must be able to access the “communication layout” that handles the PS in the European Countries.
10. All technical actors involved in the process must be able to retrieve all the information describing the process and the data involved in it (such as the identification of the HP, the identification of the patient, the information contained in the PS), and all this information must be able to be traced and recovered.

1. Check Patient ID

A patient from country A visits a HP in country B seeking healthcare consultation

1. The patient identifies himself to the health professional and offers a means of identification, e.g. patient identifier, demographics, passport.
2. The HP informs the patient about his/her data protection rights, explains the process, perform the actions related to the GDPR application (e.g. requests confirmation about the acceptance of Patient Information Notice, seeks consent when applicable) and confirms patient's identity and the GDPR related actions.
3. If identity validation is still necessary, the HP requests permission (consent where applicable) to validate the patient identity via Country A infrastructure.
 - a. The HP of Country B requests patient identity validation from Country A;
 - b. Country A confirms and provides to Country B the (positive or negative) patient's identification confirmation;
 - c. Country B confirms and provides to the HP the (positive or negative) patient's identification confirmation.

2. Consult Patient Summary of country A

Once the identity of the patient is validated and approval to retrieve the PS confirmed, the following steps are undertaken:

1. The HP requests the Patient Summary from Country A
2. Technical actors from both Country A and B are involved in:
 - a. Processing of the requests.
 - b. Checking patient consent has been provided (where applicable).
 - c. Obtaining patient summary in the agreed eHDSI format. It must contain at least the minimum (could be the maximum) data set

- d. Transforming the eHDSI format into a suitable format for PS provision in Country B. The PS must be understandable in the Country B's official language, the content of the PS should comply with the usual practice in Country B (format and content, including displaying of information).
 - e. Conveys the PS of Country A to the HP interface of Country B
- 3. The HP of Country B consults the PS of Country A

3. Report treatment received

Once patient consultation is complete it could be necessary to register any updated and clinically relevant details including any prescribed medicines. Current CEF eHDSI implementation does not include the transfer back to Country A. Possible steps, specified in epSOS process as "Health Care Encounter Report" (HCER) might be:

- 1. HP may update the PS record
- 2. Technical actors from both Country A and B may be involved in:
 - a. Electronically record information about any treatment provided in Country B.
 - b. Country B may inform Country A of same (in the agreed eHDSI format)
 - c. Country A may manage and update PS appropriately.

4. Secure payment and reimbursement

The HP offers professional advice, provides the necessary treatment and secures payment from the patient in line with National policy of Country B. The healthcare citizen/patient may be requested to pay for the encounter cost and treatments, however, payment reimbursement, if applicable, will differ from country to country. It is not a service currently provided by CEF eHDSI.

The use case is terminated.

7 Business requirements Specifications for IDMP adoption in eHealth Services

This section identifies the business requirements necessary to build the process flows and system design for the overall solution. From the eHDSI requirement catalogue (Annex 2) and the current state of the healthcare delivery environment, a representative set of use cases and variations has been detected, and a list of business requirements for the adoption of IDMP in eHealth services was generated, where the focus is on cross-border interoperability, at the level of service, functional, semantic and technical. These requirements define the scope and guidelines development to achieve the following objectives:

- ▶ Support the implementation of the ISO IDMP in interoperable eHealth Services, starting with eP services (eP/eD) within and across Member States, in order to facilitate error free recognition and delivery of medicines.
- ▶ Define the business and functional requirements for the adoption at national level and the implementation at cross-border level, as extensions of the current CEF eHDSI assets.
- ▶ Elaborate a structured functional and business analysis of the impact from the UNICOM project, and validate it in relevant unplanned care/emergency situation.

The approach started from the analysis in the previous section and is visible in the infographics which show the integrated workflows between Country A and Country B for each use case stated. This flow analysis was used as a platform to discuss, analyse, and generate current challenges and business requirements. This work was instrumental in designing a bespoke questionnaire where the current situation of eP and PS for different EU countries was gathered, the knowledge about it will allow a deep analysis and new business requirements may come out of this process.

7.1 The Business Requirements - approach

The use case analysis and legal framework described before, allows us to outline the business requirements that UNICOM is expected to present. For this, the approach is the following:

1. Consider the eHDSI use cases and update them to reflect current practices and possible impact of UNICOM
2. Create a common abstraction that allows the different use cases (and identified / Expected variations) to be supported by one common set of requirements.
3. Identify and document the requirements for each business activity within the use cases
4. Generate, distribute, and evaluate a bespoke questionnaire to determine the basic designs in use in different EU countries for the different use cases
5. Incorporate the findings into this document
6. Engage with WP9 to confirm the business activities where IDMP can positively contribute the identification of a medicinal product.
7. Engage with WP9 to identify and document specific IDMP requirements

This approach facilitates the bridging of identified gaps between the current solutions and IDMP standards. This highlights the need for a robust operational cross-border exchange, including the impact of the project on the diverse areas and possible change needs for the potentially affected parties:

- ▶ National Competent Authorities
- ▶ eHealth agencies,
- ▶ Other private Stakeholders

7.2 eHDSI Business requirements and UNICOM impact

The first step is to identify and agree on the potential UNICOM impact on the existing eHDSI requirements. While this may cover all or only a part of the full requirements set, it provides a first touch point, insofar the eHDSI are the primary focus of these requirements and the overall requirement areas can be quickly identified: it allows the identification of the eHDSI requirements that can be improved by the adoption of IDMP, while acknowledging that the functional adoption of IDMP may create new requirements.

The table 3 provides a summary of the business requirements for eHDSI (the complete requirements list can be found on Annex 2) and indicates whether the UNICOM project could introduce a need for modifying each requirement. It explains what the impact of UNICOM is – whether changes in the requirement are expected from UNICOM, or if UNICOM has no impact on the requirement.

Table 3: eHDSI Business requirements and UNICOM impact

Business requirement (eHDSI Wave 4)	UNICOM impact
<u>03.03. Assess and validate the cross-border services</u>	Yes, see next sections: Modifications and further development of test cases within the current Test Framework. New workflow tests that make use of the IDMP data structures especially in the dispensation process.
<u>03.04. Education, training and awareness among citizens of the cross-border services</u>	Yes, see next sections: Awareness of cross-border procedures and IDMP data structures should be taken into account in training and dissemination activities. Not just for citizens but also for health professionals.
<u>04. Ensure lawful processing of personal and health data</u>	No impact.
<u>05. Make Patient Summary available to HP</u>	Yes, it can increase patient safety. See details below.
<u>05.01. Create the eHDSI Patient Summary content</u>	Yes: Modifications of the data contents for the Medication Summary section.
<u>05.02. Transcode, translate and exchange cross-border the Patient Summary</u>	Yes: New procedures for translations and transcodings of the Patient Summary are expected and should be implemented by the NCPeH organizations or National/Regional institutions.
<u>05.03. Display the Patient Summary to the Health Professional</u>	Yes: The Patient Summary display software such as the CDA Display Tool will need to be updated to accommodate for the relevant data – whether this is the IDMP data structures or other data elements.
<u>06. Make ePrescription available to HP</u>	Yes, it can increase Patient safety and probability to dispense, see below:

Business requirement (eHDSI Wave 4)	UNICOM impact
<u>06.01. Create the eHDSI ePrescription(s) content</u>	The content of ePrescription documents is expected to require adjustments to accommodate for cross-border identification of the products
<u>06.02. Transcode, translate and exchange cross-border the ePrescription</u>	The translations and transcodings between different systems and IDMP should be implemented by the NCPeH organizations or National/Regional institutions.
<u>06.03. Display the ePrescription to the Health Professional</u>	The prescription will contain new data structures that should be available for display and retrieval, of prescription and reporting of dispensation data.
<u>07. Handle Dispensation of medicine and Substitution</u>	Yes, see below. Additionally, the substitution handling may need to be updated e.g. structured or supported by new data elements
<u>07.01. Create the eHDSI eDispensation content</u>	Same as ePrescription - Modifications of the data contents.
<u>07.02. Transcode, translate and exchange cross-border the eDispensation</u>	Same as ePrescription - New translations and transcodings that should be implemented by the NCPeH organizations or National/Regional institutions.
<u>07.03. Inform Country of affiliation about the dispensed medicine</u>	Yes, request to register Dispensation information with country A by including IDMP identifiers.
<u>07.04. Option to discard a previously performed dispensation</u>	Conceptually yes: also IDMP should be updated. In practice, it depends on the implementations
<u>08. Ensure high quality information (structured, equivalent, understandable) is exchanged between countries</u>	Yes, see below. Potential changes to the concept "unified meanings regarding medicines". This will probably imply both universal information (high-level concepts) and detailed information (lower-level concepts)
<u>08.01. Ensure structured and coded information is exchanged between countries</u>	Changes to the eHDSI content specifications, as well as adding new elements and respective vocabularies – in the Master Value Catalogue, (MVC) if required. New requirement: Master data governed flows to ensure Medicinal Product Dictionaries are updated.
<u>08.02. Ensure equivalent information is exchanged between countries</u>	This seems to be a very broad requirement which will necessarily be impacted by UNICOM

Business requirement (eHDSI Wave 4)	UNICOM impact
<u>08.03. Ensure understandable information is exchanged between countries</u>	This seems to be a very broad requirement which will necessarily be impacted by UNICOM
<u>eP/eD Use Case</u>	See analysis in Sect. 6, requirements below
<u>PS Use Case</u>	See analysis in Sect. 6, requirements below

7.3 Common Requirements Analysis

An analysis of eHDSI business requirements and the use cases informed the requirements for IDMP in a cross-border setting. During the analysis phase, several commonalities across the use cases were observed, including but not limited to documentation requirements (which implies the creation of a document in Country A and the consultation of that same document in Country B).

There are also many variations observed, which means that a robust solution design is required for the safe implementation and seamless flow of medicinal product data across Members States – a design that can accommodate the expected cases and variations alike. For example, a design that works seamlessly for prescription, whether prescription is "generic" or by brand name.

This starts with a common abstraction. For example, instead of Patient Summary or a Prescription, we define the notion of a "clinical document". This way we can find common, reusable requirements that are necessary to realize the known use cases and expected variations. Figure 5 below shows a generic process sequence which considers the creation of a clinical document in country A (e.g. a prescription) and its use in country B (e.g. for dispensing)

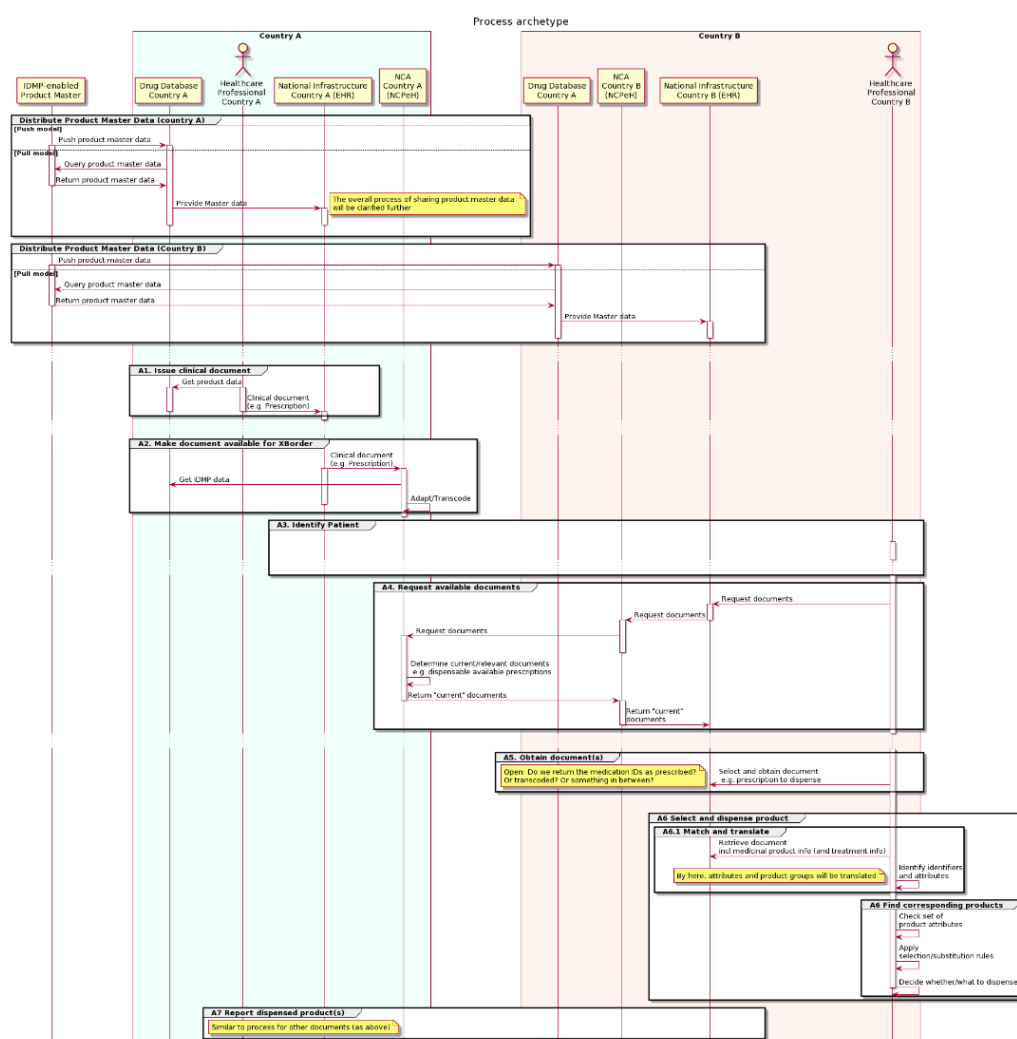


Figure 5: Generic process description for common requirements

The description of the activities and generic requirements are as follows:

A1. (Activity 1) Country A generates a specific document type for their healthcare citizen.

