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D5.6: Guidelines to implement IDMP in National eHealth Services

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Deliverable abstract

This document defines the guidelines for the adoption of ISO IDMP in the eHealth services at national level, and their connections to the Medicinal Products Dictionary both from National Competent Authorities (NCAs). Therefore, it is also acknowledged that consideration must be given to the connection of national systems to the cross-border services.

This document intends to present a set of guidelines which include:

- the adoption of ISO IDMP in the eHealth services at national level,
- their connections to the Medicinal Products databases both from NCAs and private providers,

the connection of national systems to the cross-border services.

Keywords: IDMP, eHealth agency, National Competent Authority, guidelines

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List of abbreviations

Abbreviation	Complete form
ATC	Anatomical Therapeutic Chemical Code
BDSNS	National Health System Database
CA	Certificate Authority
CBeHIS	Cross-Border eHealth Information Services
CDA	Clinical Document Architecture
CEF	Connecting Europe Facility
CHNM	hospital medicinal product code system (PT)
CITS	Cedência de Informação de Tecnologias de Saúde [Health Technology Information Transfer]
CNPEM	National Code for Medical Electronic Prescription (PT)
Compofarma	Andalusia Coding System (ES)
CTAEM	Therapeutic Classification from AEMPS (ES)
CTS	Common Terminology Service
DB	Database
DCP	Product Clinical Description (ES)
DCPF	Formatted Product Clinical Description (ES)
DG SANTE	Directorate-General for Health and Food Safety
eD	eDispensation
eHDSI	eHealth Digital Service Infrastructure
eHN	eHealth Network
EHR	Electronic Health Record
EOF	National Organization for Medicines (GR)
eP	ePrescription
epSOS	Smart Open Services for European Patients
ESB	Enterprise Service Bus
ETL	Extract, Transform and Load
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
GP	General Practitioner
Healthmail	Healthmail (IE) is a secure clinical email service that allows health care providers to send and receive clinical patient information in a secure manner
HL7	Health Level Seven International
IDMP	Identification of Medicinal Products
IFET	Pharmaceutical Research and Technology Company (Greece)
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
MPD	Medicinal Product Dictionary
MTC	Master Translation/Transcoding Catalogue
NCA	National Competent Authority
NCP	National Contact Point
NCPeH	National Contact Point for eHealth

NMPC	National Medicinal Product Catalogue (IE)
NPC code	National codification of the commercial brand (ES)
PEM	Medical Electronic Prescription (PT)
PS	Patient Summary
ReEIF	Refined eHealth European Interoperability framework
RXXI	Receta XXI – Prescription system of Andalusia, Spain
SOA	Service Orientated Architecture
WP	Work Packages
XCA	Cross-Community Access
XCPD	Cross-Community Patient Discovery
XDS	Specification for Cross Border Document Sharing
XDR	Specification for Cross-Enterprise Document Reliable Interchange

Executive summary

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

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

This deliverable defines the guidelines for the adoption of ISO IDMP in the eHealth services at national level, and their connections to the Medicinal Products Dictionary both from National Competent Authorities (NCAs). Therefore, it is also acknowledged that consideration must be given to the connection of national systems to the cross-border services.

This document intends to present a set of guidelines which include:

- the adoption of ISO IDMP in the eHealth services at national level,
- their connections to the Medicinal Products databases both from NCAs and private providers,
- the connection of national systems to the cross-border services.

1 Introduction and Background

1.1 Background

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

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

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

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

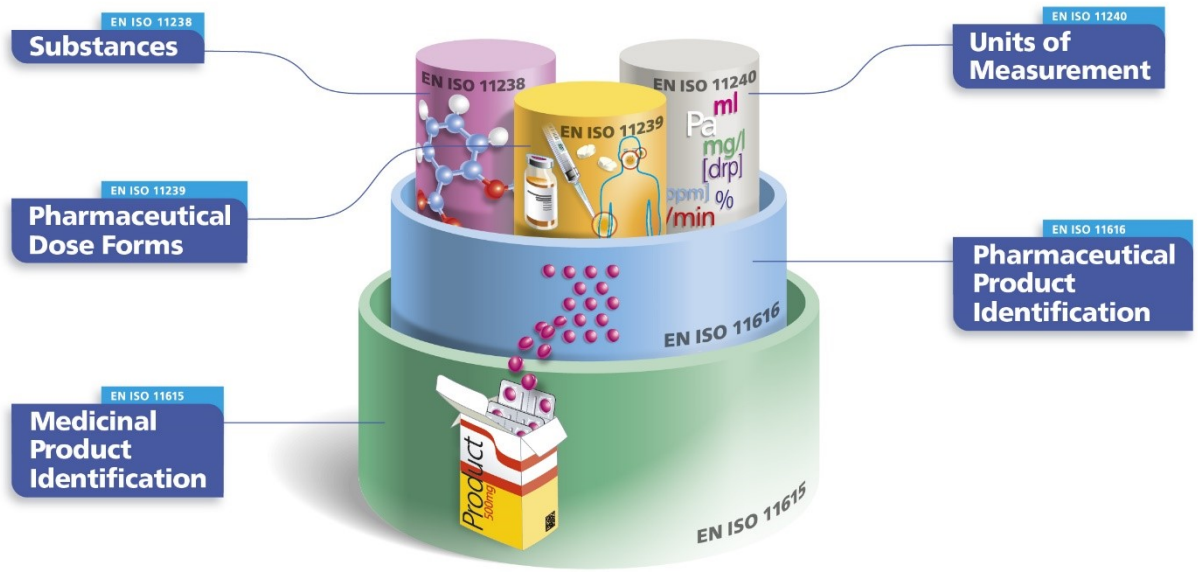

Figure 1: The 5 ISO standards used to identify medicinal products

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

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

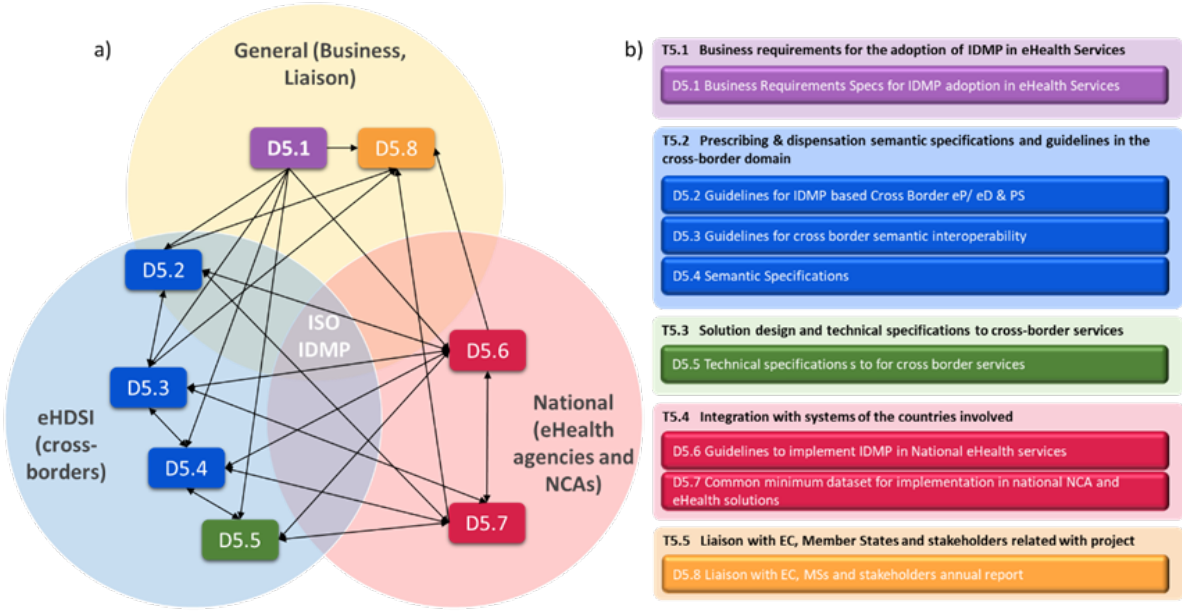

Figure 2: The WP5 deliverables relationship.

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

The outputs of previous deliverables (Figure 2) provide the basis for D5.6 Guidelines to implement IDMP in National eHealth Services. This task will define the guidelines for the adoption of ISO IDMP in the eHealth services at national level, and their connections to the Medicinal Products databases both from National Competent Authorities (NCAs) and private providers.

1.2 Introduction to D5.6

The complexity of identifying medicinal products among Member States in their ePrescription/eDispensation & Patient Summary systems means it is essential to ensure the alignment of the elements and attributes to support the full implementation of the IDMP standards. To ensure success, a comprehensive set of guidelines is necessary to ensure that all Member States can adopt IDMP to improve the identification of medicinal products.

Therefore, this task will define the guidelines for the adoption of ISO IDMP in the eHealth services at national level, and their connections to the Medicinal Products databases both from NCAs and private providers. It is acknowledged that consideration must be given to the connection of national systems to the cross-border services and will address the following critical objectives:

- Propose a few alternative architectural solutions for the integration of IDMP components in the national end-to-end services.
- The scenarios will cover different options of partial/gradual/full implementation of ISO IDMP on the national level.

Thereafter, the resultant architectural solutions will be able to support delivery of cross-border eHealth services (eHDSI).

1.3 Scope of the document

This document intends to present a set of guidelines which include:

- their connections to the Medicinal Products databases both from NCAs and private providers,
- the adoption of ISO IDMP in the eHealth services at national level,
- the connection of national systems to the cross-border services.

2 Connections to medicinal products databases

This chapter intends to provide an overview about how the national eHealth solutions connect with the medicinal products databases to provide the eP/eD & PS services in their country. It is important to consider these connections in order to provide details on how to integrate the IDMP data into the current eHealth services.

Below, a short overview about the current state is provided from a selection of different Member States. These approaches provide an opportunity for other European countries to gain knowledge on IDMP adoption in their systems.

2.1 Portugal

INFARMED (Portuguese NCA), the organisation responsible for providing medicinal product data, offers two different databases called CITS (*Cedência de Informação de Tecnologias de Saúde* [Health Technology Information Transfer]) and Hospital CITS that are consumed by the eHealth solutions managed by SPMS (Portuguese eHealth agency). Other databases are available; however, they are out of scope of UNICOM. A brief description of the databases of interest to UNICOM is outlined below.

- **CITS** – (PEM[3] – Medical Electronic Prescription).
  - This database contains information on the scope of medicines to eP/eD on community pharmacy.
- **Hospital CITS** (PEM / BDSNS – National Health System Database)
  - This database contains information on the scope of medicines to eP/eD on community pharmacy and medicines of exclusive hospital use.

To be able to issue the eHealth services in Portugal, SPMS accesses the database (DB) provided by INFARMED and copies the DBs by ETL (Extract, Transform and Load) protocol through a DB-link. It is a daily process that updates all databases at SPMS infrastructure and make it available to be consumed by the aforesaid services. These databases are also associated with the national eP code system (CNPEM) and national code to hospital medicinal product code system (CHNM) and ensures the correct association between medicinal product information and code system.

Additionally, the BDSNS has a set of triggers that generate a history of all activities made on the tables, supporting the control of the information of hospital medicinal products.

Figure 3 presents the current architecture of the medicinal database in Portugal.

[3] Electronic Medicine Prescription (PEM) is a service developed by a SPMS to implement the electronic process of ambulatory medication prescription, dispensing, and reimbursement.

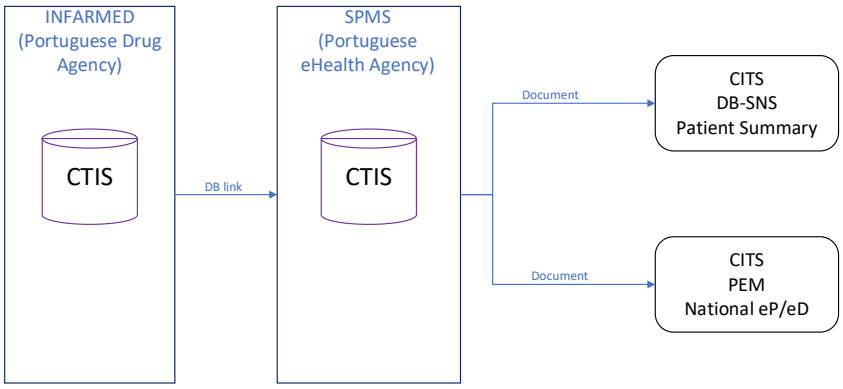

Figure 3: Architecture of the Portuguese Medicinal Product Dictionary connection

2.2 Ireland

Currently there is no common, national level medicinal product dictionary available to the various clinical information systems that underpin eHealth services such as eP/eD and Patient Summary. Work is currently underway to co-ordinate this into a desired future state for medication data.

Future State:

The National Medicinal Product Catalogue (NMPC) project is currently underway to develop a national medicines formulary that will be designed to uniquely & unambiguously code and describe medicines used in the delivery of clinical care in Ireland. It aims to facilitate interoperability of healthcare systems through the establishment and maintenance of a single electronic medicinal product catalogue available for use across all care settings for various eHealth initiatives.

It is expected that IDMP relevant data will be sourced from our National Competent Authority (Health Products Regulatory Authority) and collated along with other sources − so that over time the content authored and managed by the NMPC will continue to expand. It will cover:

- Medicinal Product Information
- Medicinal Product Pack Information
- Ingredient Information
- Regulatory/Authorisation Information
- Reimbursement Information
- Clinical Particulars
- Advanced Clinical Supports

This medicinal catalogue is expected to include the following codification for the medicinal products:

1. The National Code (NMPC Code)
2. Anatomical Therapeutic Chemical Code ATC Classification (primarily used for classification/utility rather than identity)
3. SNOMED Code (will be integrated to the NMPC code)

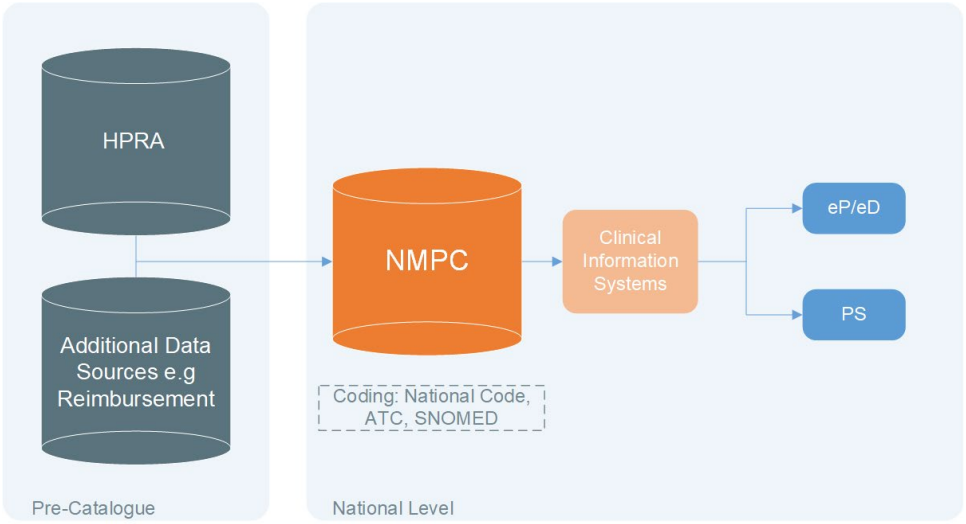

Figure 4: High level architecture of the proposed Irish National Medicinal Product Catalogue (NMPC)

2.3 Spain

AEMPS, the Spanish Agency of medicinal and sanitary products (Spanish NCA), is the organisation responsible for providing medicinal product data. AEMPS also provides the Medicinal Product Dictionary (Prescription Nomenclature) with the medicinal products authorised for its use within the Spanish territory by the eHealth systems of the different regions (Spain health competences are delegated in the regional health authorities). The Prescription Nomenclature includes all authorised and commercialised, financed and non-financed medicinal products data related to their identification, as well as technical information. The Ministry of Health of Spain includes specific information about pricing on the Prescription Nomenclator and the catalogue is distributed to the Spanish regions by the Ministry of Health. This medicinal catalogue includes the following codification for the medicinal products:

- The national codification of the commercial brand (NPC code).
- ATC classification.
- CTAEM1, CTAEM2 (therapeutic classification of the AEMPS).
- DCP (from the Spanish acronym for Product Clinical Description similar to virtual medicine product, VMP). It defines the medicine based on its principles, dose, dose unit and simplified pharmaceutical form. DCP is based on the SNOMED-CT terminology and equivalent to CTAEM1.
- DCPF (from the Spanish acronym for Formatted Product Clinical Description). DCPF is equivalent to CTAEM2 and defines the specific active ingredient of each pharmaceutical presentation, the dose and dose unit, the content and the unit of content, and route of administration.

CTAEM1, CTAEM2, DCF and DCPF can be mapped to SNOMED codification.

Updates of the Prescription Nomenclator are distributed to regions on a monthly basis in two different formats, “Alcantara” and “Digitalis Integra”. As mentioned above, the different regional eHealth services in Spain use the above medicinal data dictionaries (Alcantara or Digitalis Integra) as medicinal data input to be consumed by their eP/eD services.

Spanish regions use the national catalogue Alcantara/Digitalis Integra in different ways (

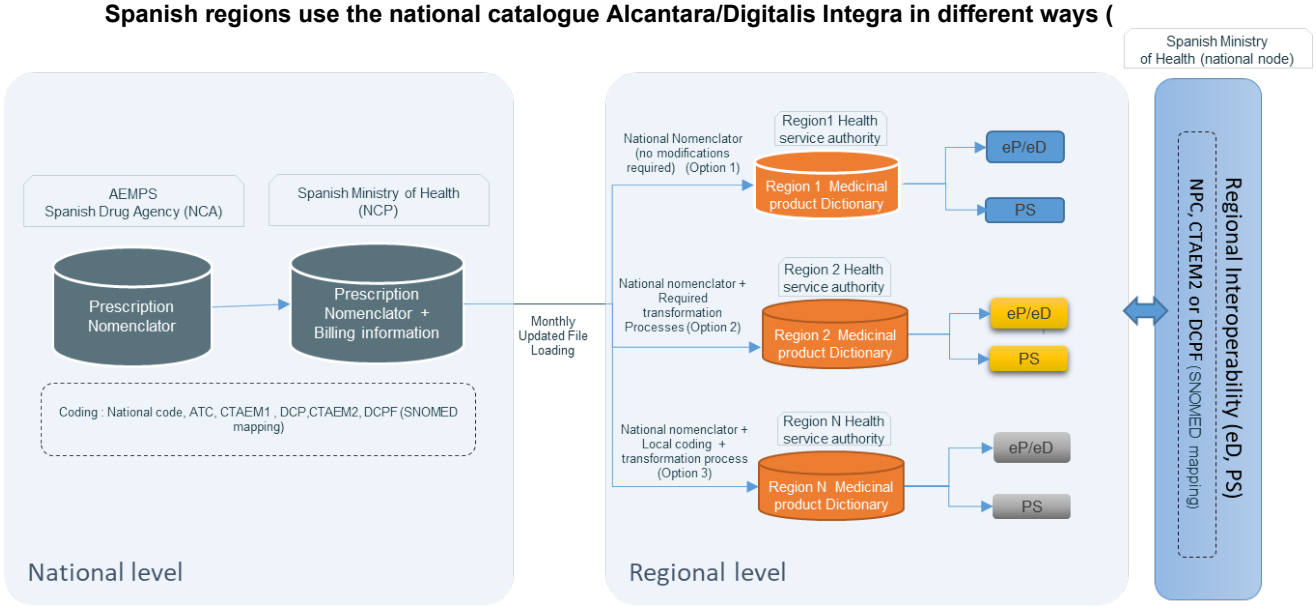

Figure 4):

1. Use National Catalogue as their medicinal data dictionary (Option 1, see figure below) without further modifications.
2. Adapt the National Catalogue (implement some processes) to ensure the correct performance of their eHealth Services (Option 2).
3. Include additional information and local/own codification on the National Nomenclator (Option3), for instance Andalusia.

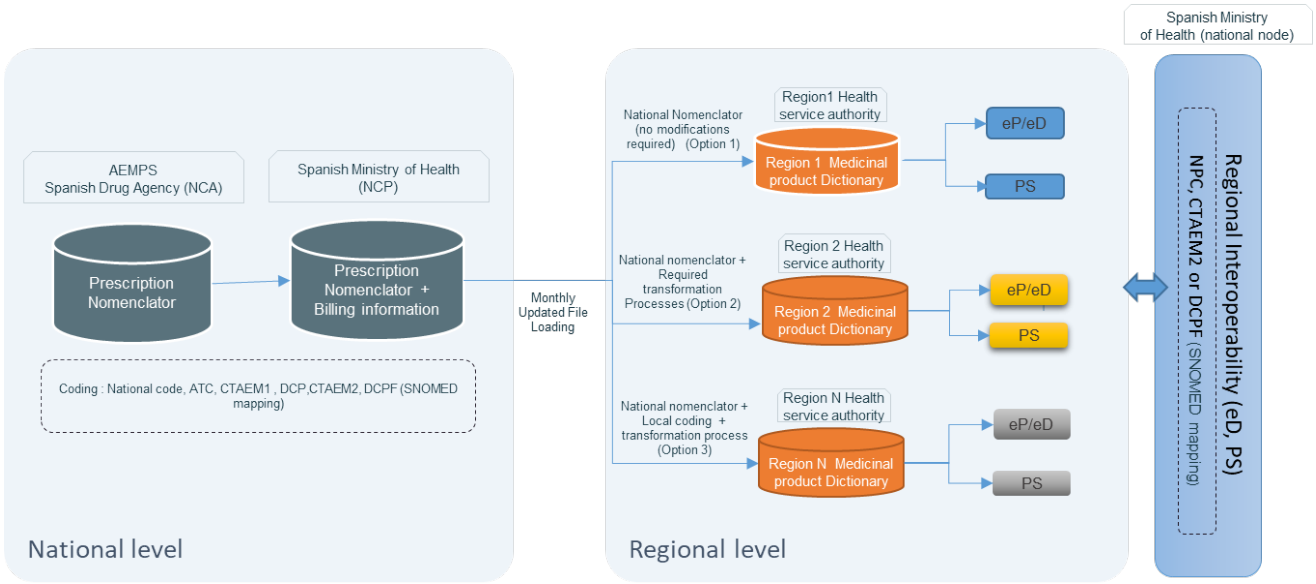

Figure 4: High-level architecture of the Spanish Medicinal Product Dictionary

Andalusia

The Andalusia Health System, which is a participating region in UNICOM, implements its own coding system (“Compofarma”) that historically was created to allow prescription and dispensation by active ingredient.

Andalusia was the first region in Spain to be able to dispense medicinal products by active pharmaceutical ingredient, as required by the Spanish act. At that time the AEMPS medicinal product catalogue did not include the necessary relationships between national codes and pharmaceutical ingredients. Since then, Andalusia maintains its own Medicinal Product Dictionary (MPD) based on the national MPD and enriched with Compofarma, as well as additional information such as interactions. Furthermore, substitution rules of the eP/eD systems are based on this local codification, which is the main reason why Compofarma has been maintained over the time (note that the current national MPD already matches active ingredient and group of commercial brands).

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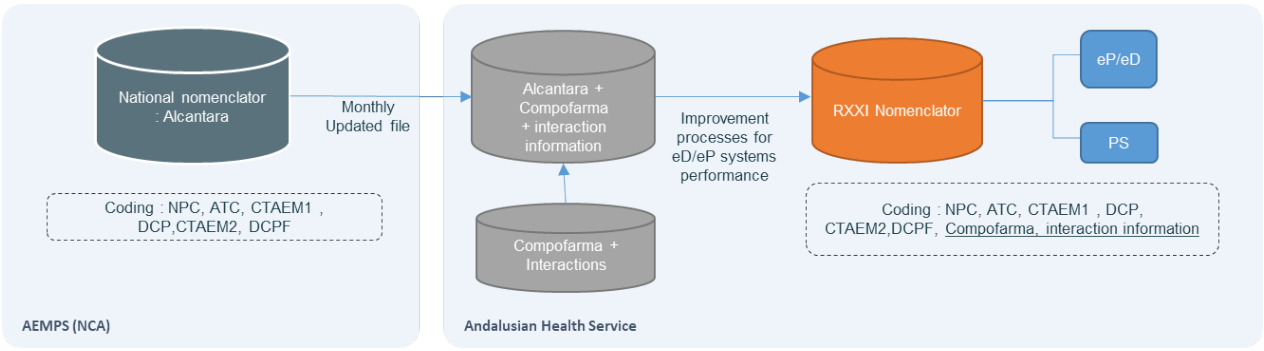

Figure 5: Andalusian MPD and relationship with national MPD

From Alcantara, an intermediate data base includes updated national information plus the local codification and interactions information. Then, some performance processes, mainly regarding data model, are implemented in order to optimise the performance of the regional eP and eD systems. For example, criteria on medicinal products visa and medicinal product Packages are merged in a single code; there are other complex criteria such as those related with interactions, which are also generated in this process.

In Andalusia, the prescription process allows prescription by commercial brand and by Compofarma (active substance). With respect to dispensation, a medicinal product can be dispensed by commercial brand and substitution is possible according to national and local rules implemented in the eD system using the regional medicinal data dictionary (Nomenclator RXXI). If the prescription includes the Compofarma codification, the pharmacist can select the related commercial brands, substitution by another Compofarma coded medicinal products is also implemented in the system.

National Interoperability

At national level, regions interoperate coordinated by the Spanish NCPeH so that in Spain, citizens can obtain prescribed medicines by their doctors at any pharmacy of the national territory regardless of the region where the medicine was prescribed. This process involves exchange of information between the region of origin and the region where the medicine is being dispensed.

The information exchange is performed according to the following IHE profiles:

- IHE XCPD (PRPA_IN201305UV02),
- XCA (CrossGatewayQuery) and
- XDS Document based on HL7 messaging including CDA documents.

For an Andalusian citizen whose medicine is being dispensed in another Spanish region, there are two use cases depending on the code of the medicine included in Andalusian prescription: national code or Compofarma.

- For a prescription including the NPC code, the region where the dispensation is done has this information in its MPD (as this codification is included in the MPD distributed by the NCA). Substitution rules for the prescribed medicinal product will be done according to the business rules of the eD system of that region.