First, the Health Professional creates a clinical document according to the National procedure, which may imply using an agreed format (e.g. CDA template), and submits this document into the National/Regional infrastructure of Country A. In some cases, the clinical document is automatically generated by the system (e.g. Patient Summary created upon request). This work is completed using internal workflows and includes different coding systems, including local codes. This part of the process is bound to national regulations and variations, and is not expected to be drastically changed with the adoption of UNICOM recommendations.

Example concretization:

An ePrescription (a specialization of a “Clinical Document”) is created and registered in a XDS infrastructure for national dispensing.

Requirements:

R1. (Requirement 1): A clinical document (i.e. a prescription, dispense, summary) SHALL follow the legal requirements in country A. This is not a new requirement, but it is stated here to ensure that UNICOM does not require a different set of clinical processes or exceptions which would be difficult to justify or support (technologically, clinically, or legally)

In short, adopting IDMP should not force a process or legal change that would be incompatible with the existing legal and operational frameworks inside the countries.

R2. The clinical document SHALL contain relevant information for internal processing – this is an evident requirement but is also recalled to ensure that UNICOM does not negatively impact clinical processes.

For example, when a prescription contains the brand name and package size, UNICOM should not mandate that a higher-level concept like Pharmaceutical Product which does not include package size, since that would not be compliant with the initial prescription in the country. In other words, the adoption of IDMP should not force a reduction of the detail in which the products are identified in the documents that are issued.

R3. 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.

- .1. There is a multitude of ways to specify a product, each of them will influence the other stages and determine which information is needed to be available for country B. Examples of variations:
 - .1.1. Prescription in generic or brand form, or country-specific concepts
 - .1.2. Providing an indication for treatment (or not)
 - .1.3. Enabling substitution (according to rules of country A)

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.

R4. The prescription/clinical document SHOULD be in a format that can be exposed in another IDMP-enabled country – i.e. 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.

In short, 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.

A2. Make document available for cross-border access

Given the fact that cross-border sharing of documents may require for example:

- ▶ A different infrastructure, e.g. a separate repository
- ▶ Some addenda in terms of data or metadata, so that it can be reached outside of the initial scope in country A, if that is not already provided in stage 1

Requirements:

R5. 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.

This requirement is for the actual transport mechanisms to exist – whether they are a simple transmission or contain format conversion (e.g. between different a national CDA and the cross-border standard CDA).

A3. 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 product identification requirements are expected from UNICOM in this step.

A4. Request available/active prescriptions / Patient Summaries / ADE / other clinical document from another country

After the successful identification of the patient, a request is made for a specific document and the requested information should be obtained from Country A. The mechanism for requesting this information is determinant on the outcome of the process – the functional and technical aspects will determine if this is done by polling for information in one specific country, or from a central metadata hub, or a specific query is sent to another country, etc.

The request stage is followed (immediately or not) with a response, which provides the information held in Country A. This includes appending to the response any additional information that is needed for the specific business activity.

Requirements:**R6. 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.

A5. Obtain specific active ePrescription / Patient Summary / ADE / other clinical document from another country

It is possible to disclose all information (depending on access rules) to the health professional in Country B. In respect of a Patient Summary, the clinical value comes with getting all the information and not selected parts; the missing information may affect the judgement and treatment options for the health professional in Country B.

However, in certain circumstances, for example, a prescription list, the dispenser will only have access to the prescription item as indicated by the patient. With the information available, the dispenser makes a judgement whether or not 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 in order to provide safe medical health care.

Requirements:**R7. 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.).

R8. Product Classifications of products from one country SHALL be visible in another country

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 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.

A6. Select and Dispense

In order to select (and dispense) a product, we divide the process in a few steps:

- ▶ Identify what dispensation is intended by matching and translating attributes and identifiers

- Find the product available that best corresponds to the dispensation intention.

A6.1 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:

R9. Products specified in one country SHALL be identifiable in another country

This is the core requirement, and it entails several requirements:

Somewhere in the data exchange between countries, there SHALL be a way to convert the specified product-related information into something that can be understood 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 as part of the product discovery, the practitioner in country B will be able to understand what characteristics are specified for the product.

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).

For this to happen, there are a few dependencies:

R10. There must be a standardized technical format and infrastructure to exchange the information

This is handled by the infrastructure and standard for data exchange. In the case of eHDSI, the infrastructure exists; other alternatives can be considered as long as this requirement is respected: a standardized format and infrastructure are essential.

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

R11. 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...).

R11. 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 and understanding what those mean (as per previous requirement), must be able to use, convert those attributes to the national reality. Some examples:

- ▶ Upon receiving the information that “active ingredient” = “paracetamol”, country B can display the substance name in the local language
- ▶ If the information is a product code, country B may use that code to lookup the code and equivalence.

Common product codes may be used in some situations, but not all. Some situations where common codes are sufficient:

- ▶ Prescription is made using a MPID and the product has been approved under the mutual recognition or common registration procedure between those 2 countries. In that case, the MPID will be recognizable in country B.
- ▶ Prescription is made at the level of Pharmaceutical Product (i.e. generic prescription). In this case, country B will receive the exact information as was intended to be used in country A – just the substance, strength and dose form.

(to do: add requirements summary at end, and illustrate identification)

In most cases, however, just one or several product codes are not sufficient:

- ▶ When MPID is used, the most common is that the MPID is not understood in both countries.
- ▶ If the prescription is by brand name or determines a package size, and a PhPID is used as a pivot, some information is lost. The PhPID cannot contain that information without more attributes. In other words, PhPIDs may not contain all the information in the prescription, which is an obstacle to safe dispensing.

For this reason, equivalence of products SHALL be done by attribute matching, not only by 1:1 mapping of codes.

For this, there is a need for a common or pivot language - In at least one part¹⁸ of the data flow, products SHALL share common identifiers OR common attributes – either:

- 1. R13. There SHALL be common product identifiers when possible**
- 2. R14. The attributes for Products SHALL follow a common language**

This is a practical consequence of the above: 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.

¹⁸ This makes the requirement scope clear: it is not essential that the same codes are used throughout the entire process, as long as there is a translation somewhere. In essence, there is no need for all systems to understand the common IDMP language besides their national language, as long as there is a pivot/transcoding mechanism in between. An analogy: to achieve communication between languages A and B, we can either require everyone to speak a common language C, or we can place a translator somewhere in the communication flow so that the communication is converted from language A to language B and vice-versa.

A6.2. Find corresponding products (may include substitution)

After identifying and understanding what was meant on the clinical document in country A, the next stage is to identify and select the corresponding medicinal product for dispensation using:

- ▶ Product identifiers and attributes, as well as product group/classification
- ▶ Prescription attributes (dose, substitution, etc). Some of these attributes may not be deterministically transposable to another country due to technical or legal constraints.
- ▶ At this moment, also grouping and substitution rules and equivalences are important

If the intention is to dispense a prescription, and depending on local policy and legislation from country B, the following options are possible:

1. An exact match (licensed or unlicensed), if the product attributes match.
2. A generic substitution, if some of the attributes match (at least substance, strength), but not all.
 - a. The substitution rules – including which attributes must match - may vary across Member States.
3. Therapeutic substitution with clinical agreement (if there is no match but an alternative is found)

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:

R.14 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.

R.15 Substitution rules SHOULD be expressed intentionally using a common vocabulary when possible

Explanation: 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).

A7. 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 product 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).

7.3.1 Dependencies / access streams

For the 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:

A.8. Set access permission rules getting ePrescriptions / 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).

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 be 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.

R.16 A minimum set of IDMP attributes and identifiers SHALL be synchronized 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 synchronized across countries wherever needed.

R.17 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).

R.18 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 is defined according to IDMP and this synchronization 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 synchronization exchange of product master data.

This alignment must be on both a conceptual and terminology level - MPDs SHALL have a consistent product data model at least for the “common language” aspects. For example:

1. Conceptual

The concept of “indication” might mean the indication for which the product is authorised by the regulators, or it can mean the indication for which the product was described for this patient. Therefore, when receiving the indication, it is important to know which one is being referred to.

2. Terminology

To express an indication, we can use SNOMED CT or ICD-10 or any other terminology. It is important to know which one is being used.

The treatment characteristics in the clinical document that are important to determine the access and action on the country B must also be shared. Clinical systems SHALL have a consistent data model for those key clinical document attributes

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 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:

R.19 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.

7.3.2 Summary of requirements:

From the above analysis (Table 4), these are the requirements that should be considered in cross-border identification of medicinal products for any type of document:

Table 4: The summary of requirements

<u>Requirements for backwards compatibility – i.e. IDMP adoption not to harm current interoperability or clinical and legal constraints</u>	
<u>R1</u>	A clinical document (prescription, dispense, summary) SHALL follow the legal requirements in country A.
<u>R2</u>	The clinical document SHALL contain relevant information for internal processing
<u>Requirements for Information sufficiency and cross-border transport: information used in one country must be available to other countries, regardless of architecture</u>	
<u>R3</u>	The clinical document SHOULD contain relevant information for cross-border processing
<u>R4</u>	The prescription/clinical document SHOULD be in a format that can be exposed in another IDMP-enabled country
<u>R5</u>	There SHALL be a way to expose the documents normally used in one country for use in other countries (for example expanding eHealth services to broader use).
<u>Requirements for Master data matching or look up: it is important that product groups and rules like substitution can be consulted between countries when needed to select medication</u>	
<u>R6</u>	Product groups/classification SHOULD be identifiable in another country
<u>R7</u>	Products used in a document from one country SHALL be visible in another country, following access control rules.
<u>R8</u>	Product Classifications of products from one country SHALL be visible in another country
<u>The key aspect of product identification, and where IDMP plays the essential role, is that products must be identified across countries – by providing a common language for attributes and identifiers, and that this language can also be used to express the product groups.</u>	

<u>R9</u>	Products specified in one country SHALL be identifiable in another country (this does not mean to a matching product – it just means that the product identification must be visible in a clinical document and must be unequivocal.
<u>R10</u>	There must be a standardized technical format and infrastructure to exchange the information (this is satisfied for example by expanding eHDSI services to all countries)
<u>R11</u>	Attributes used to identify the product shall be commonly identified to be understood across countries.
<u>R12</u>	It SHALL be possible to translate products identifiers and/or attributes from one country to the other.
<u>R13</u>	There SHALL be common product identifiers when possible
<u>R14</u>	Products groupings SHOULD be expressed using a common vocabulary when possible.
<u>R15</u>	Substitution rules SHOULD be expressed intentionally using a common vocabulary when possible
<u>Finally, it is necessary that the IDMP attributes and identifiers are deployed and synchronized to the product dictionaries and other applications across all countries. This master data synchronization is a hard dependency for UNICOM.</u>	
<u>R16</u>	A minimum set of IDMP attributes and identifiers SHALL be synchronized for all products across all member states
<u>R17</u>	For this synchronization and governance of attributes, there SHOULD be a common standard to exchange detailed product master data – i.e. a standard for exchange of Product Dictionaries
<u>R18</u>	The exchange of IDMP attributes SHALL be appended to the current descriptions of the products on a national level
<u>R19</u>	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

7.3.3 Business analysis impact

The generalisation in the analysis above can be used to produce concrete requirements:

1. The impact of cross-border prescription or cross-border patient summary IDMP related extensions SHALL NOT impact negatively the clinical processes inside the same country. For example, it is not possible to impose a technical constraint that all countries shall start prescribing on a specific PHP level.
2. Whenever a product is identified as a prescribed item, as a member of a group in a cluster prescription, magistral formula, or as a member of a list of allowed substitutions, the language and rules are determined by country A, but SHALL be possible to map them to the common language model – which is IDMP.
3. These IDMP attributes SHALL be added to the MPDs of the countries wishing to support UNICOM, to be used at least at the NCA points, but eventually at the points of care.
4. 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
5. For the purpose of EU cross-border usage, the attributes referred to in point 4 SHOULD be assigned consistent terminologies.

The following activities can help implement and validate the necessary requirements. (These are recommendations.)

- ▶ Define the Logical Data Models for product information, as a subset of IDMP
- ▶ Define the functional extension and implementation guide for implementation of ePrescription and Patient Summary for clinical document relevant data (e.g. prescription, indication)
- ▶ Adopt common vocabularies for all the attributes above.
- ▶ Define mechanism to exchange product master data (e.g. Medicinal Product Dictionaries or Medicinal Product Catalogues)
- ▶ Define and enrich a common pool of real-life cases, including example content, which can be used at all times during and after the project, to facilitate understanding, scoping, and validation.

7.3.4 Data Requirements

The business analysis shows some requirements around attributes and identifiers. A deeper analysis on the data needs provides some detailed requirements for IDMP adoption in eHDSI.

7.3.4.1. IDMP attributes in current cross-border eHealth services

The following contains a list of attributes relevant for cross-border services (as seen from the perspective of the current eHDSI implementation) that can be improved with the introduction of IDMP. The Table 5 lists the changes potentially required to the data contents exchanged cross-border and explains the impact on the currently available services.

Table 5: Attributes for cross-border (from eHDSI), possible changes and impact of IDMP adoption

Attribute(s)	Current situation	Possible changes	Impact
Substance identification	The ATC code system is used for identifying substances (active ingredients) by some countries. The same substance might have multiple entries in the ATC code system, as it was not originally designed for this use.	Use of ATC as a “pivot” substance code should no longer be required, given the issues with uniqueness and adequacy. ATC can and should be used as a classification.	Possibility to exchange and to translate coded information about substances.
	Some countries use nationally defined terminologies for substances.	Introduce coded substance identification, aligned with SPOR vocabularies	
	Information about substances is often exchanged in text form (in Country A or B language, sometimes in English).		
Product identification	Currently ATC is used (as a token to substance)	Discontinue use of ATC as the single substance identifier	Uniquely identify products in a cross-border vocabulary
	Use IDMP and/ or other identifiers e.g. PhPID, MPID, etc.	Support new product identification: In an ePrescription, depending on how the prescription is specified, the product code can be substance code, a PhPID, MPID, or a national code.	
		Any product code used should clearly identify the code system – when using a PhPID,	

Attribute(s)		Current situation	Possible changes	Impact
Product Classification			indicate that the code is a PhPID (including version, if adequate).	
			It is conceivable that more than one product code would be used, for example a national product code, and a common (IDMP) code such as the PhPID.	
	ATC		ATC code(s) can and should still be used as a classification	Add product classifications in a common way across borders
	Other classification(s)		To be added when available and needed. When using any classification, the classification system should be clearly identified – for example a drug prescribed in Sweden could indicate that it is classified as a narcotic – in this case, the “narcotic” classification would be clearly identified as <i>the Swedish narcotics schedule</i> (and point to the version of that schedule).	
Package	Package Content	Combination packages are currently not supported	Needs discussion on the potential support. Consider recursive packaging description (e.g. boxes which contain kits which contain different products)	Possibility to exchange prescriptions for combination packages that are currently excluded from the service by an MS decision.