- When Andalusian prescription includes the local code (Compofarma), this is translated to CTAEM code by the Andalusian system, which is included in the eD of the destination region based on the NCA MPD.

Regarding dispensation of prescriptions to citizens from other regions in Andalusia, these prescriptions can include both the national code or the CTAEM. For prescriptions, including the national code at the dispensation workflow is similar to regional dispensation in Andalusia (national code is included in RXXI MPD). For prescriptions including CTAEM codification, Andalusia transcodes CTAEM into Compofarma so local selection, substitution rules and interactions can be applied.

2.4 Finland

In Finland, the Pharmaceutical Database is a service aimed at professionals, containing harmonised and up-to-date information about medicines and medicinal substances for the purpose of prescribing and dispensing medicines.

In addition to basic information about medicines, the database includes information about, e.g., the price and reimbursement of medicines and substitutable medicinal products.

In addition to prescription and self-medication products with a valid marketing authorisation, the Pharmaceutical Database includes information about temporary special permit products, reimbursable emollient creams and foods for special medical purposes. The Pharmaceutical Database does not include, e.g., special permit products, general merchandise (such as surgical dressings) or compounded medicines.

The Pharmaceutical Database is not an online source for pharmacy and patient data systems. The information in the Pharmaceutical Database must be updated in the pharmacy and patient data systems on the 1st and 15th day of each month.

The information in the Pharmaceutical Database is compiled from various sources. The information about medicines is based on information in the basic register for medicinal products of the Finnish Medicines Agency (Fimea). The Pharmaceuticals Pricing Board (Hila) and The Social Insurance Institution of Finland (Kela) produce additional information related to, e.g., the reimbursement of medicines. Pharmaceutical companies provide the price information of medicines.

Organisations using the Prescription service can obtain information and updates from the Pharmaceutical Database either through an intermediary of their choice or directly from Kela. The organisations or the intermediaries of the Pharmaceutical Database shall agree with Kela on the acquisition of the Pharmaceutical Database. The intermediary must not charge its customers a fee or other consideration for providing information from the Pharmaceutical Database.

Datasets identical in content with The Pharmaceutical Database may be available also from other sources which collect or otherwise acquire pharmaceutical information to be further compiled and distributed.

The Pharmaceutical Database can be used for the prescribing, dispensing and reimbursing of medicines and for other related purposes by virtue of the act on electronic prescriptions. The Pharmaceutical Database can also be used for the services referred to in the Act on the Electronic Processing of Client Data in Social and Health Care Services and for purposes related to the supply of medicines for healthcare organisations.

2.5 Greece

The National Organization for Medicines (EOF) is a public entity of the Ministry of Health and is responsible for providing medicinal product data.

The Pharmaceutical Database includes authorised reimbursed medicinal products, as well as pharmaceutical products that are imported and distributed from Pharmaceutical Research and Technology Company (IFET), a subsidiary of EOF, which are not marketed in the Greek market by private pharmaceutical companies, but they are deemed to be indispensable for patient treatment and the protection of public health.

The Pharmaceutical Database contains information about medicines and how are they identified, as well as technical information, pricing (retail and reimbursement), substitutable medicinal products, information and restrictions on prescribing and dispensing.

The Pharmaceutical Database is part of the ePrescription system and there is not an online way to access its resources. Every time a change occurs in the database, such as new available products or changes in pricing, third-party software constructors are updated asynchronously.

3 Architectural solutions

3.1 National Contact Point for eHealth (NCPeH) overview

This section describes the National Contact Points for eHealth (NCPeH), and their connections with national and eHDSI systems.

The eHealth Network (eHN) is a voluntary network of representatives of EU Member States. It provides a coordination platform for Member States' competent authorities responsible for eHealth. Its major task is to cooperate and shape digital health policies and cross-border services at EU and national levels, and the further development of the digital health sector. Secretarial support is provided by the European Commission, DG SANTE – Directorate-General for Health and Food Safety.

Within the eHealth program, the activated initial services support the electronic exchange of PS and eP. This initiative was called "Deployment of generic cross-border eHealth services − National Contact Point for eHealth (NCPeH)" and commenced in January 2017. The initiative is being implemented incrementally and by the end of the third quarter of 2021, nine Member States had their services in routine operation (Croatia, Czech Republic, Estonia, Finland, France, Luxembourg, Malta and Portugal). It is anticipated that by 2023, the eP/eD and PS services will be implemented in all 24 participating countries (**Erro! A origem da referência não foi encontrada.**).

Building on this work, the plan is to extend this initiative in 2022 to the CEF Original Clinical Document including new services for medical images, discharge letters, laboratory results and rare diseases. This work is being supported by the X-eHealth[4] project.

[4] https://www.x-ehealth.eu/

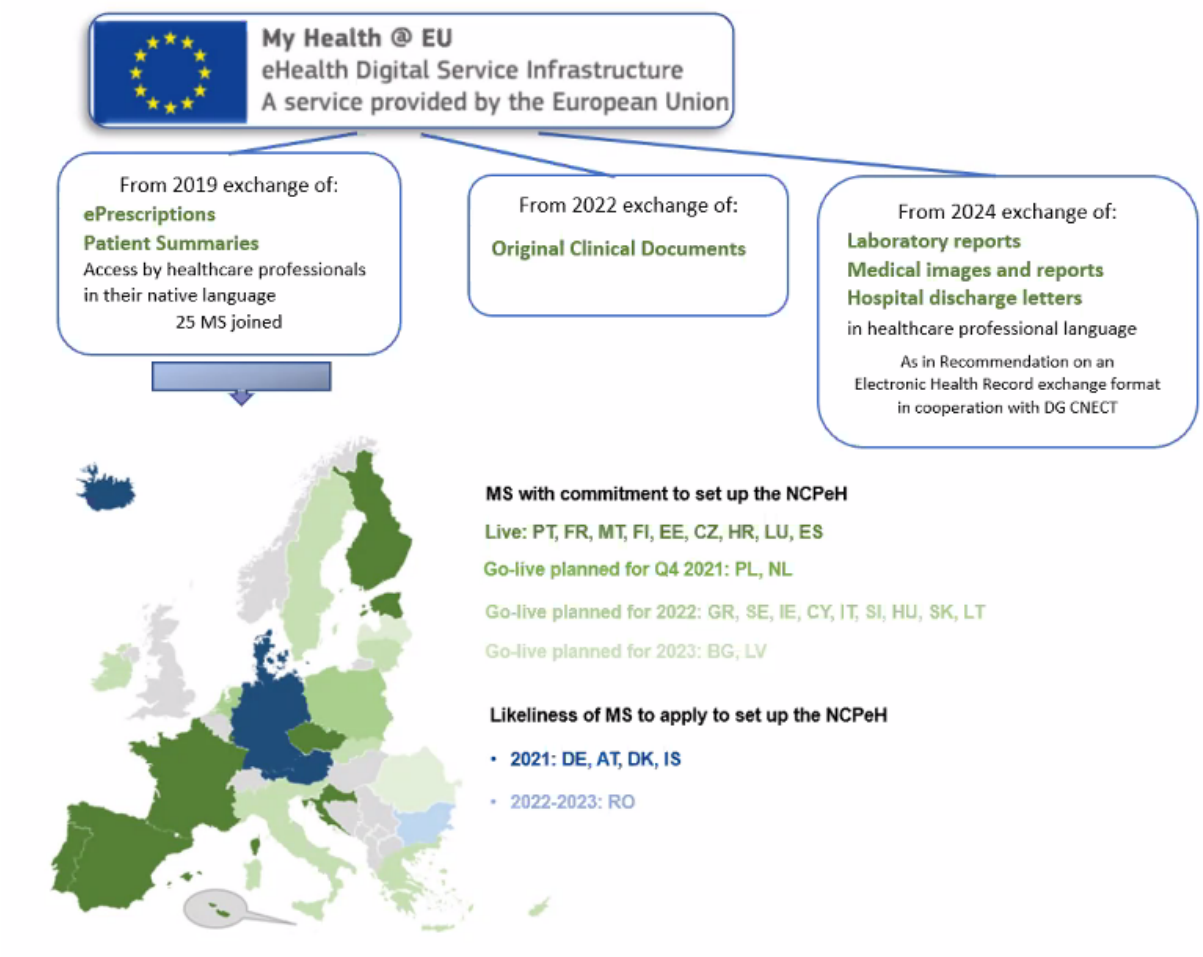

Figure 6: eHealth Project Overview[5]

3.1.1 eHDSI

eHDSI is responsible for the set up and deployment of the core and generic services, as defined in the CEF, for PS and eP/eD. The generic services are the necessary implementation of data exchange at country level, the core services at EU level. These together enable the provision of CBeHIS[6].

The core eHDSI services are summarised in the Figure 9. They are set-up and deployed by the European Commission using its own resources and through calls for tender financed by CEF. The generic services are funded from the national sources and supported by grants from the CEF through a call for proposals.

[5] Source: https://www.fascicolosanitario.gov.it/en/NCPeH; https://ec.europa.eu/digital-building-blocks/wikis/display/EHOPERATIONS/eHDSI+STARTING+TOOLKIT [eHDSI page with restricted access]

[6] https://www.ihe-europe.net/sites/default/files/KI%C3%A1ra_Jir%C3%A1kov%C3%A1_CBeHIS_Security_Requirements_and_Impact_compressed.pdf

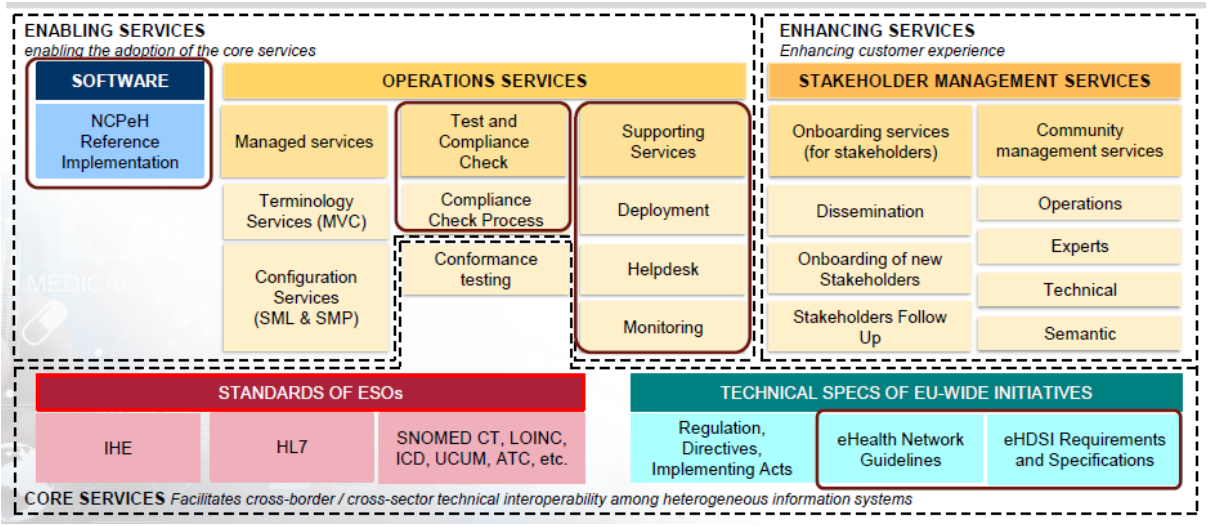

Figure 7: Core Services facilitating cross-border / cross sector technical interoperability[7].

For Member States to successfully exchange data, a common framework of standards is required. The eHDSI uses The Refined eHealth European Interoperability framework[8] ReEIF model, which is based on a system of agreements, on several levels, to ensure secure and reliable data exchange and process alignment between Member States.

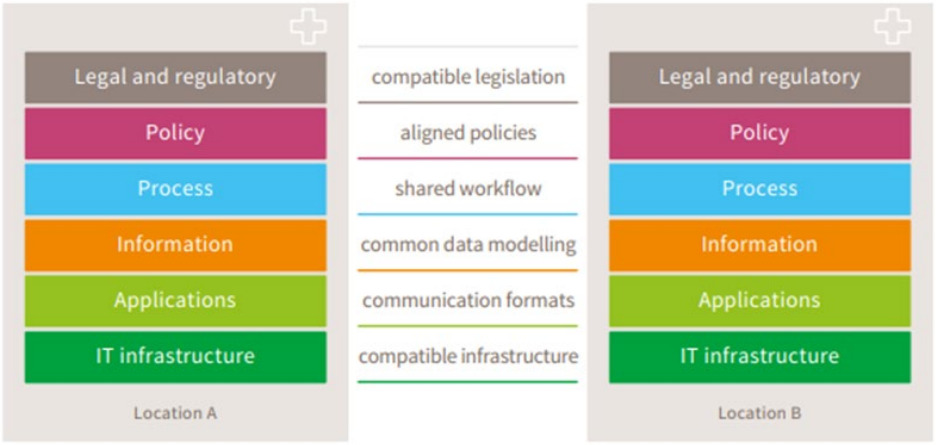

Figure 8: ReEIF model[8]

3.1.2 NCPeH

The National Contact Point for eHealth (NCPeH) is the organisational and technical gateway for the provision of eHealth cross-border services within a country.

[7] Source: https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSI/eHDSI+SERVICE+OFFERING [eHDSI page with resctricted access]

[8] https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSI/DEPRECATED-Requirements+and+Recommendations?preview=%2F888804719%2F888804720%2Fev_20151123_co03_en.pdf [eHDSI page with resctricted access]

There is one single NCP node per country, which acts as that Member States sole entry/exit in the network of European national contact points. The NCPeH provides an always-open connection between Member States of eHDSI and the tools to establish a governance structure at national level. A brief synthesis of the principles that drive NCPeH include:

1. all eHDSI communications are done via gateways and thus have a Business-to-Business communication model,
2. eHDSI must not alter existing medical data in the national systems,
3. records of all exchanges within eHDSI are required and stored,
4. business transactions are designed separately of security but rely on the provision of a security context ("Circle of Trust"),
5. the architecture and its services must be extensible to cover possible new supplementary specification in further implementations of eHDSI,
6. a Service Orientated Architecture (SOA) is suitable to provide a loosely integrated suite of services that can be used within the multiple business domains covered by country in eHDSI

At an operational level cross-border eHealth services are divided into:

- Country A - Services for your citizens abroad (in this case your country acts as Country of Affiliation),
- Country B - Services for foreign citizens in your country (in this case your country acts as a Country of Treatment)

Actors can act on the eHDSI system or is acted on by the eHDSI system.

A role is related to an actor having a specific behaviour in a particular context: provider and consumer as indicated in Figure 9 below.

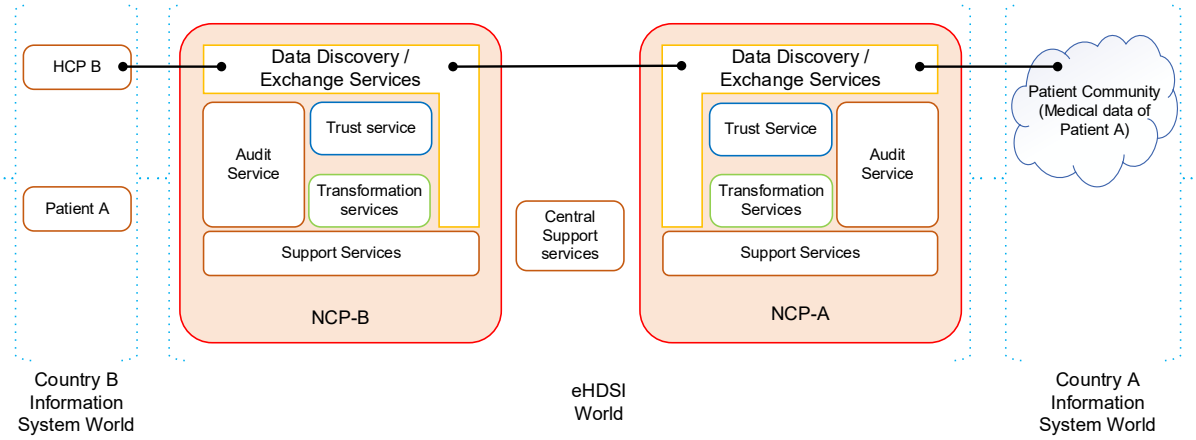

Figure 9: eHDSI system architecture Specification v3.0.0.doc

When Italy operates as Country B, health professionals or pharmacists request a PS and/or eP to the NCPeH of the country of affiliation of the person requiring treatment – Country A; Assuming everything is correct, Country B receives the documents, already translated, and provides them to healthcare professional or pharmacist, with the tools to view it.

In the event that a Member State (i.e., Italy) operates as a Country A, the NCPeH receives a request for a Patient Summary and/or an electronic prescription (for an Italian citizen-requesting healthcare at a foreign point of care – Country B). In this case, the Italian Electronic Health Record (EHR) national architecture is used to verify the citizen's personal information and consent to retrieve clinical documents.

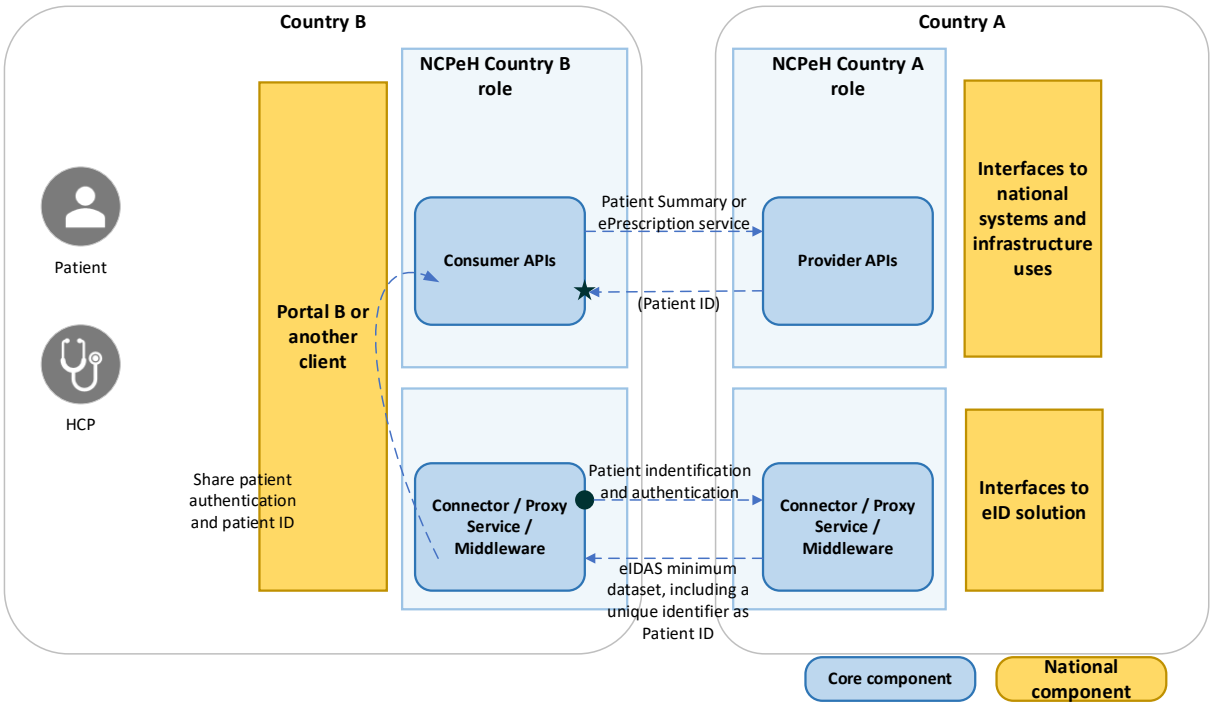

Figure 10: eHealth DSI logical view

3.1.3 NCPeH Reference Implementation

The design, implementation and testing of the NCPeH and cross-border services includes the following:

- the planning and monitoring of design activities,
- the definition of the architecture and functionalities of cross-border services,
- the creation of the software platform and its integration with the national interoperability infrastructure,
- testing in a pre-production environment.

It also includes the preparation of the organisational and legal procedures necessary for the operational management of cross-border eHealth services. In the testing phase of the NCPeH infrastructure, the functionality is checked along with the procedures for carrying out the Audits and the actions aimed at obtaining authorisation from the eHealth Network to activate the NCPeH.

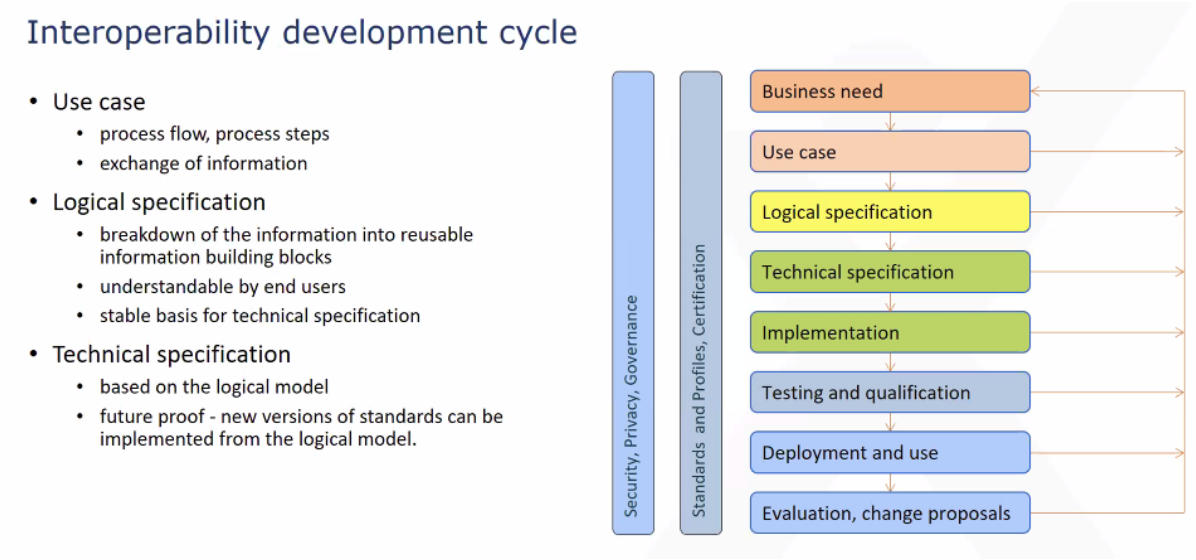

Figure 11: eHDSI Interoperability Development Cycle

A specific component of the NCPeH called 'National Connector' transforms the Member States PS into a version syntactically compatible with European specifications. Similarly, the National Connector transforms the Member State's eP, consistent with European specifications.

Cross-border interoperability uses mutual "trust", also known as the circle of trust. It is based on the application of the European Directives and Regulations issued on the subject, specifically security aspects, compliance with the rules for the privacy protection and the definition and implementation of pre-established organisational procedures.

These procedures are verified through an Audit process carried out by the European Commission, with the support of experts appointed by the other Member States participating in the CEF eHDSI Project. The results of the audit and tests, together with the demonstration of having complied with all legal and organisational requirements is provided to the eHealth Network who in turn give approval for activation of the NCPeH. After this approval, the platform will be transferred to production together with all the technical, semantic and organisational components necessary for the implementation of cross-border eHealth services subjected to non-regression tests, to ensure the functionality of the active components before implementation. The test will be repeated after the adoption of new releases or the implementation of new services.

3.1.4 NCPeH infrastructure development and deployment

The NCPeH infrastructure development and deployment created an infrastructure capable of guaranteeing interoperability between the Member States participating in the project.

The infrastructure assures the provision of services 24 h, 7 days a week, to ensure operational and care continuity for patients and operators.

There is monitoring and evaluating of performance in order to optimise the expected results and expectations of users and healthcare professionals.

3.1.5 Communication and training strategy

Communication and training are key aspects for the introduction and operation of the NCPeH.

Working in collaboration with healthcare professionals, citizens and other relevant stakeholders, the overarching objective of these activities is to identify the needs and solutions to make the cross-border exchange of clinical data effective.

3.2 Connectivity between the NCPeH and the national systems

The NCPeH deployment Guide details the specifications and requirements on how to handle legal, technical, organisational and practical issues when setting up an NCP and when the national system is up and running. The national side of the NCP is left to the deploying country to handle themselves, with local experts, and must be configured according to eHDSI requirements, as illustrated in the Figure 12.

The NCP is the single gateway/point of contact between the national system(s) and the eHDSI. The national health organisation & infrastructure differs within each Member States, where you can have 1 single national health service (i.e. Ireland) or regional divisions (i.e. Italy, Spain).

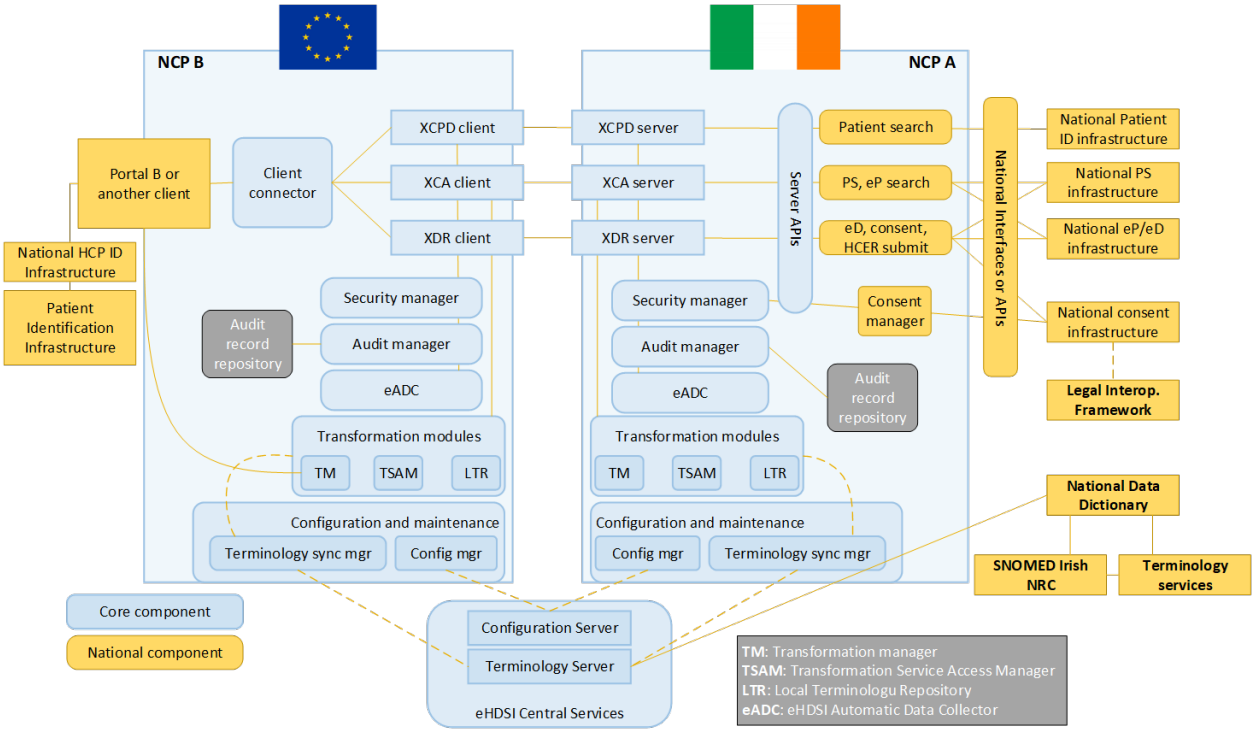

Figure 12: The Open NCP Component Architecture.