Attribute(s)		Current situation	Possible changes	Impact
	Package Type	One field for representing the package type. The value set based on EDQM values describing Administration devices, Closures and Containers. Closures might be removed from the value set after a change proposal.	Information about administration device, closure, and container to be separated.	More detailed description of packaging might be possible, but no significant impact is foreseen.
	Device		Support adding Device information to the product description when needed	
Dose Form		One field for representing the pharmaceutical dose form. The value set based on EDQM values from PDF (Pharmaceutical Dose Forms), PFT (Patient-Friendly Terms), CMT (Combined Terms), and CDF (Combined Pharmaceutical Dose Forms) are included.	Consider the possibility to add several dose forms (of different types). Ensure alignment of Dose Form Types (Administrable, Basic, etc) with the corresponding IDMP attributes.	Possibility to provide context-specific information on the dose form. Improved database searches and matching of products as part of the product selection step performed in the pharmacy.
		Nationally defined dose forms cannot be always mapped to their EDQM equivalents, preventing the exchange of certain ePrescriptions across borders	Common vocabulary: Nationally defined dose forms can be replaced or complemented by IDMP- and SPOR-compatible vocabularies Find IDMP terms and SPOR vocabularies (handled in WP2, WP3 and WP4)	Prescriptions currently excluded from cross-border exchange due to the use of

Attribute(s)		Current situation	Possible changes	Impact
			Common / specific hierarchies – consider defining “hierarchies of Dose Forms” to allow considering products with different but related dose forms as belonging to the same Cluster.	incompatible dose forms can be exchanged.
	Administrable dose form		Consider adding support for Administrable dose form in ePrescription; Common vocabulary	
	Basic dose form		Consider the use of “Basic dose forms”	
	Patient friendly dose form		Consider the use of “Patient friendly dose form“, Common vocabulary	
	Pharmaceutical dose form		Common vocabulary	
	State of matter		Consider adding support for State of matter and Administrable dose form.	
Routes and Methods of Administration		Currently used. No significant challenges identified.	No changes required.	No changes foreseen.

Attribute(s)		Current situation	Possible changes	Impact
Units	Units of presentation	UCUM is used for representing units in package sizes and strengths. Units of presentation are not used. The meaning of the UCUM unit “1” (unity) is not always clear and is sometimes complemented with the curly braces’ notation such as “1 {ampoule}”.	Add support for exchanging information on Units of presentation, to improve representation of package sizes and strength. Harmonise units with SPOR vocabularies	Possibility to translate information about units of presentation and provide more understandable information on package size and strength.
	Units of measurement			
Strength	Strength Type	Meaning of “Strength” is not unambiguous; When strength is used, it should be unambiguous	Identify Strength type when necessary (see WP1 D1.1)	
	Strength units		Express units consistently; Harmonise units with SPOR vocabularies	
Other attributes not currently used	Ingredient Role	Not currently used	Consider adding Role: When describing product compositions, the role is an important attribute	

Attribute(s)		Current situation	Possible changes	Impact
	European Regulatory Authorization: Country, Domain, Procedure ID, Regulatory Entitlement Status		This is part of IDMP, and therefore should be accommodated by the inclusion of IDMP identifiers	(why?)
	Intended site		Part of the description of the treatment; investigate if useful	
	Language		All language-specific or language-sensitive attributes must be tagged with the language used	
	Legal Status of Supply	This is an important attribute when identifying the equivalence across borders – whether a product needs a prescription or not.		
	Marketing Status			

Attribute(s)		Current situation	Possible changes	Impact
	Quantity Operator			
	Release characteristics	Useful to define a product		
	Special Precaution for Storage	Useful when describing a product		
	Transformation	Transformation procedures may be relevant in describing a product		

7.4 Comparison of national eHealth Services (eP/eD & PS) and their respective legal base in EU countries

A survey was distributed among several stakeholders (CEF eHDSI communities, eP and PS clusters, Legal Task Force (LTF), and within the UNICOM consortium) from different European countries to evaluate specific characteristics and similarities among countries concerning eP/eD, PS and their respective legal context, as well as possible elements that could be an issue for the UNICOM implementation. We have divided the analysis into three different categories: eP/eD, PS and respective legal framework. In the following subchapters, we will display the results and discuss their influence on the UNICOM implementation.

The surveys used for eP/eD, PS and respective legal basis can be found on Annex 3, which can be used to consult the complete questions used to elaborate the figures in the next subchapters. The European countries that have submitted answers are Austria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Republic of Ireland, Italy, Netherlands, Norway, Poland, Portugal, Slovak Republic, Sweden, and Spain. These countries submitted different degrees of answer for each category, which is indicated at the beginning of each subchapter. Furthermore, the percentages shown in the figures were calculated in accordance with the number of non-blank responses to each question, thus in the case of a blank question, the total number of complete answers was considered to calculate the percentages.

It should be noted that this survey only included the answers of few MS to attempt to have a picture of the eP/eD and PS context in EU and the respective impact on the implementation of UNICOM. Therefore, it should be promoted a more thoroughly analysis of the EU context so that the scale-up of ISO IDMP adoption in EU and other countries can be achieved in a more effortlessly manner.

7.4.1 ePrescription / eDispensation

To analyse the eP/eD current development situation in Europe, 22 questions were elaborated for the questionnaire. We received answers from 17 countries (Austria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Slovak Republic, Spain and Sweden), with different levels of completeness. As mentioned previously, only complete answers for each question were considered, which is indicated in the analysis.

According to the overall results, there was a 50% response rate (17 out of 27 EU countries), which is considered high/excellent result. A high response rate is driven by high levels of motivation to complete the survey or a strong personal relationship between the UNICOM project and the countries. Therefore, these results indicate that there is good collaboration between D5.1 and individual countries recognising the importance of the survey

The majority of the respondents (82%, 14 out of 17) declared to have electronic Prescription (eP) in operation (Figure 6a). The remaining three countries, one (France) is currently in the pilot phase, and two (Austria and Germany) plan to pilot or have in operation in the next five years. Therefore, these results indicate that the eP system presents a high level of implementation among the responders. Many of the countries favour National implementations (Figure 6b), however, some variances occur, for example Spain (with 18 regions) has a mix of National/Regional systems with varying maturity levels. The majority of responders (14 out of 17) have eP/eD solutions that provides integration capabilities between their eP systems and other systems (e.g. a system between a selected hospital and pharmacies) and most of the countries allows eP service at cross-border level (11 out of 17). It can indicate a more advanced development and alignment of the eP systems among the countries through the

CEF eHDSI cross-border services. Additionally, most countries (80%, 13 out of 17) with eP/eD in use have mature systems in place, with more than 80% of all prescriptions being **electronic**. **Netherlands** stated to have between 50% and 80% of eP over all prescriptions, indicating that this system is in expanding phase. In France, eP is used on a limited basis as a pilot project (<20% of all prescriptions are electronic). Thus, ISO IDMP solution could potentially improve the expansion/implementation process and facilitate the future interoperability on cross-border context.

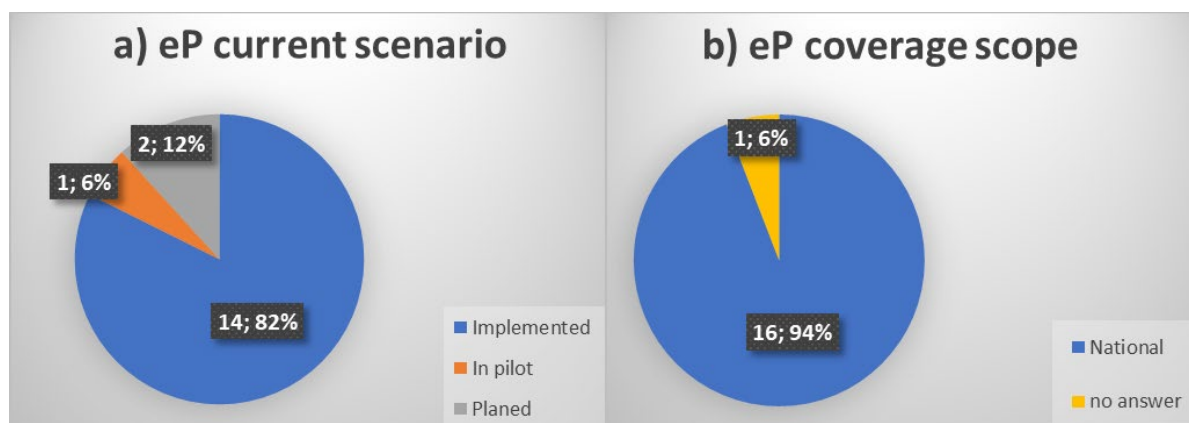


Figure 6: eP solution among 17 European countries.

On the Figure 6 a) Current state of eP implementation. Implemented; In Pilot: pilot stage; Planned: planned as a pilot or full-scale project in the next five years; No: not implemented b) eP coverage scope among the responding countries.

The Figure 7 a) and b) summarizes the care settings that use the national / regional / local eP and the professionals in these care settings. It is important to note that the countries that answer, have the service “in pilot” or “planned” are considered in the analysis.

These results indicate that most prescriptions are written in a community setting providing healthcare as opposed to acute hospital level as expected.

Concerning the Care Settings (Figure 7a), other answers were considered. For instance, Cyprus referred for all physicians that participate in their newly established reimbursement health system, and Czech Republic states that eP is mandatory to all types of HP, and thus it is used in their respective care settings. Moreover, Finland referred Social services, Italy and Poland mentioned certain outpatient departments, and Sweden denotes Veterinarian practices. Regarding other HP in Figure 7b) feldshers, midwives, doctors' assistants (Poland), veterinarians (Sweden), and podiatrists and physiotherapists (Spain) were also considered as other users of eP service.

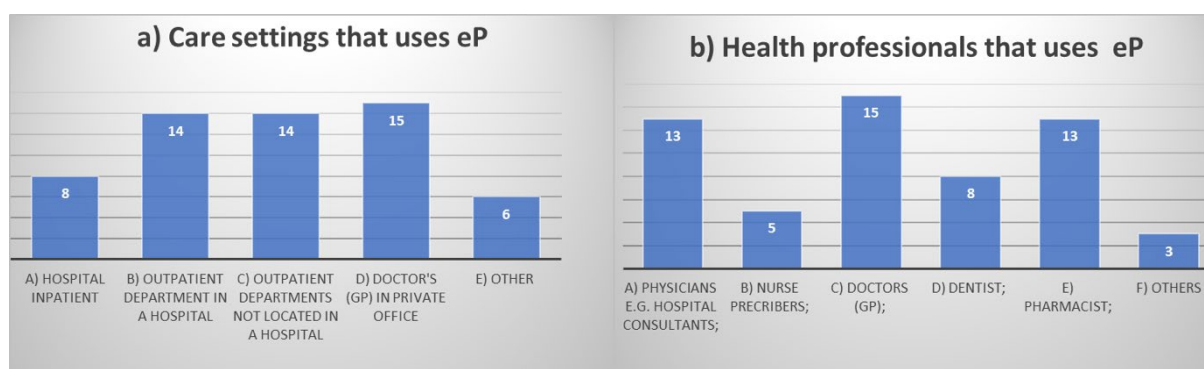


Figure 7: Use the eP a) on the Care settings and b) by the health professionals among the responders.

According to the survey responses, there is a legal obligation in a majority of the countries on HP (both prescribers and pharmacies) to use eP/eD systems and the data suggests there is a high level of usage of electronic systems (70%, 12 out of 17). However, France, Germany, Ireland and Sweden reported that there is no legal obligation for prescribers to use the eP system. Thus, it is important to further analyse the regional differences among the European countries. As for pharmacies, only France, Germany and Ireland reported that there is no legal obligation for pharmacies to accept eP.

Contraindication is a patient characteristic that may suggest that the patient is at an increased risk of experiencing a bad outcome if given a certain drug or combination of drugs. The data indicates that 41% (7 out of 17) of countries have the functionality to record contraindications, of which 71% (5 out of 7) capture contraindications in a structured format and consequently can be used for data analytics insights. Patient safety is fundamental to delivering quality essential health services. It aims to prevent and reduce risks, errors and harm that occur to patients during the provision of health care. In light of this, the statistic of 41% would seem low and serious consideration should be given to identifying opportunities to improve this scenario.

An adverse event is an incident that results in harm to the patient. Adverse drug events are one of the most common preventable adverse events in all settings of care, mostly because of the widespread use of prescription and non-prescription medications. For the responders that are capturing additional information about the medicinal product, the data suggests a consistent approach to collecting information about but not limited to contraindications and adverse events. In addition to these, other relevant information such as educational notes, patient allergies, age related dosing, gender specific medications and drug interactions are also collected. There needs to be a common approach to the capturing of additional pharmacovigilance information requirements to ensure a standardised approach to patient safety across the different MS and other countries.

While medications can improve patient's health, the process of prescribing is complex and error prone and medication errors may cause preventable injuries. The systems with Clinical decisions support can improve patient safety and lower medication related costs. 71% (12 out of 17) of responders have Decision Support System (DSS) functionality in their eP/eD systems. While acknowledging that this is a very significant number, statistically the goal should be to achieve 80%. Additionally, 82% (14 out of 17) of responders reported to used advanced functions on their eP/eD systems. Most of these were noted as for reimbursement services specific to the MS.