3.2.1 Portugal

The Portuguese NCP is under the responsibility of SPMS (Shared Services for the Ministry of Health, E. P. E.), the central eHealth agency in Portugal. SPMS provides, as well, the national services which are essential to operationalise the Cross-Border eHealth Information Services (CBeHIS):

- The national ePrescription/eDispensation services, which are connected to all clinical points-of-care and pharmacies in the country.
- The national Patient Summary service, which collects data from different national repositories to create a clinical document and make it available to both patients and health professionals (HP) through the national eHealth platform. The data repositories, in turn, are fed directly by HP's activities or indirectly receive data from other decentralised solutions.

In general, the Portuguese NCP follows the common architecture depicted in Figure 13, with small changes to fit in the national reality:

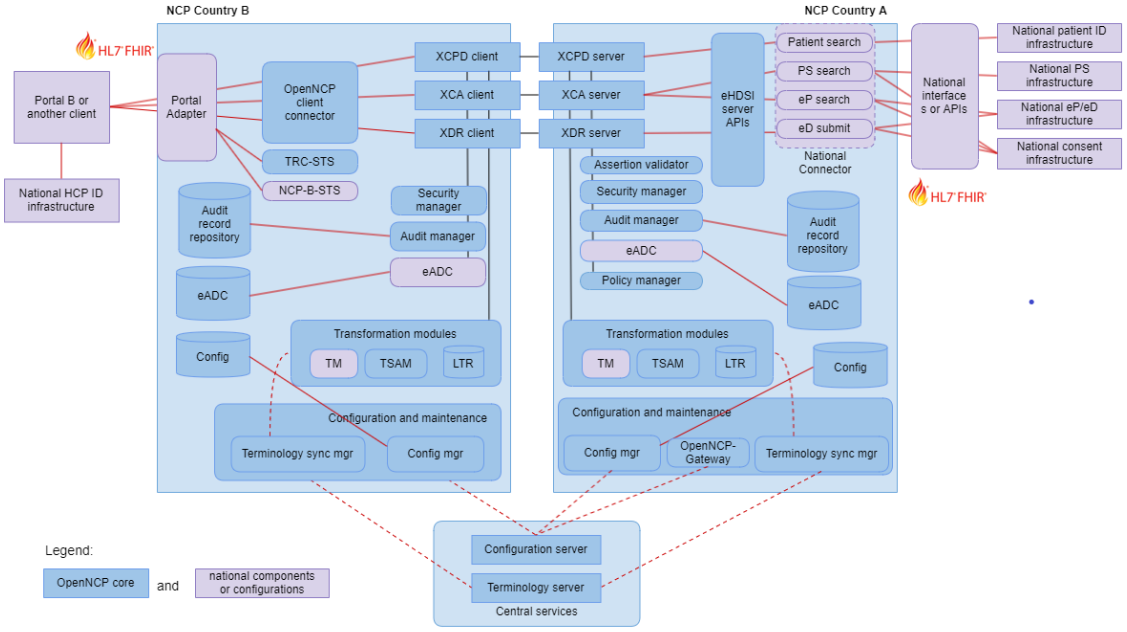

Figure 13: Portuguese NCP architecture

The main points in this context are highlighted by the purple boxes within each NCP side.

In NCP-A, there is a National Connector that maps IHE XCPD/XCA/XDR transactions data to HL7 FHIR messages, which are distributed to the national repositories by the national HL7 FHIR broker. When it comes to fetching the clinical documents from the national infrastructure, the National Connector receives eHDSI Friendly-A CDA L3 documents, i.e., it does not receive neither a national version of the documents, neither their constituting data elements. Instead, the whole Clinical Document Architecture (CDA) is prepared by the national infrastructure, bundled in an HL7 FHIR message and delivered to the National Connector. The national Patient Summary and ePrescription services are responsible for generating such CDAs.

The situation is the same with the eHDSI CDA L1 documents, where the ePrescription flavour contains an embedded PDF of the national, legally defined, ePrescription document, while the Patient Summary flavour contains an embedded custom PDF. Regarding the processing of incoming eDispensations, the national eDispensation services do not generate any new document, they simply process the incoming eHDSI Friendly-A CDA L3 and apply the dispensation rules.

In NCP-B, the National Connector counterpart is the Portal Adapter, which also speaks the HL7 FHIR protocol with the national HL7 FHIR broker and performs the transformation of such protocol to the one expected by the OpenNCP Client Connector. Further to the side of the national infrastructure, there are two realities:

- For Patient Summary, the HL7 FHIR broker communicates with the distributed portals that have integrated the CBeHIS PS service into the usual HP's IT solution. There is no further transformation of the eHDSI Friendly-B CDA L3 document that comes out of NCP-B, i.e., these portals use the OpenNCP CDA Display Tool, complemented with the TSAM-Exported translations, for visualisation purposes.
- For ePrescription/eDispensation, the HL7 FHIR broker communicates with the national eDispensation services. The latter transform the received eHDSI Friendly-B CDA L3 ePrescription document into the national format, which is normally received by the pharmacies when performing the national dispensation business. The pharmacies, which are connected to the SOAP-based national services, receive the ePrescriptions documents in the national format and visualise them in their usual decentralised community pharmacy software. The latter, in turn, generates eDispensations messages in the national format, which are later transformed into eHDSI Friendly-B CDA L3 eDispensation documents by the national services and then bundled and forwarded to the HL7 FHIR broker up until the Portal Adapter in NCP-B. Some

business rules are applied within the national services in order to help the dispensing pharmacist make a decision, e.g., by using a custom medicinal product matching algorithm. On a side note: there is no equivalent to the ePrescription PDF for the national eDispensation.

With regards to semantic transformation within the NCP, it is worth mentioning the following:

- Both the Portal Adapter and National Connector perform semantic mapping of unit values (in every element where a concept from the eHDSIUnit Value Set is expected). This mapping is performed by using TSAM's capabilities to access the Master Translation/Transcoding Catalogue (MTC), where the units' mappings are defined (Table 1Table 1: Value Sets used in Portugal).
- The Transformation Manager component is configured to skip the translation process for ATC codes, since Portugal uses the ATC catalogue in English at national level.

Every other semantic transformation in the NCP happens in accordance with the common transformation configurations provided by default by the OpenNCP, using the national MTC. Based on the list of the main Value Sets impacted by ISO IDMP identified in D5.4, the following table provides the full picture with regards to translations and transcodings currently done in the Portuguese MTC:

Table 1: Value Sets used in Portugal

Value Set name	Code system(s)	Code System(s) ID	Version	Translation	Transcoding
eHDSIActiveIngredient	ATC Classification	2.16.840.1.113883.6.73	2021-01	No	Yes
eHDSIDoseForm	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16	Yes	Yes
eHDSIPackage	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16	Yes	Yes
eHDSIRouteofAdministration	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16	Yes	Yes
eHDSIUnit	Table of Example UCUM Codes for Electronic Messaging	2.16.840.1.113883.6.8	2021-04	Yes	Yes

As seen and explained earlier, the eHDSIActiveIngredient is the only impacted Value Set for which Portugal does not provide translations in the MTC. For all the others, there are translation and transcodings in place.

3.2.2 Ireland

The Irish NCP is operated by the Health Service Executive under the direction of the Department of Health. The Irish NCP follows the common architecture depicted in Figure 13 and uses a centralised XDS based architecture for eP and PS, as illustrated in the following diagram:

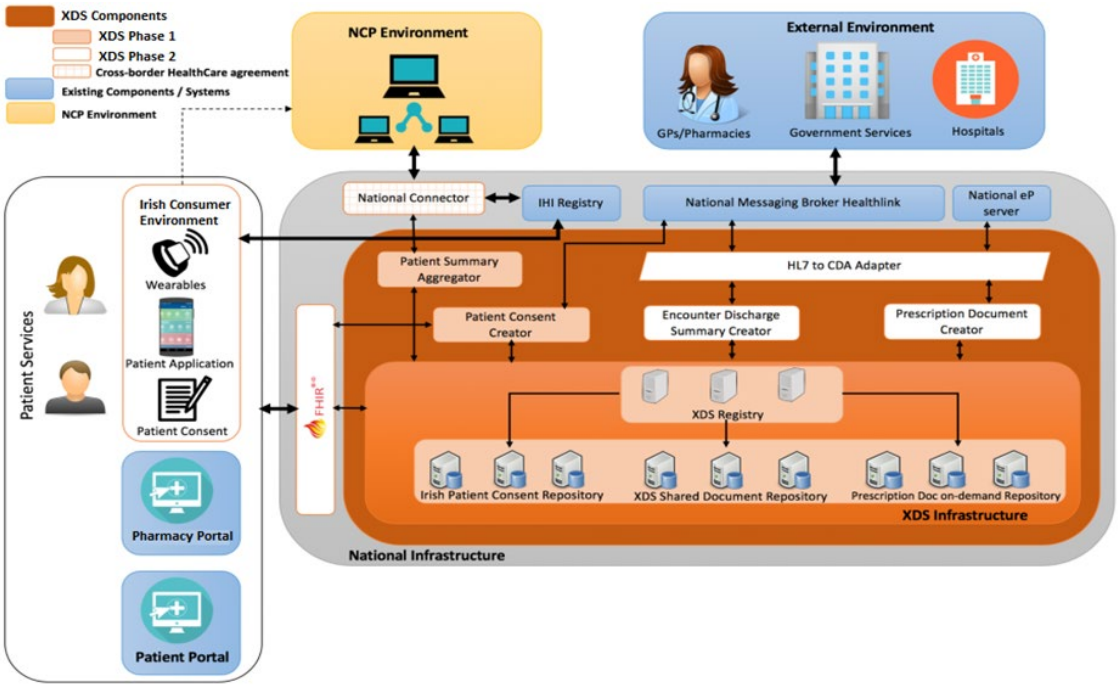

Figure 14: Irish XDS Architecture

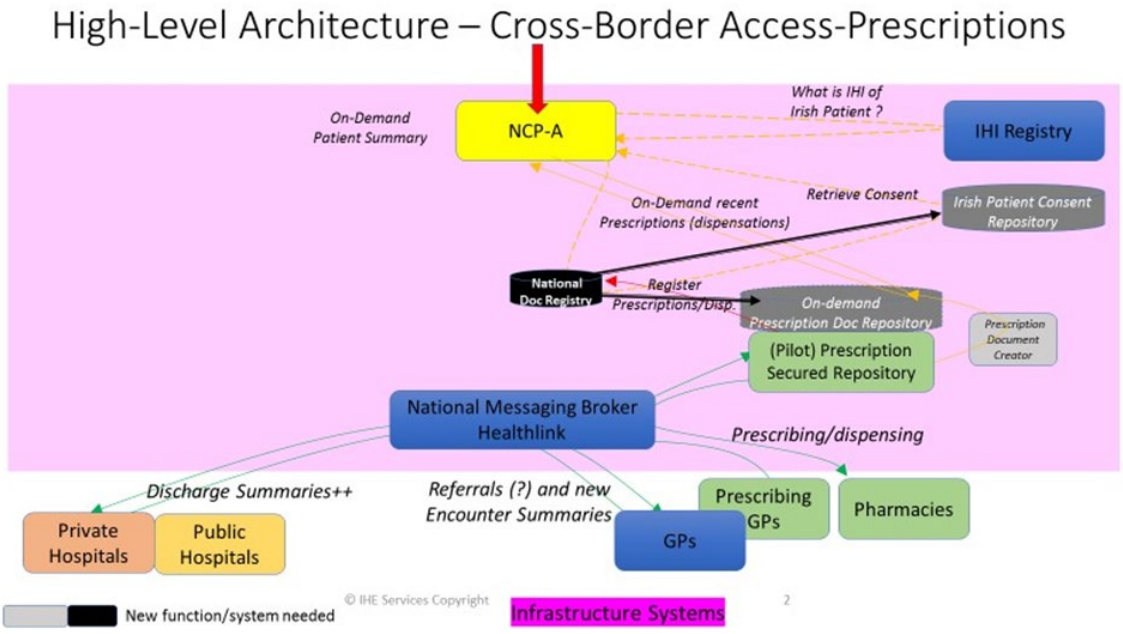

Figure 15: High-level Irish cross-border access prescriptions

The prescriptions are sent from the General Practitioners (GPs) through the national messaging broker (Healthlink) using HL7 v2 messages to the prescription secured repository which allows pharmacists to request the prescription.

An actor called prescription document creator extracts information from the messages and creates a CDA prescription document on demand for an Irish patient abroad (called friendly document). The creator will request the IHI number of the patient from the IHI Registry service. The ePrescription documents (CDA and PDF) are indexed in the XDS Registry but not created.

National coding systems and identification of the medicinal products should be mapped to the eHDSI terminologies.

In the case of errors, the documents will not be indexed in the national repository. Further investigation shall be performed for the design of the correction process.

Finally, the documents are accessed by the NCP-A (XDS query) if the patient has given his/her consent (document stored at the national level) prior to his/her travel abroad.

This architecture has no direct impact on the existing deployment of the ePrescription and allows future usages of the ePrescription in the country.

3.2.3 Spain

The Spanish NCP is under the responsibility of the Spanish Ministry of Health. The Spanish NCP provides the necessary services to allow cross-regional interoperability within the national territory: national patient summary and dispensation services among the 17 regions of Spain. In a similar way, the Spanish NCP facilitates services to make possible the Cross-Border eHealth Information Services (CBeHIS).

With respect to the region of Andalusia:

- Andalusia Health System has a central repository of regional Prescriptions and Dispensations and Medicinal Product data. All clinical points-of-care and pharmacies in the region are connected to the Prescription System (Receta XXI). Prescription and Dispensation information from Andalusia will be sent to other countries through NCP services.
- Andalusia Health system has EHR solution that includes health data from local repositories of their public health care centre (DCC: Centralised Clinical Data). DCC includes, among other clinical data, active medication data. Andalusian data is sent to the National infrastructure where the Patient summaries are assembled (HCD SNS system).

In Spain, only Patient Summary services are currently in operation in some regions. Region of Valencia PS services are in operation since October 2021, Basque country and Aragón could start operation by February/March 2022, Madrid, and Catalonia by October 2022.

Regarding Andalusia, PS is in pre-production environment and tests with the Spanish node (NCPeH) have been performed for Andalusia as country B (receiving PS from other countries) and should be in operation before June 2023 as for the rest of Spanish regions.

With respect eP/eD services, in general are under implementation. The following regions in Spain are prepared to start operation in eHDSI Wave 4 (June 2022): Extremadura, Basque Country, Madrid and Catalonia. The rest of the Spanish regions (including Andalusia) should be operative in eP/eD services before June 2023.

The following figure shows the common architecture that Andalusia will follow as country A:

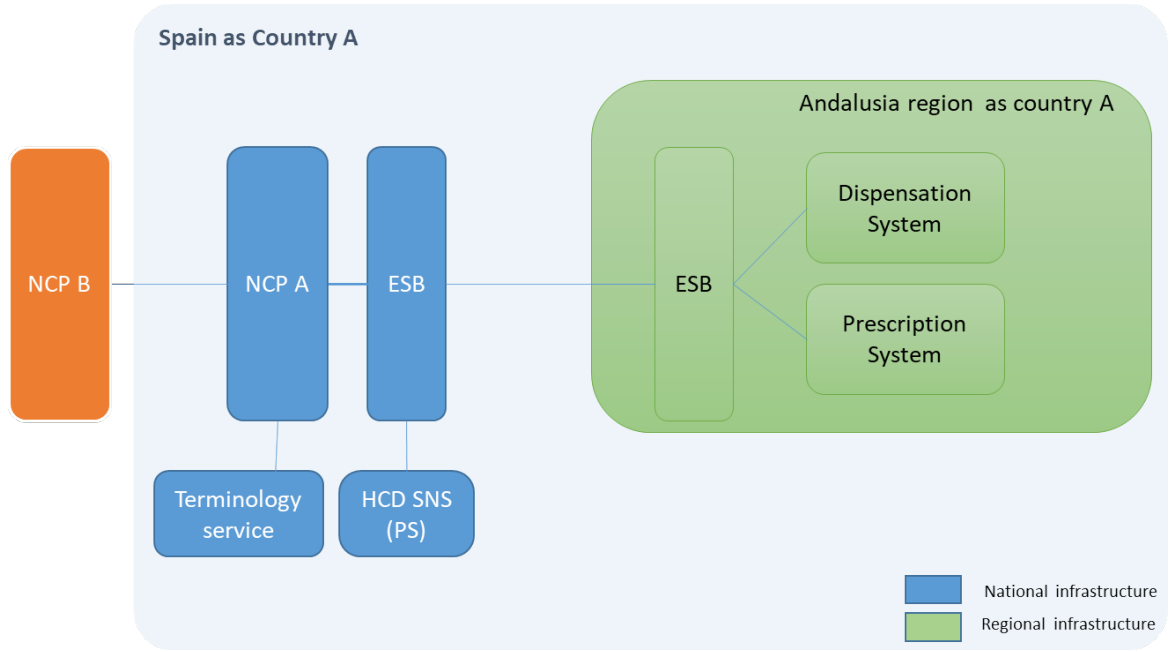

Figure 16: Spain- Andalusia NCP architecture- Country A

Andalusia uses its regional ESB, communication system between interacting and heterogeneous software applications in a service-oriented architecture for the exchange of information with the ESB of the national services. For other regions regional connectors are being used. On the other hand, as country A only eD system will need to be involved, as this is the system that validates that dispensation can be issued in country B by consulting the national identity provider.

The following figure shows the common architecture that Andalusia will follow as country B:

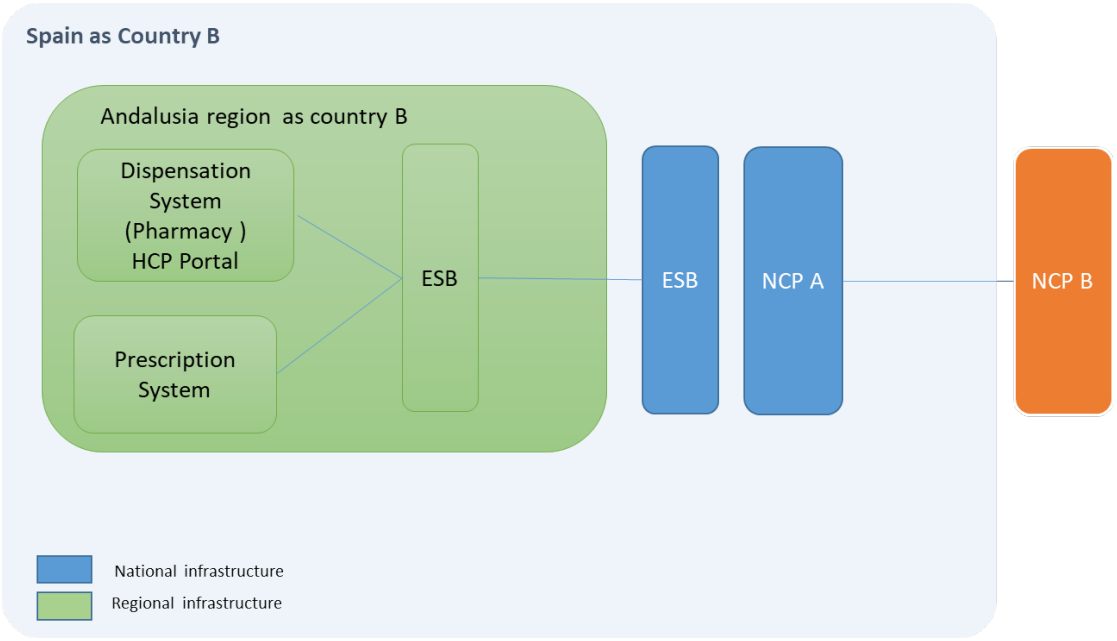

Figure 17: Spain- Andalusia NCP architecture - Country B

Implemented messaging is performed according to IHE, specifically the following profiles are used: XCPD for patient identification, XCA to obtain the active treatment, XDS to consult prescription details and XDR to perform the related dispensation.

Based on the list of the main Value Sets impacted by ISO IDMP identified in D5.4, Table 2 provides the full picture with regards to translations and transcoding agreed in the Andalusia region with the Spanish NCPeH:

Table 2: Value Sets used Andalusia (exchanged with Spanish Node)

Value Set name	Code system(s)	Code System(s) ID	Version	Translation	Transcoding
Medicinal product code (*)	Spanish NCA National Product Code	2.16.724.4.21.5.15.4		No	Yes
Medicinal product code (*)	Spanish NCA DCPF	2.16.724.4.21.5.15.3		No	Yes
eHDSIDoseForm	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16	Yes	No
eHDSIPackage	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16	Yes	No
eHDSIRouteofAdministration	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16	Yes	No
eHDSIUnit	Table of Example UCUM Codes for Electronic Messaging	2.16.840.1.113883.6.8	2021-04	Yes	No

(*) As it can be seen in the table, Andalusia does not consider the eHDSIActiveIngredient, but the Medicinal product code. In order for the Spanish NCPeH to obtain the eHDSIActive ingredient (in ATC) for cross-border interoperability:

- For medicinal products coded with commercial brand code, Andalusia will exchange the national product code (included in the regional and national MPD)
- For medicinal products coded with local code (Compofarma), Andalusia will exchange the DPFC code (included in the regional and national MPD, as long as the codification is synchronised in both MPDs).

3.2.4 Greece

The Greek NCP is under the responsibility of Ministry of Health and IDIKA (Electronic Governance of Social Security Services), which has been designated by law to operate as the Greek NCPeH.

The data flows from NCPeH services are presented in the diagrams below (Figure 18 and Figure 19), each applicable for any of the 4 cases (Patient Summary and ePrescription both for Greek patients abroad and for foreign patients in Greece, that is Greece acting as country A and country B, respectively)

Patient Summary

Figure 18 presents the PS NCP Greek architecture. A European doctor logs into the NCP portal (1). In this process, their credentials are verified by the identity provider of that country (B), which returns the doctor's role. The request to provide data (with patient's information) is transferred through country B's NCPeH API to the Greek NCPeH (XCPD request). The Greek NCPeH retrieves the patient's demographics through the National Prescription System' API in XML format and then returns this XML to country B's NCPeH (XCPD response). The latter displays this information to the doctor so that they can proceed with the patient's identification (according to the ID document of the Greek citizen). The Greek NCPeH retrieves the medical history information from the Personal Electronic Health Record system in a friendly CDA document (PS-A). It then transforms that PS-A friendly CDA to pivot CDA,

through calls to MVC (mappings). The Greek NCPeH returns the pivot CDA ("XCA RESPONSE"). The country B's NCPeH receives the pivot CDA and translates it through calls to the MVC. The patient summary (PS) is displayed on the doctor's user interface (UI).

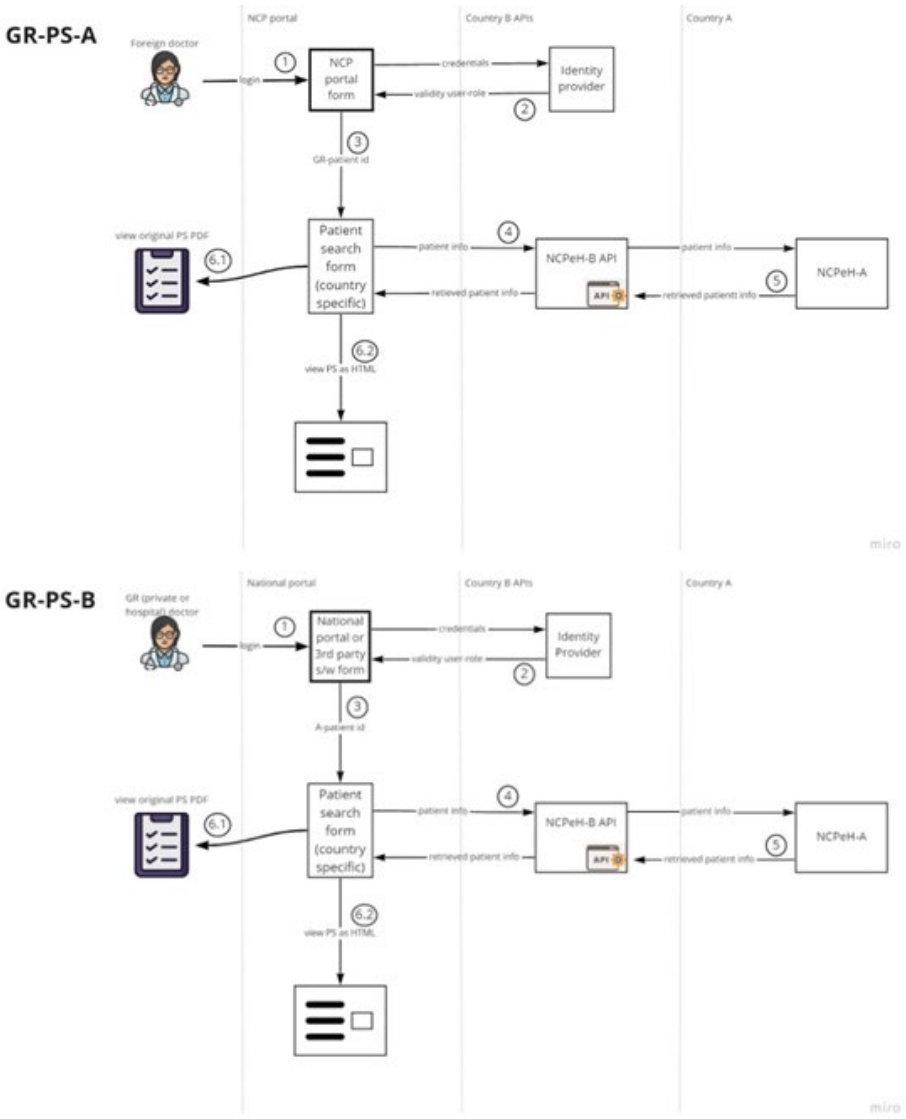

Figure 18: Patient Summary Greek NCP architecture for Country A and Country B

ePrescription

Figure 19 presents the eP/eD NCP Greek architecture. A European pharmacist logs into the corresponding NCP portal and searches for the patient in question by filling in the search form with the patient's ID. The request to provide data (with patient's information) is transferred via the country B's NCPeH API to the Greek NCPeH (XCPD request). The Greek NCPeH retrieves the patient's demographics through the National Prescription System' API and then returns the XML to country B's NCPeH (XCPD response), which displays it to the pharmacist for them to complete the patient's identification (according to the ID document of the Greek citizen). The pharmacist clicks on the 'patient prescription display' button (or as indicated in the corresponding UI) and declares the purpose for this access (treatment or emergency). Finally, the foreign pharmacist clicks on the "Confirm" button. A list of pending prescriptions for that patient is then displayed (calling "XCA LIST" having the purpose as a parameter). Each prescription can be either displayed in HTML or downloaded in PDF (calling "XCA