Falsified medicines include those medicines with little or no active ingredient, with the wrong active ingredient, fake or tampered packaging and those where products and/or packaging that have been stolen or reused for sale. 53% (8 out of 17) of respondents use protocols for tracking falsified medicines. Of that only 3 countries (Finland, Ireland, and Portugal) reported using the Falsified Medicines Directive as the protocol in use, (3 others did not respond as to the protocol used and 2 others used different protocols)

Figure 8 shows the critical pieces of prescribing information required to dispense a prescription or provide substitution safely. As it can be observed, active substance, dose, dose form and strength are the most critical pieces of prescribing information required to dispense a prescription or provide substitution safely. These attributes fit well with ISO IDMP mapping initiatives and offer significant benefit to healthcare providers in different MS when dispensing or smart selection of medication.

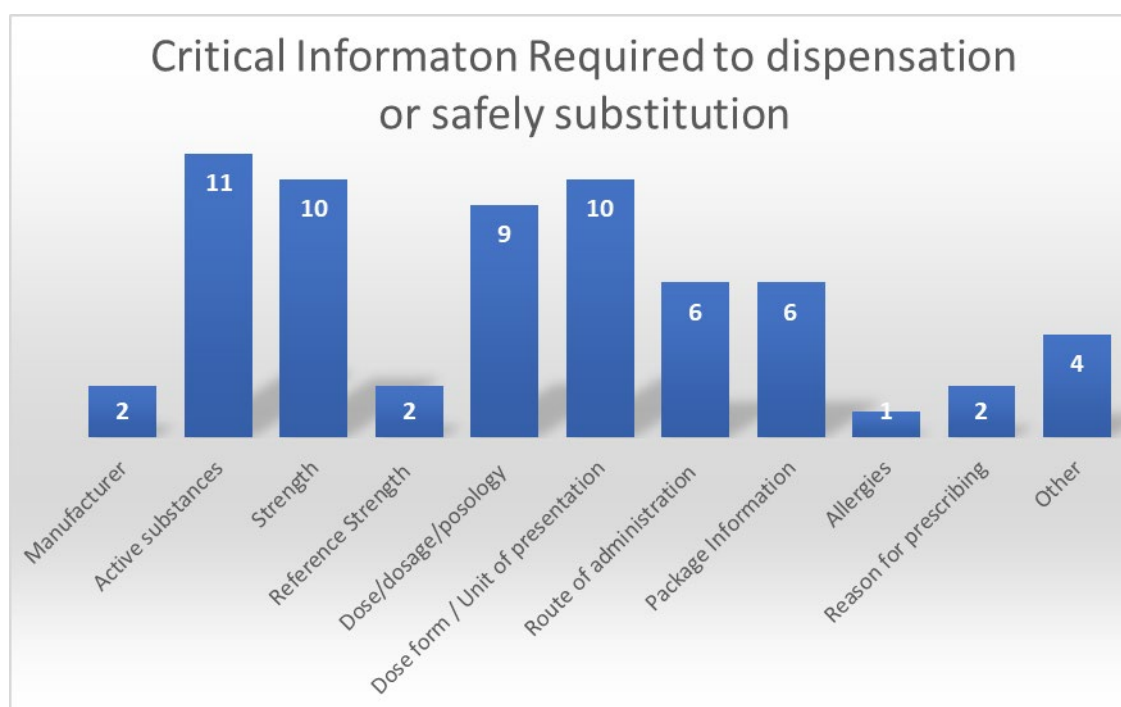


Figure 8: Critical pieces of prescribing information required to dispense a prescription or provide substitution safely.

Considering the coding systems for identification of medicines (i.e. drug codes) 14 countries have highlighted which codes are currently in use or planned. The Anatomical Therapeutic Chemical Code (ATC) is an active ingredients classification system controlled by WHO¹⁹. This code is widely used among the countries and by the CEF eHDSI eP/eD services. Most countries (10 out of 14, and planned by 2) reported to use this code system on the national prescriptions, related with the cross-border scenario, 5 countries reported to use this code and 6 planned to use in the future. This code is mapped with the national product dictionary in 6 countries and Ireland intends to map this coding when their national code system is created. Only Spain uses SNOMED CT coding system in their national prescriptions system, while Ireland is planning to use it at national and cross-border levels, Cyprus at cross-border level and Italy uses this code limited to their MVC. The national drug coding system is used by 10 countries (planned by 2) at national level, 3 countries (planned by 5) at cross-border level, however only 3 countries mapped their national code with the national product dictionary. Additionally, 5 countries stated to use a 'National product' cluster or classification', the presence of this drug classification system can support the health professional in a substitution case. Other drug codes were used by 6 country responders, and these codes intend to support the current drug codes used on prescriptions/dispensations at national and cross-border levels. The knowledge about these codes is fundamental to UNICOM to ensure the interoperability between the current eP system and the adoption of ISO IDMP.

The products' information that the eP system is able to provide was also analysed. Figure 9 shows the product information format in the eP system. As it can be observed, all responders (13) reported to have a defined format (unstructured/textual or structured coded/quantified) for the attributes "active substance", "strength", and "dose form/unit of presentation", which correlates with Figure 8, since these attributes were also identified as critical pieces of

¹⁹ https://www.whocc.no/atc/structure_and_principles/

prescribing information required to dispense a prescription or provide substitution safely. Thus, these attributes have a more matured level of development in the eP system.

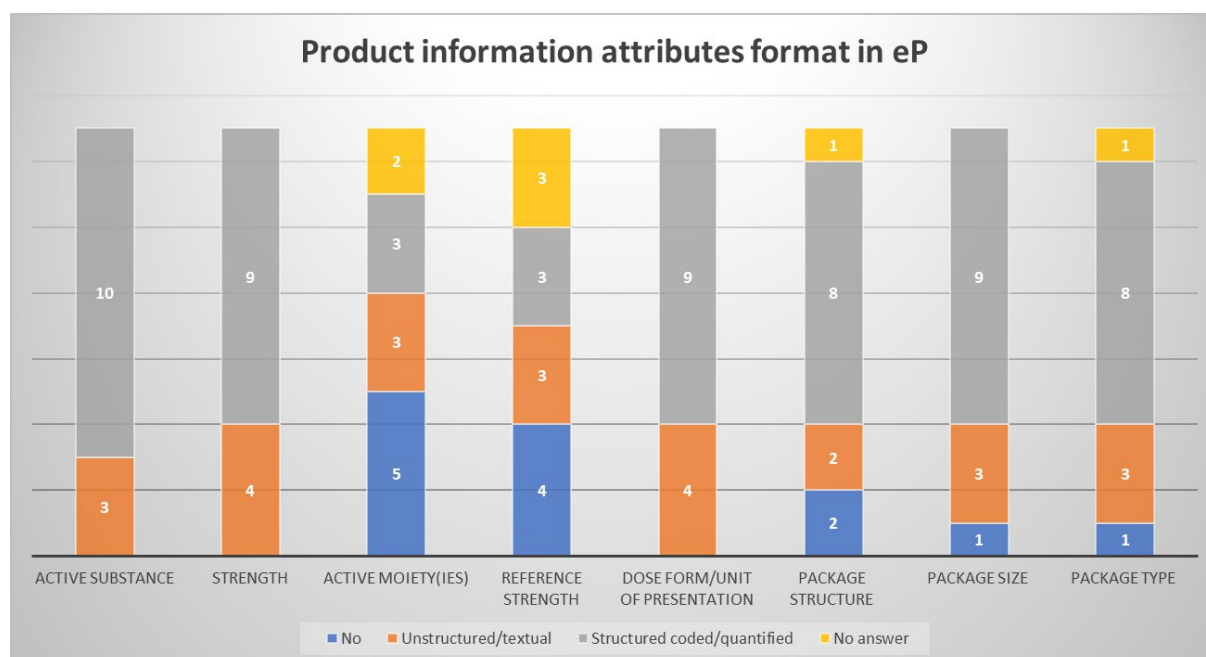


Figure 9: Type of format for each product information attribute (X axis).

Considering the situation where the attribute is structured coded/quantified, countries indicated the following information about which code system they are using:

- ▶ **Active substance:** local (Austria, Norway), ATC (Estonia – but not for all ingredients, Greece), national code system (Finland, Portugal), SNOMED CT (Spain).
- ▶ **Strength:** UCUM (Austria), partly structured, textual form for more complicated strengths (Finland), UCUM / EDQM (Italy), local (Norway), SNOMED CT (Spain).
- ▶ **Active moiety:** National code system, the same as for active substances (Finland), local (Norway), SNOMED CT (Spain).
- ▶ **Reference strength:** UCUM (Austria), SNOMED CT (Spain).
- ▶ **Dose Form/Unit of presentation:** Local (Austria, Norway), EDQM (Czech Republic, Italy), national code system (Finland), SNOMED CT (Spain).
- ▶ **Package structure:** Local (Austria, Norway), two fields: number of inner packages (e.g. 3 vials), size of one inner package (e.g. 5 ml) (Finland), UCUM / EDQM (Italy), national code system (Portugal), SNOMED CT (Spain).
- ▶ **Package size:** UCUM (Austria), two fields: number of inner packages (e.g. 3 vials), size of one inner package (e.g. 5 ml) (Finland), UCUM / EDQM (Italy), local (Norway), national code system (Portugal), SNOMED CT (Spain).
- ▶ **Package type:** Local (Austria, Norway), EDQM (Czech Republic), national code system (Finland, Portugal), UCUM / EDQM (Italy), SNOMED CT (Spain).
- ▶ **Others:** Finland referred that in cross-border eP, they map national code systems for dose forms and package types to EDQM; also, there is mapping to UCUM; Ireland indicated that the current solution is a Mail Box solution, there is no structured content within the eP mail. The above sections will be mapped as appropriate when the fully fledged national eP service is implemented.

When specified, most countries indicated this system is based on original information, which will impact the ISO IDMP implementation and thus, it should be carefully analysed for the successful adoption of ISO IDMP.

These code systems are interlinked with the answers provided previously for the coding systems for identification of medicines showing a structuration of the information of drug identification that can support the ISO IDMP implementation.

Concerning the standards currently employed to support eP, HL7 standards (HL7 messaging (5), HL7 CDA (11), and HL7 FHIR (3)) were found to be the preferred standards for interoperability). Among the responders 7 MS uses more than one version of HL7: Finland, and Ireland use the 3 HL7 standards versions specified; Czech Republic used HL7 CDA and other (national standard); Estonia, Netherlands and Spain use HL7 messaging and HL7 CDA; and Italy uses HL7 CDA and CDA L3 for EHR, and proprietary format for eP. Additionally, Sweden mentioned the SOAP message, SOAP API, ENV 13607 system, and Andalusia region of Spain XML in addition to above-mentioned systems reported by Spain. The preferential use of the HL7 standards can facilitate the creation of the software connectors in order to support the adoption of ISO IDMP among the countries, however the identification of different standards is important to create specific connectors for the countries that do not use HL7 standards, ensuring the implementation of ISO IDMP in these countries.

Regarding the standards used for sharing eP/eD information, 9 countries provide information which varied among them. For instance, Finland reported to use HL7 messaging (v3) for Kanta services and IHE XDS following the eHDSI specification for cross-border use, and FHIR is upcoming. Moreover, Ireland mentioned to have implemented an XDS infrastructure to support national eP integration and exchanging eP/eD on cross-border (eHDSI), but the fully fledged national eP service has yet to be implemented. Italy reported to use IHE X* for EHR, and proprietary protocols for the eP services, while Netherlands uses AORTA_LSP. Moreover, Poland reports that there is a national interface between Central eP system and pharmacies' systems and between Central eP system and medical facilities. Finally, Portugal and Sweden report to use SOAP services and message, and Spain IHE.

A central repository system was found to be the preferred system for transferring information, with 15 out of 17 respondents using this type of system, however 7 countries use more than one system. The mobile applications can be seen as a complementary tool. If this is indeed the preferred system, it may be necessary to provide MS with the appropriate standards and profiles for a central repository that provides the efficient and effective transfer of prescription information.

Greater than 80% (15 out of 17) of responders have the capability to share eP electronically on a National basis to a pharmacy. Italy and Spain deliver healthcare at a regional level and the analysis indicates that both countries can share eP electronically at regional/local levels. Additionally, 7 out of the 16 respondents are capable of cross-border transfer of eP - national system in country A to foreign system in country B, while only 3 countries can transfer eP from a regional/local system in country A to foreign system in Country B (Czech Republic, Estonia, and Greece). Moreover, 7 out of 17 countries reported to be possible a cross-border transfer of an eDispensation report national system in country B to national system in Country A.

Concerning the accessibility to information about previously prescribed medications, the analysis of the data indicates that the prescribers have good visibility about the dispensed medications compared to pharmacists and patients (Figure 10). Perhaps further analysis is required to determine what functionality exists and what additional functionality is required at a national level in respect of previously dispensed medication to improve these figures.

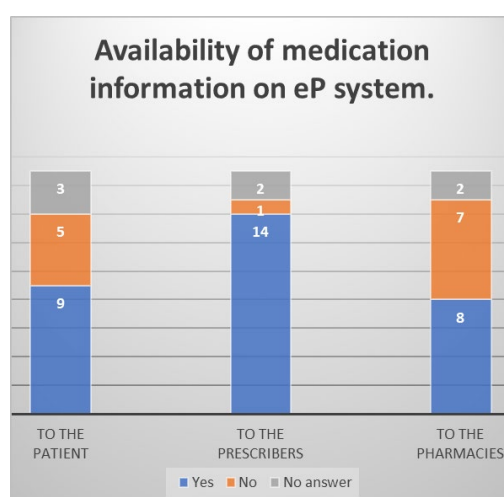


Figure 10: Availability of the history medication regarding the actor.