RETRIEVE" with the proper parameter value in document ID). The Greek NCPeH retrieves the prescription's friendly CDA from the National ePrescription System and returns it ("XCA RESPONSE") to the country B's NCPeH, whereas this CDA is transformed to pivot through calls to MVC (mappings). The ePrescription is displayed on the pharmacist's user interface (UI). The pharmacist fills in the medicine for disposal, number of packages and quantity per package. After submission, an eDispension CDA is created in country B's NCPeH, which transmits it to the Greek NCPeH (calls "XDR REQUEST") to execute a prescription of the National ePrescription System.

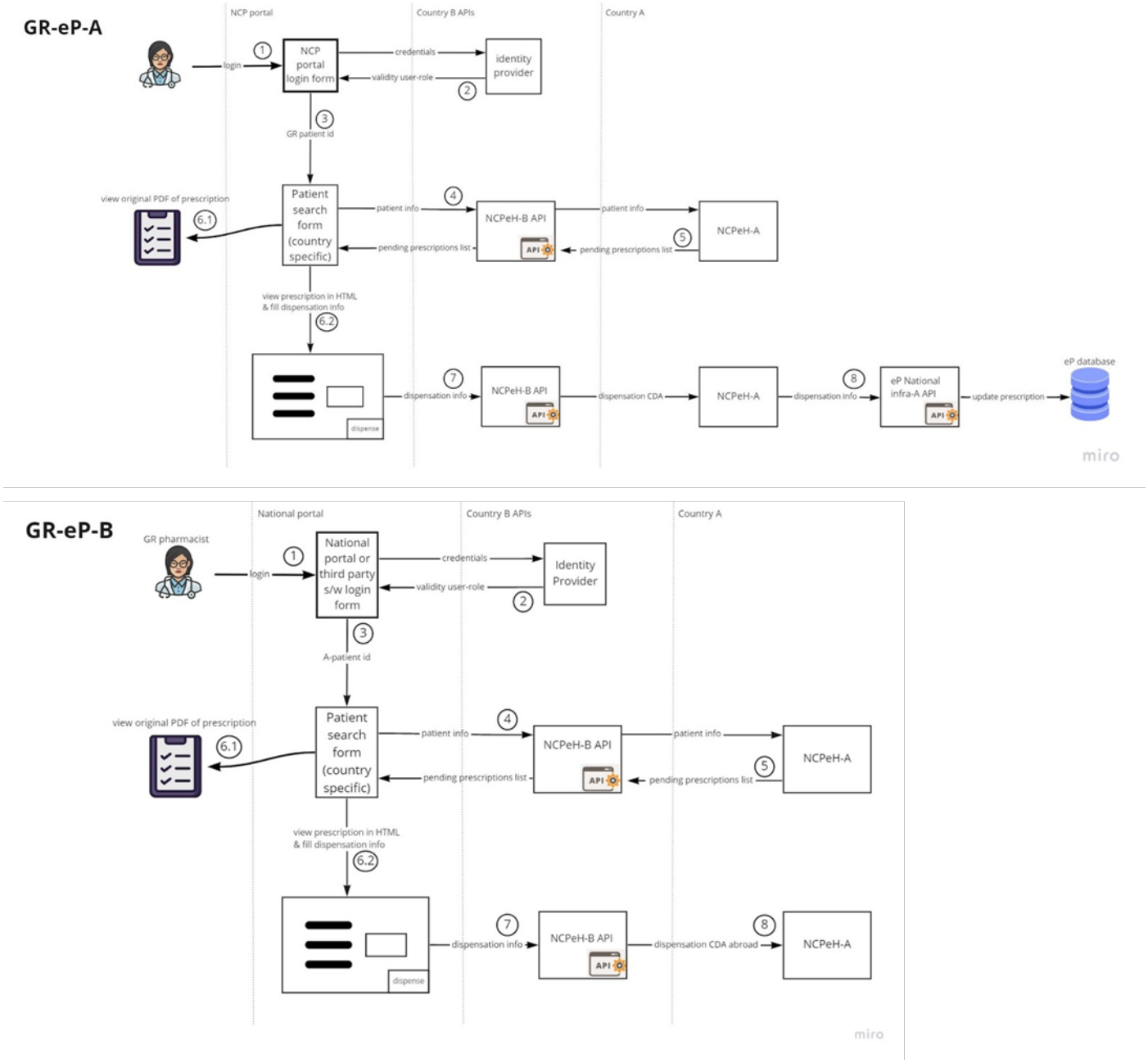

Figure 19: ePrescription Greek NCP architecture for Country A and Country B

3.2.5 Italy

In Italy, the NCP Consortium is formed by the Ministry of Health as Project Coordinator, the Ministry of Economy and Finance, AgID and the Emilia-Romagna, Lombardia and Veneto Regions. The Ministry of Health took care of the participation in the Call "2015 CEF Telecom - eHealth" in order to identify and

test the technical and operational criteria necessary to ensure the interoperability of the electronic prescription (ePrescription / eDispensation or eP/eD) and the Patient Summary at the European level. Emilia-Romagna, Lombardia and Veneto Regions were identified as they had tested both solutions for interregional interoperability in line with the specifications of the epSOS (Smart Open Services for European Patients) project for the Patient Summary and ePrescription and interoperability with the national infrastructure for the Electronic Health Record prepared by AgID. Within the Consortium:

- AgID, assisted by the Lombardia Region, coordinates the activities envisaged under Action 1 "Design and implementation of the NCPeH and cross-border services";
- the Veneto Region coordinates the activities envisaged under Action 2 "Testing and Distribution Services of the NCPeH and cross-border services";
- The Ministry of Economy and Finance coordinates the activities planned under Action 3 "Development of the NCPeH infrastructure and deployment";
- the Emilia-Romagna Region coordinates the activities planned under Action 4 "Communication and training strategy";
- the Ministry of Health plays the role of coordinator of the Italian partners involved in the project ensuring the activities provided for under Action 5: "Government and Management".

3.2.6 Finland

The Finnish NCP is under the responsibility of Kela (Kansaneläkelaitos - The Social Insurance Institution of Finland). Kela provides, as well, the national Kanta-services, which are essential to operationalise the Cross-Border eHealth Information Services (CBeHIS):

- The national Prescription Centre having a central repository of national Prescriptions and Dispensations and Medicinal Product data. All clinical points-of-care and pharmacies in the country are connected to the Prescription Centre.
- The national Health Record Archive service, which collects health data from local repositories of public and private health care provider organisations. This data along with the data of Prescription Centre are used for assembling Patient Summaries.

In general, the Finnish NCP follows the common architecture depicted in Figure 20. Only ePrescription/eDispensation services are in operation. Patient Summary services are under implementation.

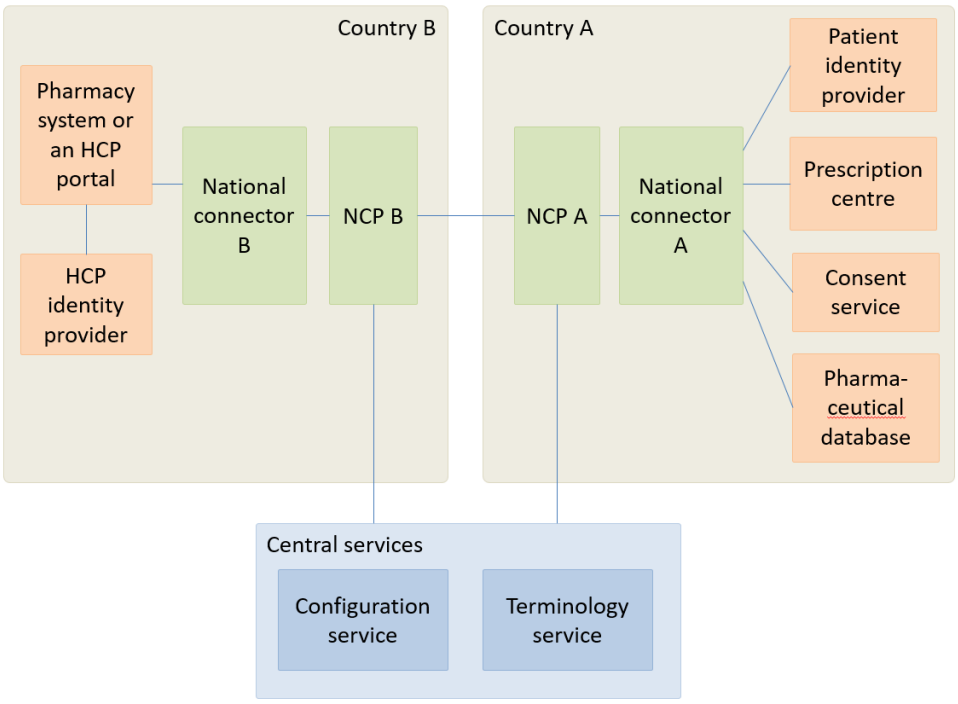

Figure 20: Finnish NCP architecture

In NCP-A, the National Connector maps IHE XCPD/XCA/XDR transactions data to HL7 MR v.3 messages to Prescription Centre. When it comes to fetching the prescriptions, the National Connector fetches national CDA L3 prescriptions from Prescription Centre and transforms them to eHDSI Friendly CDA L3 documents and/or eHDSI CDA L1 documents with custom PDF contents. Regarding the processing of incoming eDispensations and discarded eDispensations, the National Connector transforms the eHDSI Friendly CDA L3 documents to national CDA L3 dispensations and saves them to Prescription Centre.

In NCP-B, the National Connector gets the prescription retrieval requests from local pharmacy systems as HL7 MR v.3 messages and transforms eHDSI Friendly CDA L3 documents to national CDA L3 prescriptions with minor differences. The National Connector also receives national CDA L3 dispensations from local pharmacy systems as HL7 MR v.3 messages and transforms them to eHDSI Friendly CDA L3 documents. These documents are not saved in Prescription Centre.

With regards to semantic transformation within the NCP, it is worth mentioning the following:

- Other transcodings but ATC are currently performed by the National Connector without CTS/MTC. Finnish Friendly CDA in NCP-A uses directly eHDSI Code Systems. This is about to change in near future for UNICOM and Patient Summary and all transcoding is transferred to MTC.

Based on the list of the main Value Sets impacted by ISO IDMP identified in D5.4, Table 3 provides the full picture with regards to translations and transcodings currently done in the Finnish MTC:

Table 3: Value Sets used in Finland

Value Set name	Code system(s)	Code System(s) ID	Version	Translation	Transcoding
eHDSIActiveIngredient	ATC Classification	2.16.840.1.113883.6.73	2021-01	Yes	Yes
eHDSIDoseForm	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16	Yes	No
eHDSIPackage	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16	Yes	No
eHDSIRouteofAdministration	EDQM Standard Terms	0.4.0.127.0.16.1.1.2.1	2021-03-16	Yes	No
eHDSIUnit	Table of Example UCUM Codes for Electronic Messaging	2.16.840.1.113883.6.8	2021-04	Yes	No

3.3 Connection between the NCPeH and eHDSI

In order to connect an NCPeH to the eHDSI, each participating Member State must adhere to eHDSI published processes, procedures and deployment guidelines. Each Member State must establish one, and only one, NCPeH per country. This NCPeH is the connection point to the eHDSI and to their national health system(s). Each Member State is responsible for implementing and maintaining the functioning of the NCP and the described functions are established and implemented for cooperation between deploying countries. Organisational guidelines are required to support Member States implementing and maintaining their NCP.