The authentication mechanism for eP services varies among countries and users (Table 6), but National Identification methods and/or Smart cards are the preferred choice. Table 6 shows the answer of each respondent in detail and can be used for a more comprehensive analysis. The electronic authentication mechanism of the HP and patients is a very relevant subject that attracts attention of several entities, since it ensures the correct and secure identification of HP and patients among EU.

Table 6: The authentication mechanisms for eP services.

Countries	Physicians / Pharmacists	Patients to obtain information on previously prescribed drugs	Patients in the pharmacy to obtain their medication
Austria	National ID	National ID	National ID
Cyprus	Username and password, via secure line	Does not exist in cross-border health care	National ID card number
Czech Republic	Qualified certificate	National Identification Authority (NIA)	Unique identifier of the prescription or identity ID card
Estonia	ID-card or Mobile-ID	ID-card, Mobile-ID or smart-ID	ID-card or a passport (and if getting the prescription for someone else, the buyer needs to present their own ID and the prescription owners ID code)
Finland	Smart cards, for which there is a national system.	National e-Identification system (Suomi.fi) which supports bank- ID, mobile-ID, and smart cards.	Personal identifier. "Hidden" prescriptions can only be dispensed with the bar code on the patient information sheet.
Greece	National eP System Registry credentials.	N.A.	National ID, Unique Prescription Identifier (barcode)
Ireland	National ID	N/A	Public Patients: Medical Card (GMS Scheme) Private Patients: National Form of ID
Italy	HP smart card, SPID (the Italian Digital Identity, eIDAS compliant)	Citizen smart card, OTP, SPID (the Italian Digital Identity, eIDAS compliant),	Citizen identifier (Tax code) + eP Number
Netherlands	National ID (UZI -ID)	DigiD (national Digital ID)	BSN (national ID, one- time verification at pharmacy)

Countries	Physicians / Pharmacists	Patients to obtain information on previously prescribed drugs	Patients in the pharmacy to obtain their medication
Poland	Login + password is generally used in the doctors'/pharmacists' systems. Also, there are additional authentication and authorization in the Central eP Repository while receiving/providing e-P and/or e-D (depends on the context)	Possibility to check in Online Patient Account and in the mobile app (planned)	Identity of the patient is not checked in the pharmacy only the age is checked specifically for children. In order to obtain medicines from the ePs are required code+PESEL (national ID number) or key of ePs
Portugal	Smart Card (citizens card + professional order card) and Mobile keys. For the pharmacist user and password authentication system.	Smart Card (citizens card) and Mobile keys.	prescriptionID + dispensation access PIN (available only to the patient)
Slovak Republic	EHIC	National ID	National ID
Spain	e-signature	N.A.	National ID
Spain - Andalucia	Pharmacist use a digital certificate stored in a smart card plus a user and password. Additionally, only access from specific IP address is allowed. Physicians access the system through a user and password in a secure intranet environment."	Digital certificate, authentication through identity provider (National eID Cl@ve) that allows OTP or digital certificate	Regionals Health Card that may include national health ID (codsns) or national ID only for Andalucians in their own region.

N.A.: No answer; N/A: Not applicable; NIA: National Identification Authority

Interestingly, 65% of the respondent' avail of smart selection in line with Pharmaceutical advice protocols. Thus, ISO IDMP provides an opportunity to improve the information provided to HP's to safely dispense a smart selection when necessary.

Of the countries (13) that completed the question regarding the information about the dispensation that is currently recorded, nearly all reported to record pharmacy details, date of dispensation, medicinal product dispensed, substitute medicinal product dispensed (if any) and quantity (Figure 11). Only 3 responders referred to recorded other information, Poland record more details as the number of prescription, medicinal product details and info regarding the identification of the patient and pharmacy, Portugal record information about the price/reimbursement and Spain the product ID. The consistency of the results provides a good foundation for quality initiatives that offer greater visibility regarding dispensation in different countries. This would suggest that there is scope for a minimum dataset requirement for dispensation that could be used by all MS's on their eP/eD systems. Therefore, ISO IDMP is key to this transformation.

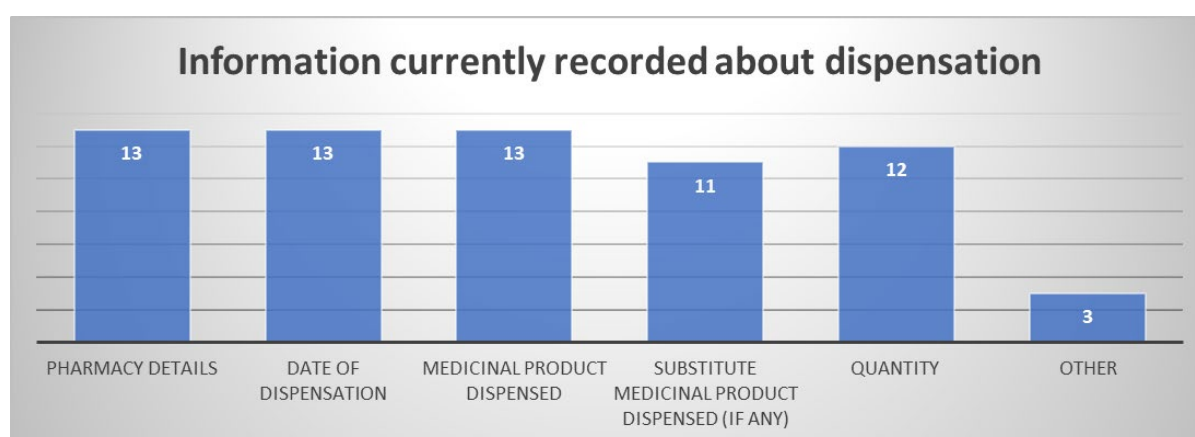


Figure 11: Information currently recorded about the dispensed medicines among the responder countries.

7.4.2 Patient Summary

It was proposed 13 questions in the questionnaire regarding the Patient Summary implementation. We received responses from 14 European countries (Austria, Cyprus, Czech Republic, Estonia, Finland, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Slovak Republic, Spain and Sweden) and with it, is possible to have an initial picture about this service among Europe.

The large majority of the respondents declared to have electronic PS in operation (Figure 12a), and only one (Austria) stated to have PS “not used and not planned in the next five years”. Ireland and Cyprus are currently piloting, while Finland and Estonia plan to pilot or to have in operation PS in the next five years. Therefore, there are still different levels of PS implementation across EU.

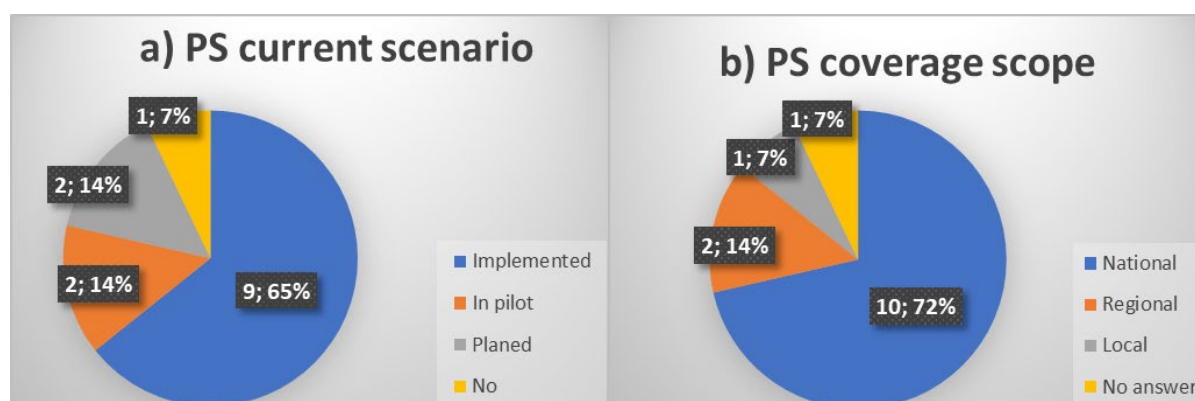


Figure 12: Patient summary solution among 14 European countries.

On the Figure 12 a) Current state of PS implementation. Implemented; In Pilot: pilot stage; Planned: planned as a pilot or full-scale project in the next five years; No: not implemented b) PS coverage scope among the responding countries.

Most of the countries having, or planning to have PS, declared to have *National* Patient Summary. While Ireland (2 regions) and Spain (18 regions) stated to have *Regional* PS covering the full region. Only Czech Republic implements *local* Patient Summary solutions (Figure 12b).

With the exclusion of Estonia, Norway and Cyprus²⁰, all the other have or plan to have their PS solution integrated with other systems in their countries; but all excluding Norway allow/will allow for cross-border exchange. Additionally, 4 countries allow for both, automatic and doctors PS updates; 5 for only doctors' updates; and 5 for automatic only. Spain, Sweden, Netherlands and Czech Republic have a PS coverage higher than 80% of population; while the rest remains under the 20%, and Estonia intends to reach more than 80% of coverage after the implementation (no answer from Norway). It shows that the PS solution is in the process of maturing their service in most countries. So, a solution as ISO IDMP could improve this process and facilitate the future interoperability on cross-border context.

Regarding the clinicians are legally obliged /controlled to use electronic PS 6 over the 9 countries that have PS services in place answered affirmative, with Netherlands, Norway and Portugal being the exceptions.

The Figure 13 a) and b) summarizes the care settings that use the national / regional / local PS and the professionals in these care settings. It is important to note that the countries that answer, have the service “*in pilot*” or “*planned*” are considered in the analysis.

Regarding the Care Settings (Figure 13a), other answers were considered. For instance, Finland considers “all care settings” for the PS implementation on upcoming years; Ireland refers as “The intention is for it to be used in an unscheduled care setting first and then scale to encompass all other scenarios” for the piloting PS; Italy uses at “Emergency departments”; Portugal uses PS to “Doctors (Public Service)”; and Sweden to “Local care at municipalities”. Regarding other Health Professionals in Figure 13b “Secretaries/local administrators” and “Nurses” were considered in the cases of Sweden and Portugal, respectively.

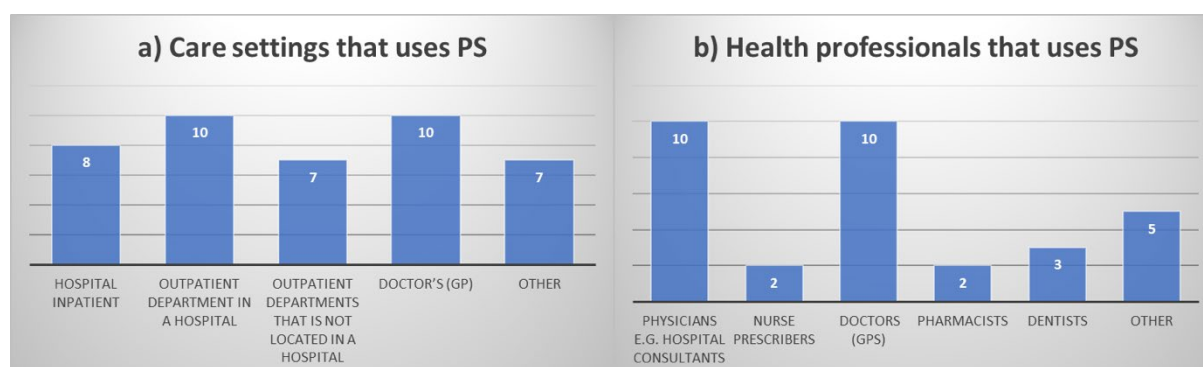


Figure 13. Use the PS a) on the Care settings and b) by the health professionals among the responders.

For all those providing an answer (12 out of 12), the coding systems (i.e. drug codes) in use in their countries to identify the medicinal products in the PS are the same used for the eP (see the previous section for more details). Similarly, the products information that the eP system is able to provide was also found in this case to be the same as for PS in all of those that provided an answer (11 out of 11). These data present a strict relation between the eP and PS services on the European countries. This relation could facilitate the ISO IDMP implementation among the Europe since both services share the same semantic base.

Concerning the existence of a patient adverse item in the PS, only 5 countries indicated to have implemented this functionality with 2 using structured format and 3 with free text. 5 countries declared that the functionality is not implemented, and 1 did not know the answer at the moment that they responded the survey.

²⁰ Here and hereafter Austria will not be considered declaring not to have or planning to have a PS in the 5 next years.

Regarding the architecture of the PS, 9 countries transfer the PS to a central repository that can be national, regional or local. In term of architecture overview, 1 of the countries explained that the PS is available on mobile applications, 2 as a document sharing and 2 by controlling hubs. In total, 12 countries responded to the question which means that 5 countries provide two answers (e.g. central repository and document sharing).

In term of standards that support the Patient Summary, 9 of them use HL7 CDA, 5 use HL7 messaging and 4 use HL7 FHIR. Among the responders 5 MS uses more than one version of HL7, Finland, Ireland and Sweden use the 3 HL7 standards versions specified, Portugal uses HL7 CDA and FHIR and Spain HL7 messaging and HL7 CDA. It is noteworthy that Slovak Republic is using EN 13606 standard and Czech Republic uses HL7 CDA and the national standard messaging format DASTA v4. Among the 8 respondents, 5 of them answered that they are using XDS/IHE services to share PS. The 3 other countries use messaging service and Sweden uses an eService (central IT organization form), but they did not provide more information about the infrastructure.

Regarding the accessibility of the information about medicinal products in PS, most of the countries answered that this information is available for consultation by the patient (12 out of 13), clinicians (13 out of 13) and 3 countries complemented the answer as “other” option that could be “any authorized person that the patient gives permission”, or “social services”. Among the countries, there is a different information captured related with the use of medicinal products, that can be viewed on the table 7. These elements could be important to be present in an emergency situation on a national and cross-border context.

Table 7: Medicinal product information accessible using the PS service.

Medical product information	Number of responses
Vaccines	10
Allergies to drug	10
Medication history	11
all	4
5 years	1
last year	1
Current active prescription	8
Adverse events	4
Other	3*

**not related to the medicinal products*

Regarding the identification / authentication mechanisms that are in place for the access to the PS, 10 respondents answered this question (Table 8). As it can be observed, the mechanisms to access PS at the national and cross-border levels vary across countries, and between HP (physicians) and patients. For instances, several countries reported the use of national ID for both physicians and patients, but others reported the use of a specific username/password via a secure website and the use of smart cards. Some countries also reported the possibility to use more than one system (e.g., bank ID, mobile ID, or smart cards) or a combination of more than one system. Moreover, Cyprus reported that the PS access is not available at this moment

for patients, and Estonia reported the PS is only available for patients in the cross-border context (in country B). Interestingly, in the cross-border level some countries stated that the PS access is determined according to the specifications of country B. Table 8 shows the answer of each respondent in detail and can be used for a more comprehensive analysis. The electronic identification of HP and patients is a very relevant subject that has been discussed by key EU bodies in order to ensure the correct identification of the HP and patients among EU.

Table 8: The identification / authentication mechanisms for physicians and patients to access the PS services on national and cross-border levels.

Countries	Physicians		Patients	
	National	Cross-border	National	Cross-border
Austria	National ID	National ID	National ID	National ID
Cyprus	Username and password via a secure website	N.A.	Not available yet	Not available yet
Czech Republic	NIA	Depends on country B	NIA	NIA
Estonia	ID-card or mobile-ID	N.A.	National patient portal, but PS is only available for cross-border situations. It is accessible via ID-card, mobile-ID or smart-ID	Patient portal is accessible via ID-card, mobile-ID or smart-ID. For patients to see their PS in foreign countries they need to provide the documents needed by the other country (most commonly ID-card or passport)
Finland	Smart cards, for which there is a national system	Defined by Country B. If Finland is Country B, smart cards, for which there is a national system	National e-identification system, which supports bank ID, mobile ID, smart cards	The same patient portal My Kanta works also abroad. See the previous answer
Greece	eP System's Registry credentials	eHDSI NCPeH service.	Greek Primary Health Care or Tax Systems' credentials.	Greek Primary Health Care or Tax Systems' credentials.
Ireland	National ID	As per eHDSI specifications.	National ID	A combination of 2 factor authentication is planned.
Italy	Smart card + PIN, SPID (National Digital Identity eIDAS complaint)	Smart card + PIN, OTP, SPID (National Digital Identity eIDAS complaint): when the HP acts as Country B HP. No requirements on	Smart card + PIN, SPID (National Digital Identity eIDAS complaint)	Citizen ID (Tax Code) + digits from the EHIC N.A.

Countries	Physicians		Patients	
	National	Cross-border	National	Cross-border
		HP B, to access the Italian citizens PS		
Netherlands	National ID (UZI-nr)	N.A.	DigID (National Digital ID)	N.A.
Portugal	Smart Card (citizens card + professional order card) and Mobile keys.	Smart Card (citizens card) and Mobile keys.	National ID (based on certificates)	National ID (based on certificates)
Sweden	Nationally level electronic ID card with organisational certificate	Not yet decided; based on the eHDSI/PS NCP supporting functions for authentication; need to be integrated to the national PS authentication and access control mechanism i.e. to control access to specific patient and data sets	Patients access their EHR PS data using another e-service application based on the same infrastructure as the PS; i.e national ID techniques supported today: Bank-ID, Mobile Bank-ID, Telia e-leg, Freja eID Plus, Foreign eID	Same as before, using some national eID or Foreign eID
Spain - Andalucia	N.A.	Regional Physician ID	National eID	National ID / National (Regional) Healthcare Card

NIA: National Identification Authority. N.A.: No answer.

7.4.3 Legal framework

Nine MS have answered the survey regarding the eP and PS legal framework, with different degrees of completeness. In the case of a blank question, the total number of complete answers was considered to calculate the percentages. As it can be observed in Figure 14, 78% (7 out of 9) and 50% (4 out of 8) of responders have legislation already implemented that cover the eP and PS services, respectively. It shows that the eP legislation is more advanced in comparison with the PS, probably due to the time of implementation of these services in each MS. In this sense, the PS legislation needs to be improved among the MS responders in order to achieve the same level of maturity from eP. Importantly, 33% (3 out of 9) and 25% (2 out of 8) of responders identified constraints that may impact the adoption of new services regarding medicinal products identification, which may impact ISO IDMP implementation. For example, Netherlands reported that consent is mandatory, and the use of ID-number abroad is not allowed, so ID-check by organisation is not possible. This situation indirectly affects the implementation of ISO IDMP. Additionally, 56% (5 out of 9) and 75% (6 out of 8) of responders reported that specific national legislation is required for the implementation of a new standard on eP and PS, respectively, in their respective countries. This should be considered during the implementation of ISO IDMP, and close collaboration with stakeholders should be maintained in order to anticipate any further legal issue and find the best solution for each case.

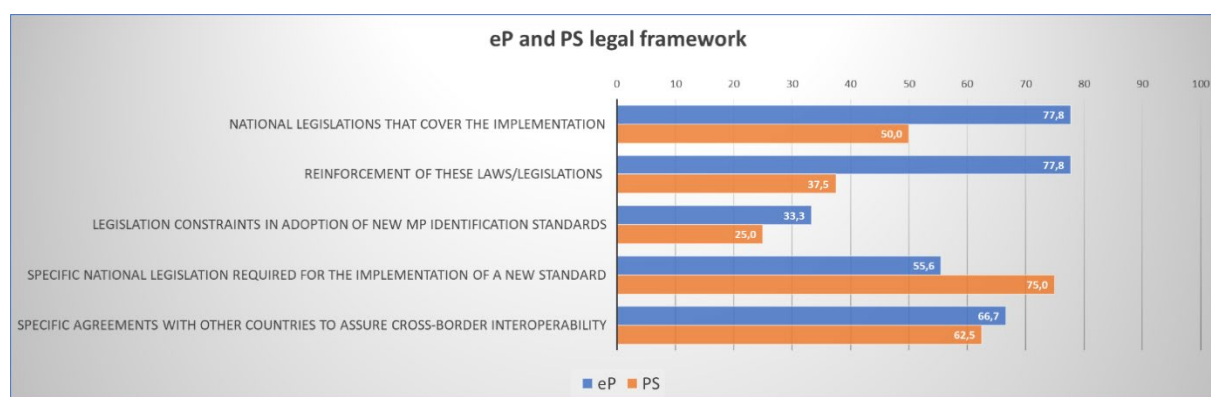


Figure 14: Percentage of positive answers obtained from the questionnaire regarding the eP and PS legal framework.

The complete questions (axis Y) used for the questionnaire can be found on Annex 3. Data was obtained from nine different MS. The percentages shown were calculated in accordance with the number of non-blank responses to each question. MP: medicinal product.

Considering the interoperability aspect, 67% (6 out of 9) and 63% (5 out of 8) (Figure 14) of responders reported possible agreements with other countries to assure cross-border interoperability for eP and PS, respectively. For example, three countries are developing multilateral agreements, while two are developing/considering bilateral agreements. These agreements include initiatives such as CEF grant agreement for eHDSI eP-A/eP-B and PS-A/PS-B services implementation, and the EC cross-border initiative.

Considering that UNICOM is an external data source initiative, it is relevant to analyse possible constraints in the enhancement of Medicinal Product Databases by Medicinal Products Dictionaries (MPDs) provided by external providers. Thus, the MS that answered this question indicated that it might be possible if it is approved by the competent entity. In most countries, the NCA (Drug Agencies) is responsible for providing the database to be used by the eHealth services, and in that sense, UNICOM has established a liaison with 11 NCAs (Drug Agencies that's participating in the project) among EU to ensure that the data provided by this project can be implemented properly in their respective countries. However, the certification of these enhancements is required at least in five MS, which in most cases is carry out by the NCA or equivalent entity.

8 Patient empowerment through UNICOM

Patient Empowerment (as defined by the European Patients' Forum (EPF)²¹) is a key element of patient-centred healthcare and is both a goal and a process that helps people gain control over their own lives and **increases their capacity to act on issues that they themselves define as important**. Aspects of empowerment include **health literacy, shared decision-making, healthcare information and self-management**. EPF frames patient empowerment as a relational concept where the environment, the patient finds themselves in, plays a critical role in the outcome.

Since the Use Cases in this document 5.1 - 1) cross-border ePrescription, 2) cross-border Patient Summary – and their Business Requirements are elaborated and oriented to the eHealth infrastructure of CEF eHDSI, the patient is a direct beneficiary of the services, but not the primary actor. Therefore, in order to address patient empowerment in these use cases, there is a need to first develop patient journey maps to better understand how the patient interacts with the various activities of the use case, their experiences within to ensure that the voice is understood and their needs understood. This activity will be carried out in alignment with WP8, specifically in Task 8.3 'IDMP and Patient Information Empowerment Apps' and subtask 8.3c 'Patient Use Cases in cross-border Pilots'.

Similar to how UNICOM Partner HSI (Health Services Ireland/eHealth Ireland) has done in previous related projects, we will develop a set of patient journey maps and personas tailored to the cross-border use cases of 5.1 to help explore and identify with citizens and patients what they consider to be important, problematic and working well. A suggested methodology would be to engage with patients, listen to their opinions, id key decision points where patients value engagement and id any gaps, obstacles and pain points that should be addressed. We are doing this in order to determine the requirements that empower patients in respect of cross-border use cases.

WP8 will lead this study by inviting EU citizens / residents who meet one of the following criteria:

- ▶ live outside their home country²² and may get medical care in more than 1 country;
- ▶ live near a border and may get medical care in more than 1 country;
- ▶ engage in international travel frequently (at least 3 times a year over the past 5 years) such as students, researchers, tourists and business professionals;
- ▶ engage in medical tourism

The above described target group is most likely to have already experienced such events and therefore can draw on first-hand experience when responding to survey or interview questions about their needs and values. Their participation will provide supporting evidence for patient empowerment considerations in UNICOM as a whole. The research methodology that will be applied for this study will include at least two of the following approaches:

- ▶ An online survey developed specifically for the target group to be distributed digitally to a wide range of EU citizens from different member states and demographics;
- ▶ A focus group composed of approximately 8-10 key actors in the target group (such as tourists, citizens travelling abroad for business, those who have travelled for medical

²¹ <https://www.eu-patient.eu/whatwedo/Policy/patient-empowerment/>

²² **Home country** means primary country of identity or residence (such as citizenship, member of national health system where the majority of treatments have been received over the course of life, mother-tongue language, country where the GP with his/her longitudinal EHR resides, and/or other factors to be later defined) Within the above described target group, our research aim will be to include the most balanced group of participants in terms of gender, age, socio-economic status (profession, family status, income, etc), health background and ethnicity whenever possible. For example, they may be healthy people or people with existing conditions and active medications. Minors under the age of 18 will not be included.

tourism, and a minority of clinical actors such as a pharmacist and a GP) who have had extensive experience in cases with patients and foreign medicine;

- ▶ Online research using social media channels to track events related to medical issues while travelling abroad (specifically related to medicines) and locate existing evidence on what citizens are reporting directly;
- ▶ Search relevant policy documents and grey literature on the subject of medication use in cross-border situations and provision of health services;
- ▶ Search and review of existing publications on the topic that are available online via PubMed and Google Scholar.

The results of this study will then be analysed using a combination of methods: (a) journey map/personas (b) business capability map (c) root cause analysis findings and (d) design thinking to provide a solid foundation for diagnosing the people, process and technology issues that underpin poor customer experience. Finally, recommendations for solutions and their implementation will be made in support of the design and development of patient-empowerment tools that can have the most impact on improving the patient journey and experience in the 5.1 use cases.

The recommendations will then be cross-referenced with the T8.3a Patient-Facing App survey results in order to evaluate how the UNICOM project and the implementation of IDMP might be able to best respond to the identified problem(s) and its root causes by contributing to the design and development of software tools for health literacy, shared decision-making and self-management.

It is critical to note that these tools will be designed and developed for providing additional support to the patient actor in the 5.1 use cases that can run in parallel to the CEF eHDSI infrastructure but do not require direct integration or interaction with the other actors. These tools are meant to compliment and support existing infrastructures, such as eHDSI, but not depend on them nor detract from their importance. They will empower the healthcare citizen which in turn will enrich the overall landscape of cross-border care from within the patient journey. They can serve as an added, optional safety-check to validate, from the patient standpoint, the contents of their ePrescription and Patient Summary (e.g. a crosscheck with the real world in the case that the Patient Summary was not complete, accurate or up-to-date) is correct. We will reference existing research on health literacy, such as applying the Ophelia (OPTimise Health Literacy and Access) framework²³ to patient use cases in terms of language and messaging to patients.

Some pre-study material has already been developed in WP8 in a document titled 'Helping traveling patients to deal with a foreign ePrescription' (document titled 'UNICOM foreign ePrescription use case V1.1' in Sharepoint-WP8 folder), which falls into the 5.1 Use Cases. The results and materials generated in this type of activity will be shared with WP5 partners, so they are able to be informed about and consider the patient voice and at the same time helping to align stakeholders in WP5-6-7-8. The details that will be teased out and/or addressed in the process, such as different needs (a Patient that has access to their Patient Summary from abroad vs. does not) and scenarios, may be useful for all stakeholders.

²³ Beauchamp, A., Batterham, R. W., Dodson, S., Astbury, B., Elsworth, G. R., McPhee, C., et al. (2017). Systematic development and implementation of interventions to OPTimise Health Literacy and Access (Ophelia), BMC Public Health pp. 1–18

9 Recommendations to adoption of ISO IDMP in EU

After analysing the business requirements, we propose some initial recommendations in order to ensure the development of the project and facilitate the process of adoption ISO IDMP on the eHealth services. This is the first version of the document that will be updated on the end of the project, and then it will present more concrete and direct recommendations.

- ▶ Ensure a strict cooperation with the EU key bodies and NCAs to facilitate the ISO IDMP adoption in eHealth services

9.1 Organisational/Service

- ▶ Defining the services for product identification, and providers to implement those services
 - Master data exchange and synchronization across borders
 - Product matching and lookup by identifiers and attributes
- ▶ Guarantee open access to the terminology resources or other resources if needed

9.2 Functional

- ▶ Support cross-border exchange as a complement to national product identification
- ▶ Define the IDMP set of identifiers and attributes that can be added in a ePrescription
 - Ensure that cross-border documents (e.g. ePrescriptions) can include these attributes
 - Ensure these attributes have a consistent (or at least compatible) vocabulary across borders
- ▶ Guarantee access by authorised professionals to necessary documents or product data across borders (besides prescription)
 - Identify and harmonise access control constraints and rules
 - Use product classification to support access control (e.g. narcotics or psychotropic medication)

9.3 Semantic

- ▶ Establishment and governance of consistent/universal information models / ontologies (i.e. ensure that attributes have the same meaning) for
 - ▶ Product master data
 - ▶ Prescription data
 - ▶ Patient summary data
- ▶ Adoption of appropriate technical terminologies for the relevant attributes

9.4 Technical

- ▶ Development of technical standards by SDOs:
- ▶ Inclusion of all needed information (according to the models established) in clinical documents (i.e. extend CDA documents etc to support the attributes deemed important)
- ▶ Development of standard mechanisms to exchange Reference Data (terminologies) and Master Data

Annexes

Annex 1 – Non-exhaustive list of elements to be included in medical prescriptions (Directive 2012/52/EU)

Headings appearing in bold in this Annex are not required to feature in prescriptions

Identification of the patient

- Surname(s)
- First name(s) (written out in full, i.e. no initials)
- Date of Birth

Authentication of the prescription

- Issue date

Identification of the prescribing health professional

- Surname(s)
- First name(s) (written out in full, i.e. no initials)
- Professional qualification
- Details for direct contact (email and telephone or fax, the latter both with international prefix)
- Work address (including the name of the relevant Member State)
- Signature (written or digital, depending on the medium chosen for issuing the prescription)

Identification of the prescribed product, where applicable

- 'Common name' as defined by Article 1 of Directive 2001/83/EC of the European Parliament and of the Council of
 - 6 November 2001 on the Community code relating to medicinal products for human use
 - The brand name if:
 - a) the prescribed product is a biological medicinal product, as defined in point 3.2.1.1.(b) of Annex I (Part I) to Directive 2001/83; or
 - b) the prescribing health professional deems it medically necessary; in that case the prescription shall shortly state the reasons justifying the use of the brand name
1. Dose Form (tablet, solution, etc.)
 2. Quantity
 3. Strength, as defined in Article 1 of Directive 2001/83/EC
 4. Dosage regimen

Annex 2 – eHDSI Requirements Catalogue

The following Table 9 presents the complete requirement list from CEF eHDSI²⁴ accessed on 23/09/2020.

Table 9: CEF eHDSI requirement catalogue

Title*	Target release	Document status
01. Ensure Health Professional (HP) Identification, Authentication and Authorization	W5-Release Candidate	DRAFT
01.01. Uniquely identify and authenticate the Health Professional (HP) in Country of treatment	W4-Operation Ready	DONE
01.01.01. Identification and authentication of a HP with a unique identifier	W4-Operation Ready	DONE
01.01.02. Identification and authentication of a HP using an internet portal	W4-Operation Ready	DONE
01.01.03. Identification and authentication of a HP using a local system	W4-Operation Ready	DONE
01.02. Authorize Health Professional (HP) according to assigned roles and profiles	W5-Release Candidate	DRAFT
02. Ensure Patient Identification	W5-Release Candidate	DRAFT
02.01. Uniquely identify the Patient	W5-Release Candidate	DRAFT
02.01.01. Identification and authentication of a patient	W4-Release Candidate	DONE
02.01.01. Identification and authentication of a patient with demographic data	W5-Release Candidate	DRAFT
02.01.02. Creation of the national patient and document search file	W5-Release Candidate	DRAFT
03. Create and apply policies and procedures to ensure trust between countries	W4-Operation Ready	DONE
03.01. Manage Incidents, Problems and Support services	W4-Operation Ready	DONE
03.02. Manage the changes to the cross-border services	W4-Operation Ready	DONE
03.03. Assess and validate the cross-border services	W4-Operation Ready	DONE
03.04. Education, training and awareness of the cross-border services	W5-Release Candidate	DRAFT
04. Ensure lawful processing of personal and health data	W4-Operation Ready	DONE
04.01. Identify the applicable legal basis for processing personal and health data within eHDSI	W4-Operation Ready	DONE
04.02. Identify the controller(s) and processor(s) of the personal and health data and their responsibilities	W4-Operation Ready	DONE
04.03. Inform data subjects about their rights as concerns the protection of their personal and health data	W4-Operation Ready	DONE
04.04. Ensure compliance of the eHDSI central services with the applicable data protection provisions	W4-Operation Ready	DONE
05. Make Patient Summary available to HP	W4-Operation Ready	DONE
05.01. Create the eHDSI Patient Summary content	W5-Release Candidate	DRAFT

²⁴ <https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/1.+eHDSI+Requirements+Catalogue>

Title*	Target release	Document status
05.02. Transcode, translate and exchange cross-border the Patient Summary	W4-Operation Ready	DONE
05.03. Display the Patient Summary to the Health Professional	W4-Operation Ready	DONE
06. Make ePrescription available to HP	W4-Operation Ready	DONE
06.01. Create the eHDSI ePrescription(s) content	W4-Operation Ready	DONE
06.02. Transcode, translate and exchange cross-border the ePrescription	W4-Operation Ready	DONE
06.03. Display the ePrescription to the Health Professional	W4-Operation Ready	DONE
07. Handle Dispensation of medicine and Substitution	W4-Operation Ready	DONE
07.01. Create the eHDSI eDispensation content	W4-Operation Ready	DONE
07.02. Transcode, translate and exchange cross-border the eDispensation	W4-Operation Ready	DONE
07.03. Inform Country of affiliation about the dispensed medicine	W4-Operation Ready	DONE
07.04. Option to discard a previously performed dispensation	W4-Operation Ready	DONE
08. Ensure high quality information (structured, equivalent, understandable) is exchanged between countries	W4-Operation Ready	DONE
08.01. Ensure structured and coded information is exchanged between countries	W4-Operation Ready	DONE
08.02. Ensure equivalent information is exchanged between countries	W4-Operation Ready	DONE
08.03. Ensure understandable information is exchanged between countries	W4-Operation Ready	DONE
09. Ensure the security, performance, traceability and auditability of the services, data and systems	W4-Operation Ready	DONE
09.01. Ensure confidentiality of the services, data and systems	W4-Operation Ready	DONE
09.02. Ensure the integrity of the exchanged data	W4-Operation Ready	DONE
09.03. Ensure service availability	W4-Operation Ready	DONE
09.04. Ensure and monitor service performance	W4-Operation Ready	DONE
09.05. Ensure traceability of the exchanged data	W4-Operation Ready	DONE
09.06. Ensure auditability of the exchanged data	W4-Operation Ready	DONE
10. Ensure the non-repudiation of the exchanged data	W4-Operation Ready	DONE
10.01. Handle the non-repudiation mechanism	W4-Operation Ready	DONE
eP/eD Use Case	W5-Release Candidate	DRAFT
eP/eD Use case diagrams	W5-Release Candidate	DRAFT
PS Use Case	W5-Release Candidate	DRAFT
PS Use case diagrams	W5-Release Candidate	DRAFT

*The titles contain a hyperlink to each requirement presented on this table.

Annex 3 – Questionnaire D5.1

Comparison of national eHealth Services [electronic Prescription (eP), Patient Summary (PS) services] and their respective legal base in EU countries

Introduction

UNICOM²⁵ – an EC supported Innovation Action - focuses on implementing the International Organization for Standardization (ISO) suite of IDMP (**I**dentification of **M**edicinal and **P**harmaceutical Products) standards. Work involves further development, testing, implementation, and diffusion of these standards, inter alia, for advancing cross-border digital health services, particularly ePrescription.

This survey on eHealth Services (electronic Prescription (eP) and Patient Summary (PS)) aims to gather information about the current state of national eHealth services in EU countries. The results of this survey will inform the UNICOM Business Requirements' report through the comparison of eP and PS activities in different countries.

For the purpose of this survey, the definitions of ePrescription and Patient Summary was extracted from the CEF eHDSI Glossary²⁶.

The concept of the **ePrescription** service is understood as the ordering of a prescription in software, the electronic transmission of that prescription from the Prescription provider to a Dispense provider, the dispensing of the medicine and the electronic transmission of the dispensed medicine information from the dispensing provider to the prescription provider.

Patient Summary is an identifiable “dataset of essential and understandable health information” that is made available “at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care”; it can also be defined at a high level as: “the minimum set of information need to assure Health Care Coordination and the continuity of care”.

Respondent Information

Name	*
Email address	
Role	
Organisation	
Country	*

* Obligatory fulfilment

Data Protection notice: In line with the requirements of the EU GDPR. We request that you leave us your information, so we can better understand your background and verify that you fit into one of the target groups of survey respondents, but please note that any response you provide in this Survey will be fully anonymised.

²⁵ <https://unicom-project.eu/>

²⁶ <https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Glossary>

ePrescription services questions

The purpose of this section is to understand the current situation regarding ePrescription developments in EU countries, its adoption and change of management requirements.

Q1. Do you currently have an ePrescription solution in your country?

- ☐ Yes
- ☐ In Pilot *(please answer the survey with the information about the pilot project)*
- ☐ planned as a pilot or full-scale project in the next five years *(please answer the survey with the information about the pilot project)*
- ☐ not used and not planned in the next five years

- Why ePrescription are still not established in your country or planned for the next five years? *(In this case and after leaving your answer here, please skip the following questions and go straight to Patient Summary questions.)*

Q2. If an ePrescription service is available in your country:

a) is the solution a: (please select only one of the following options)

- ☐ a national system (e.g. for most of/ the whole country)
- ☐ Regional

If yes, please indicate

How many different regions _____

Do they each cover the whole region

☐ Yes

☐ No.

- ☐ local (Individual pharmacy, local company / development)

b) Does this system allow for? (you can choose more than one option)

- ☐ Integration (e.g. a system between a selected hospital and pharmacies)?

If yes, please indicate

How many exist _____

Coverage (region/city etc) _____

- ☐ Cross Border

If yes, please indicate

In operation since: _____

Planned for: _____

Q3. How well established is the ePrescription service in your country?

- ☐ Well established (> 80% of all prescriptions are electronic)

- ☐ Widely used (> 50% and <80% of all prescriptions are electronic)
- ☐ Somewhat used (>20% to <50% of all prescriptions are electronic)
- ☐ Used on a limited basis as a pilot project (<20% of all prescriptions are electronic)

Q4. What care settings provide ePrescriptions?

- ☐ Hospital Inpatient
- ☐ Outpatient Department in a hospital
- ☐ Outpatient Departments not located in a hospital / Community health centres
- ☐ Doctor's (GP) in private office
- ☐ Other (please specify)

R: _____

Q5. What professionals use ePrescription solutions in these care settings? (you can choose more than one option)

- ☐ Physicians e.g. hospital consultants
- ☐ Nurse prescribers
- ☐ Doctors like general practitioners/family physicians or specialists in private office
- ☐ Dentists
- ☐ Pharmacist
- ☐ Others - please specify

R: _____

Q6. Are prescribers legally obliged / controlled to use electronic prescription systems?

☐ Yes; ☐ No,

if no please specify:

R: _____

Q7. Are pharmacies legally obliged /controlled to accept ePrescriptions?

☐ Yes; ☐ No,

if no please specify:

R: _____

Q8. Does the national/regional/local current ePrescription system have the functionality to record contra-indications?

- ☐ Yes
- ☐ Structured Content
- ☐ Free Text

- ☐ Other. *Please specify R:* _____
- ☐ No.
- ☐ Unknown

Q9. Does the ePrescription system have the ability to capture/display additional information about the medicinal product?

- **Contra indications** ☐ Yes; ☐ No, ☐ Planned
- **Adverse events** ☐ Yes; ☐ No, ☐ Planned
- **Other** ☐ Yes; ☐ No, ☐ Planned. (*please specify*)

R: _____

Q10. How are ePrescriptions transferred to a pharmacy for dispensation?

- ☐ Automatic **transfer from the** prescriber to a specified pharmacy
- ☐ Direct transfer **from the prescriber to a pharmacy nominated** by the patient (consent)
- ☐ **Central (national/ regional/local) repository** (receives prescriptions and transfers them on request to the dispensing pharmacy where the patient has identified itself)
- ☐ **Controlling hub** (the repository issues Identifiers for both prescriptions and dispensations and has “authorisation” functionality (based on business or clinical rules or both). The prescription must “request” authorisation before it can be issued.)
- ☐ **Index repository** (the repository holds information about all prescription and dispensation messages that have been sent/received in its jurisdiction and can be queried for this information)
- ☐ **Mailbox-like solution** (data delivered to an actual pharmacy)
- ☐ **Mobile applications**, *please specify:*

R: _____

- ☐ **Other**, *please specify:*

R: _____

Potential interoperability of EU solutions questions

The purpose of this section is to understand the current situation regarding technical solutions and the opportunity for cross-border interoperability

Q11. Can ePrescriptions be shared via the electronic system to a pharmacy? (you can select more than one option)

Definitions:

Country A: Country of patient affiliation, where the ePrescription is issued.

Country B: Country of treatment.

- ☐ In the same country (national system)
- ☐ In the same country (regional/local system to regional/local system)
- ☐ Cross-border transfer of ePrescription – national system in country A to foreign system in Country B
- ☐ Cross-border providing ePrescription – regional/local system in A to foreign system in Country B
- ☐ Cross-border transfer of an eDispensation report – national system in country B to national system in Country A

Q12. Considering the ePrescription system from your country:

- a) What are the coding systems (i.e. drug codes) in use in your country's ePrescribing systems to identify the products prescribed?**

Use one line to insert each coding system (for national product or products cluster, and 'other' and specify the name). In the following columns, specify if it is used as national or cross-border levels.

Coding System	Specify the name	National ePrescription <i>Dropdown list: (No use / Current use / Planned)</i>	Cross Border ePrescription <i>Dropdown list: (No use / Current use / Planned)</i>	Mapped with the National product dictionary? <i>Dropdown list: (Yes / No)</i>	Notes <i>(optional text)</i>
WHO ATC codes					
SNOMED CT					
National product coding system					
National products' cluster or classification					
Other (more than one allowed)					

(option to insert more lines if needed)

- b) What are the products' information that the ePrescription system from your country are able to provide and how? (Consider only the cross-border context)**

For each identified information please indicate if you can provide that information and in which format. If available, please indicate if it is an original information, i.e. that can be provided with the ePrescription/eDispensation, or it can be derived from other data present in the ePrescription/eDispensation as the product code.

(select one of the three options for each attribute below)	No	Yes unstructured / textual	Yes structured coded/quantified	If [Yes – coded] indicate which code system are you using (optional text)	How (indicate if this is an original or a derived information)
Active Substance(s)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (, please specify) R:
Strength	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (, please specify) R:
Active moiety(ies)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (, please specify) R:
Reference Strength	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (, please specify) R:
Dose Form /Unit of presentation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (, please specify) R:
Package structure (i.e. inner/intermediate/outer packages; e.g. 3 vials of 5 ml per box)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (, please specify) R:
Package size (per package; e.g. 3 vials of 5 ml per box; 50 tablets per box)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (, please specify) R:
Package type (per package e.g. 3 vials of 5 ml per box)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (, please specify) R:
Other (, please specify) R:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (, please specify) R:

(option to insert more lines if needed)

Q13. What standards are currently employed to support ePrescription?

- ☐ HL7 messaging (i.e. HL7 v2, v3)
- ☐ HL7 CDA
- ☐ HL7 FHIR
- ☐ Other please specify

R: _____

Q14. What services are being used in your country for sharing ePrescription/eDispensation information? (e.g. IHE XDS, other)

R: _____

Q15. Are commonly used prescribing systems supported by decision support systems or other prescription protocol systems that help or restrict the clinicians from prescribing a medicinal product?

☐ Yes; ☐ No.

If yes, please specify:

R: _____

Q16. Is the information about previously prescribed medications accessible in ePrescription system?

a) to the patient – ☐ Yes; ☐ No, *please specify:*

R: _____

b) to the prescribers – ☐ Yes; ☐ No, *is there an OPT-OUT/OPT-IN option, please specify, indicating who can do it:*

R: _____

c) to the pharmacies – ☐ Yes; ☐ No, *is there an OPT-OUT/OPT-IN option, please specify indicating who can do it:*

R: _____

d) Does the ePrescription system have the functionality to identify medications prescribed but not fully dispensed and the remaining dispensations?

a) ☐ Yes; ☐ No, *please specify:*

R: _____

Q17. What are the authentication mechanisms for the ePrescription Service(s)?

a) for the physicians/pharmacists to use the system (national ID, EHIC, E-signature, e-mail, other), *please specify:*

R: _____

b) for the patients to obtain information on previously prescribed drugs (national ID, EHIC, E-signature, e-mail, other), *please specify:*

R: _____

c) for the patients in the pharmacy – what does the patient need to provide to get his/her medication dispensed? (national ID, EHIC, E-signature, e-mail, unique identifier of the prescription, other), *please specify*:

R: _____

Q18. Are there more advanced functions available in your ePrescription system (Consider National or regional systems)? (e.g. decision-making, reimbursement, connection to EHR systems, APIs, counterfeit drug management, formulary).

☐ Yes; ☐ No. *If Yes, please specify.*

R: _____

Q19. Does your country permit substitution in line with Pharmaceutical advice protocols?

☐ Yes; ☐ No. *If Yes, please specify.*

R: _____

Q20. Does your country use protocols for tracking falsified medication?

☐ Yes; ☐ No. *If Yes, please specify.*

R: _____

Q21. What are

a) the critical pieces of prescribing information required to dispense a prescription or provide substitution safely?

- ☐ Manufacturer
- ☐ Active substances
- ☐ Strength
- ☐ Reference Strength
- ☐ Dose/dosage/posology
- ☐ Dose form / Unit of presentation
- ☐ Route of administration
- ☐ Package Information
- ☐ Allergies
- ☐ Reason for prescribing
- ☐ Other. *Please specify.*

R: _____

b) What other information is used to support the safe dispensation of a substitute for a prescribed medicinal product? (e.g. formularies)

R: _____

Q22. What information about dispensation is currently recorded? (you can select more than one option)

- ☐ Pharmacy details
- ☐ Date of dispensation
- ☐ Medicinal product dispensed
- ☐ Substitute medicinal product dispensed (if any)
- ☐ Quantity (number of packages or tablets when is it is applicable)
- ☐ Other

R: _____

Patient summary questions

The purpose of this section is to understand the current situation regarding Patient Summary developments in EU countries, its adoption and change management requirements

Q1. Does your country currently have an electronic Patient Summary solution?

- ☐ Yes
- ☐ In Pilot *(please answer the survey with the information about the pilot project)*
- ☐ planned as a pilot or full-scale project in the next five years *(please answer the survey with the information about the pilot project)*
- ☐ not used and not planned in the next five years

- Why ePrescription are still not established in your country or planned for the next five years? *(In this case and after leaving your answer here, please skip the following questions and go straight to Patient Summary questions.)*

Q2. If Patient Summary is available in your country,**a) is the solution a:**

- ☐ National system (e.g. for the whole country)
- ☐ Regional

If yes, please indicate

How many _____

Do they cover the whole region Yes / No

- ☐ Local (individual pharmacy, local company/ development)

b) Does this system allow for?

- ☐ Integration (e.g. a system between a selected hospital and pharmacies)

If yes, please indicate

How many exist _____

Coverage (region/city etc) _____

☐ Cross Border

If yes, please indicate

In operation since: _____

Planned for: _____

c) it is automatically updated after a visit to a doctor/hospital in case of new patient?

☐ Yes; ☐ No. *If no please specify:*

R: _____

d) Who is responsible for updating the Patient Summary? (you can choose more than one option)

☐ automatic in (e.g. a regional EHR system)

☐ doctors/physicians

☐ other – (please specify)

Q3. How many citizens have a Patient summary in your country?

☐ > 80%

☐ > 50% to <80%

☐ >20% to <50%

☐ <20%

Q4. Are Clinicians legally obliged /controlled to use electronic Patient Summary?

☐ Yes; ☐ No. *if no please specify:*

R: _____

Q5. What care settings uses the national/regional/local Patient Summary?

☐ Hospital Inpatient

☐ Outpatient Department in a hospital

☐ Outpatient Departments that is not located in a hospital

☐ Doctor's (GP)

☐ Other (please specify)

Q6. What professionals use Patient Summary solutions in these care settings? (you can select more than one option)

☐ Physicians e.g. hospital consultants

☐ Nurse prescribers

☐ Doctors e.g. general practitioners

☐ Pharmacists

- ☐ Dentists
- ☐ Others - please specify

R: _____

Q7. Considering the Patient Summary System infrastructure from your country, please answer:

a) What are the coding systems (i.e. drug codes) in use in your country to identify the medicinal products in the Patient Summary?

- ☐ Exactly the same as your response to the ePrescription Question 12 (a).
- ☐ There are some differences, please specify:

Use one line to insert each coding system (for national product or products cluster, and 'other' and specify the name). In the following columns, specify if it is used as national or cross-border levels.

Coding System	Specify the name	National ePrescription (No use / Current Planned)	Cross Border ePrescription (No use / Current Planned)	Mapped with the National product dictionary? (Yes / No)	Notes (optional text)
WHO ATC	=====				
SNOMED CT	=====				
National product coding system					
National products' cluster or classification					
Other (more than one allowed)					

(option to insert more lines if needed)

b) What are the products information that the ePrescription system from your country are able to provide and how?

- ☐ Exactly the same as your response to the ePrescription Question 12 (b).
- ☐ There are some differences, please specify:

For each identified information please indicate if you can provide that information and in which format. If available, please indicate if it is an original information, i.e. that can be provided with the ePrescription/eDispensation, or it can be derived from other data present in the ePrescription/eDispensation as the product code.

(select one of the three options for each attribute below)	No	Yes unstructured/textual	Yes structured coded/quantified	If [Yes – coded] indicate which code system are you using (optional text)	How (indicate if this is an original or a derived information)
Active Substance(s)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (please specify) R:
Strength	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (please specify) R:
Active moiety(ies)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (please specify) R:
Reference Strength	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (please specify) R:
Dose Form /Unit of presentation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (please specify) R:
Package structure (i.e. inner/intermediate/outer packages; e.g. 3 vials of 5 ml per box)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (please specify) R:
Package size (per package; e.g. 3 vials of 5 ml per box; 50 tablets per box)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (please specify) R:
Package type (per package e.g. 3 vials of 5 ml per box)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (please specify) R:
Other (, please specify) R:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	R:	Original / derived (please specify) R:

(option to insert more lines if needed)

Q8. Does your current Patient Summary system have the functionality to record adverse events?

- ☐ Yes
- ☐ Structured Content
- ☐ Free Text
- ☐ Other. *Please specify*
- ☐ No.
- ☐ Unknown

Q9. How are Patient Summary transferred for consultation?

- ☐ **Central (national/ regional/local) repository** (receives Patient summary and transfers them on request to the healthcare professional where the patient has identified itself)
- ☐ **Controlling hub** (the repository issues Identifiers for both Patient Summary and PS consult and has “authorisation” functionality (based on business or clinical rules or both). The PS consult must “request” authorisation before it can be issued.)
- ☐ **Index repository** (the repository holds information about Patient Summary messages that have been sent/received in its jurisdiction and can be queried for this information)
- ☐ **Document sharing** (the content of the Patient Summary is to be made available to be consulted, the Patient Summary information must be shared).
- ☐ **Mailbox-like solution** (data delivered to an actual consultant)
- ☐ **Mobile applications**, *please specify:*

R: _____

- ☐ **other**, *please specify:*

R: _____

Q10. What standards are currently employed to support Patient Summary?

- ☐ HL7 messaging (i.e. HL7 v2, v3)
- ☐ HL7 CDA
- ☐ HL7 FHIR
- ☐ Other. *Please specify*

Q11. What services are being used in your country for sharing Patient Summary information? (e.g. IHE XDS, other)

R: _____

Q12. Regarding the medicinal products information present in the Patient Summary:

a) Is the information about previously and current prescribed medicinal products accessible in Patient Summary system?

i) to the patient – ☐ Yes; ☐ No, *please specify:*

R: _____

ii) to the clinicians – ☐ Yes; ☐ No, is there an OPT-OUT/OPT-IN option, please specify:

R: _____

iii) Other – ☐ Yes; ☐ No, please specify:

R: _____

b) Which kind of medicinal products information is accessible using the Patient Summary in your country? (You can choose more than one option)

☐ Vaccines

☐ Allergies to drugs

☐ Medication history

☐ all

☐ last 5 years

☐ last 1 year

☐ Currently active prescriptions

☐ Adverse events

☐ Other, please specify.

R: _____

Q13. What are the identification authentication mechanisms for accessing the Patient Summary Services(s)? (consider the previous patient consent on all options when it is applicable).

a) for the home physicians to use the system (National level) (national ID, EHIC, E-signature, e-mail, other), please specify:

R: _____

b) for a foreign physician to use the system (cross-border level – in country B) (national ID, EHIC, E-signature, e-mail, other), please specify:

R: _____

c) for the patients to access their own information (national ID, EHIC, E-signature, e-mail, other), please specify:

R: _____

d) for the patients to access their own information abroad (country B) – (national ID, EHIC, E-signature, e-mail, unique identifier of the prescription, other), please specify:

R: _____

THANK YOU VERY MUCH FOR YOUR HELP!

Legal framework questions

Q1. a) Are there current legislations in your country that cover the implementation of ePrescription?

☐ Yes; ☐ No. *If Yes, please specify*

R: _____

b) Are these laws/legislations reinforced?

☐ Yes; ☐ No. *If Yes, please specify*

R: _____

c) Are there any constraints in your country's legislation that may complicate the adoption of new ePrescription services regarding the medicinal products identification?

☐ Yes; ☐ No. *If Yes, please specify. If NO, why not?*

R: _____

Q2. a) Is there any current legislation in your country that covers the implementation of Patient Summary?

☐ Yes; ☐ No. *If Yes, please specify*

R: _____

b) Are these laws/legislations reinforced?

☐ Yes; ☐ No. *If Yes, please specify*

R: _____

c) Are there any constraints in your country's legislation that may complicate the adoption of new Patient Summary services regarding the medicinal products identification?

☐ Yes; ☐ No. *If Yes, please specify. If NO, why not?*

R: _____

Q3. Is there any specific national legislation required for the implementation of a new standard on ePrescription services in your country?

☐ Yes; ☐ No. *If Yes, please specify*

R: _____

Q4. Is there any specific national legislation required for the implementation of a new standard on Patient Summary services in your country?

☐ Yes; ☐ No. *If Yes, please specify*

R: _____

Q5. Do you foresee/have specific agreements with other countries to assure the interoperability of cross border ePrescription?

☐ Yes; ☐ No. *If Yes, please specify*

a) the scope of the agreements?

R: _____

b) if they are bilateral or multilateral agreements?

R: _____

Q6. Do you foresee/have specific agreements with other countries to assure the interoperability of cross border Patient Summary?

☐ Yes; ☐ No. *If Yes, please specify*

a) the scope of the agreements?

R: _____

b) if they are bilateral or multilateral agreements?

R: _____

Q7.a) Is it possible to use for ePrescribing services the Medicinal Product Databases enhanced by Medicinal Products Dictionaries (MPD) private providers?

R: _____

b) Should these enhancements be certified by the National Drug Agencies?

R: _____

Q8. Any other comments or details you would like to add:

R:

THANK YOU VERY MUCH FOR YOUR HELP!