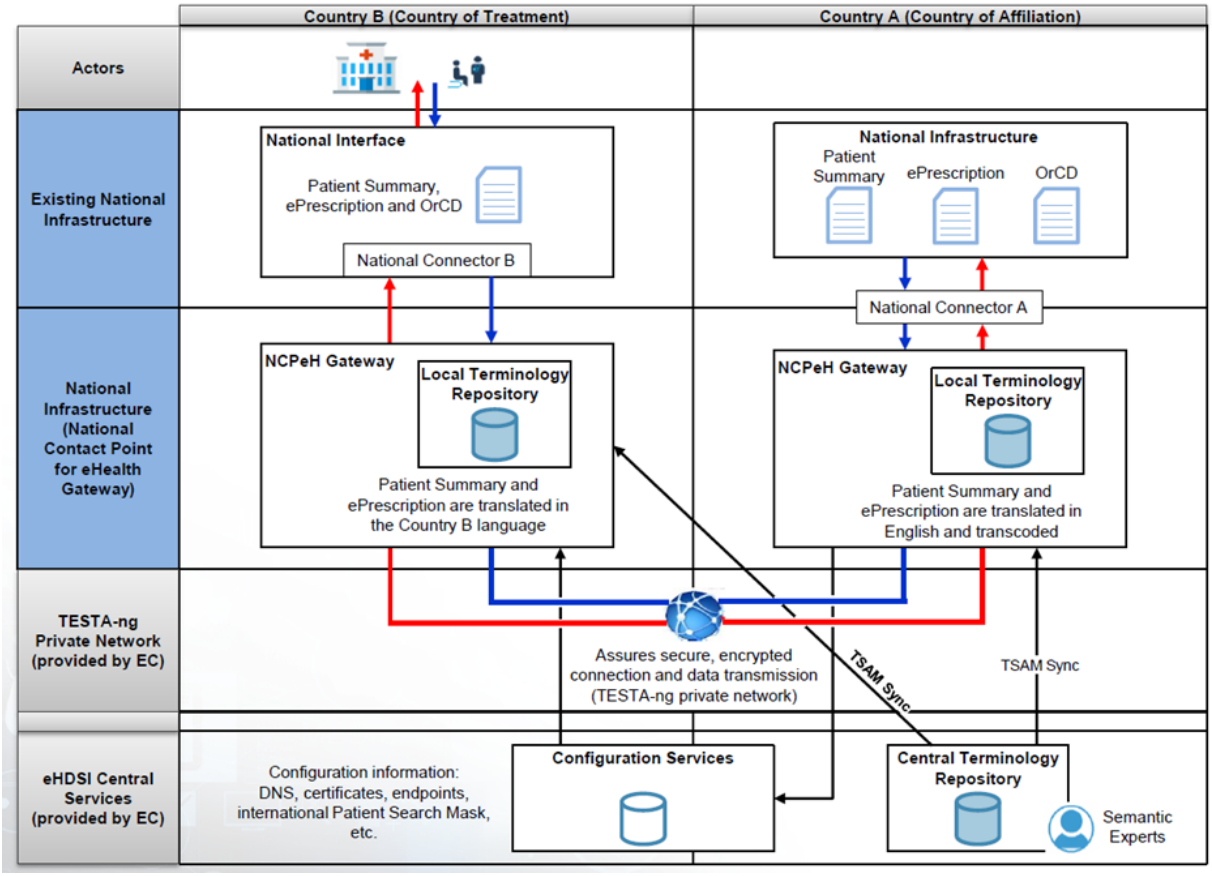

Figure 21: eHDSI service infrastructure – system and data flows[9]

The primary responsibility of an NCP is to support the eHDSI, both as a provider (role NCP-A) and as a consumer (role NCP-B). When NCP-B provides the eDispensation to NCP-A (as a notification), the NCP is to be connected to two infrastructures:

i) it is to be legally connected to its deploying country's national eHealth infrastructure and

ii) it is to be connected to the other eHDSI countries in the circle of trust.

As the NCP-A, the NCP must have a mandate from the national organisation to access the medical information (also identification & authorisation) of patients. As NCP-B, the NCP must have a mandate from the national organisation to use the national infrastructure for authentication and authorisation of healthcare professionals and identification of patient process.

[9] https://webgate.ec.europa.eu/fpfis/wikis/display/EHDSI/eHDSI+STARTING+TOOLKIT [page with restricted access]; https://ec.europa.eu/cefdigital/wiki/x/WKgSB [page with restricted access]

The NCP must take into account that any adaptations in the national infrastructure as a result of supporting the eHDSI (now and in the future) must be specified in agreements between eHDSI and the deploying country.

Against this backdrop the NCP must also consider the following:

- The connection to the national infrastructure should be checked to see what the effect of local adaptations are to the national infrastructure.
- The NCP must be connected to the eHDSI infrastructure: The NCP is part of a "federation" (called the eHDSI circle of trust).
- Public Key infrastructure (PKI) credentials (keys and certificates), used to technically implement the circle of trust, must be protected by technical and organisational measures. Procedures for requesting new credentials in case the current credentials are compromised or in case of failure should be setup with the certificate authority (CA).

The deploying country can decide on the actual implemented operating management framework, as long as the described functions are established and implemented for cooperation between deploying countries.

Each deploying country must have their own national support organisation setup before entering the eHDSI operation. This assumes national responsibility for Incident Management, Problem Management, Change Management and Service Level Management to provide 95% uptime 24 x 7, configuration and security management.

There are 3 main stages involved in ensuring NCPeH compliance to the eHDSI (Figure 22), namely:

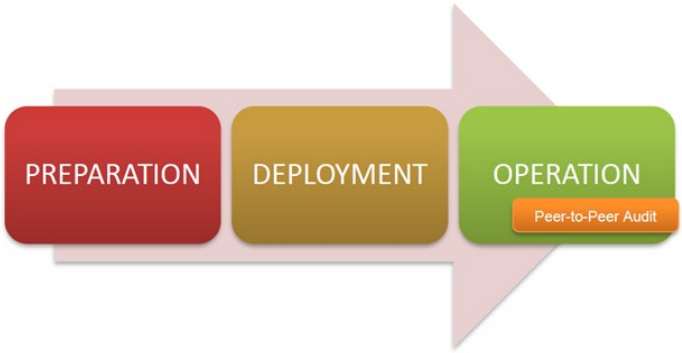

Figure 22: Compliance establishment process[10]

- PREPARATION, where Member State design the national deployment plan and perform national preparatory activities towards the provision of cross-border eHealth services.
- DEPLOYMENT, where Member State test (nationally and internationally), audit and provide evidence of the readiness level towards the provision of services.
- OPERATION, where Member State provide evidence about the quality and level of service provided, as well as Key Performance Indicators about service provision.

3.4 National specifications (Survey analysis)

UNICOM conducted a survey with the different Member States representing entities participating in this project. See Annex 1 for the technical specification questionnaire. Annex 2 contains some tables with the raw data.

[10] JAseHN.D5.1.1 Organisational Framework of Health NCP v2.0, https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5a4e14c1a&appId=PPGMS

This survey gathered information about the current state of Medicinal Product databases (National Competent Authorities (NCAs) and National eHealth services) with respect to eP, eD and PS.

This section provides the analysis and main conclusions of the survey's responses, which are crucial to the development of UNICOM guidelines. The survey has been structured in three parts: i) the current technical services, ii) semantic specifications and iii) substitution rules

The analysis is based on the responses received from the following UNICOM participating countries /regions: Spain (Andalusia), Ireland, Finland, Portugal, Italy, Croatia and Austria.

3.4.1 National Technical specifications

This section documents the result of the survey on National Technical specifications.

Citizen and/or Health Professionals access a self-service portal to view health information

Table 4: Citizens' access to their health data (self-service portal)

Country / Organisation	eP	eD	PS	Other comments
Spain (Andalusia)	Yes	Yes	Yes	Medication and dispensation information is within the patient summary available in the portal and App. Medication and dispensation information on the PS is only for active medication.
Ireland	Not	Not	Not	N/A
Finland	Yes	Yes	Yes	Other information provided to Finnish citizens is: Lab results, imaging, dental care, health and care plan, referrals
Portugal	Yes	Yes	Yes	
Sweden	Yes	Yes	Yes	
Greece	Yes	Yes	Yes	Medication and dispensation information available via the EHR and mobile app.

Table 5: Health Professionals' access to health data (self-service portal)

Country/Organisation	eP	eD	PS	Other comments
Spain (Andalusia)	Yes	Yes	Yes	eD and eP for healthcare professionals are only accessible from the corporative network because of security issues (intranet)
Ireland	Not	Not	Not	N/A
Finland	Yes	Yes	No	Other information provided to healthcare professionals is: Lab results, imaging, dental care, health and care plan, referrals. PS information can be accessed by healthcare professionals only through hospital EHR
Portugal	Yes	Yes	Yes	N/A

Sweden	Yes	Yes	Yes	
Greece	Yes	Not	Yes	Only the GP has access to patient's medical information or any doctor if the patient provides a secure number (pin)

The majority of the organisations that responded to the questionnaire have indicated the use of an online portal for the eP/eD and PS services. Spain (Andalusia), Finland, Portugal and Sweden highlighted that citizens and healthcare professionals have access to self-service portals.

Citizens in Spain only have access to PS services, through a portal and App, where the information on current medication and associated dispensation information is available. For eP and eD services, there are eP/eD portals in use, professionals can gain access through the corporate network for security reasons.

Ireland does not currently provide online portals for the access of eP/eD and PS services and have indicated that further plans for the implementation of self-service health data within next 2 years are currently under consideration.

Finland, in addition to eP/eD and PS services, also provides lab results, imaging, dental care, health and care plan and referrals through their portals and apps.

Messaging standards

Figure 23 provides an overview of the messaging standards used by the survey's participants to support eP/eD and PS services.

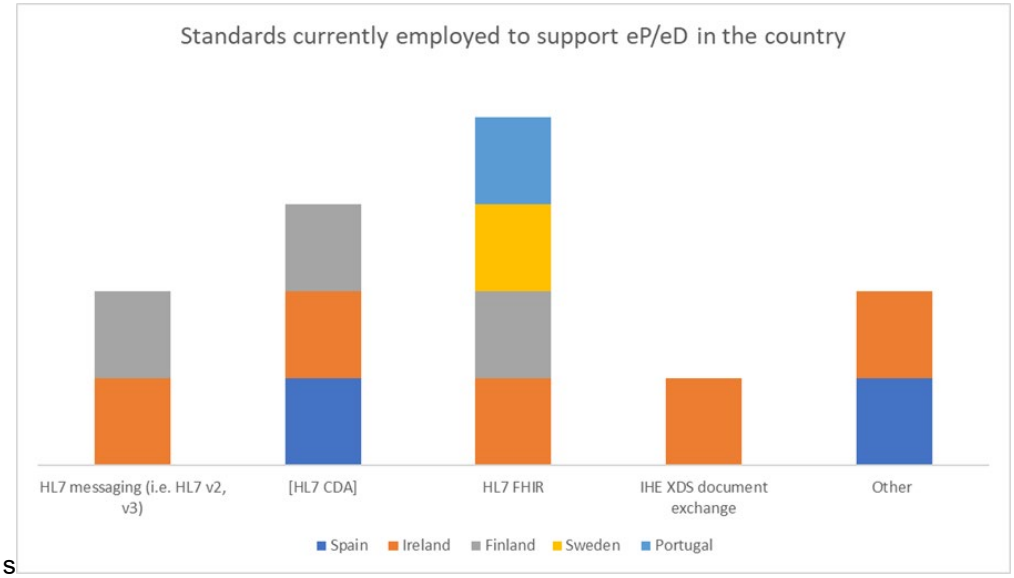

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Figure 23: Standards employed to support eP/eD & PS in each country

Of the seven countries, Finland and Ireland have implemented all standards that are specified in the previous figure.

IHE XDS is only being used in Finland for imaging (not currently used for national eP/eD, except in eHDSI).

Document exchange in Ireland is currently being implemented via a PDF in Healthmail[11]. However, its HL7v2 infrastructure is maturing to XDS, CDA and FHIR within the next two years.

The region of Andalucia, Spain, uses local codification that is exchanged through HL7 CDA in its eP/eD system. As a rule, the strategy is to adopt FHIR standards for new services.

Portugal and Sweden use HL7 FHIR to issue the national medications list in their systems.

Cloud-based applications

Erro! A origem da referência não foi encontrada.mmarises plans on the use of cloud-based applications in the UNICOM countries.

Table 6: UNICOM countries cloud-based deployment of eP/eD and PS plans

UNICOM Country	Plan to use cloud-base applications and services	Within the organisation infrastructure	External but within the country	In your cloud partners ecosystem
Spain	No	-	-	-
Ireland	Yes	Yes	-	-
Finland	No	-	-	-
Portugal	-	Yes	-	-
Greece	No	-	-	-

Portugal has adopted a cloud-based infrastructure within their organisation, and Ireland plans to adopt a similar model to Portugal that would be deployed within the organisation in line with Government policy.

Finland, Greece and Spain do not plan using cloud-based applications in the deployment of eP/ eD or PS.

Mobile solutions

The table below presents the key standards used for adoption to support mobile solutions.

[11] *Healthmail* is a secure clinical email service that allows health care providers to send and receive clinical patient information in a secure manner.

Table 7: Member States with plans to develop mobile solutions to deliver eP / eD and / or PS within their country

Country or entity	Key standards
Ireland	XDS; HL7 CDA rel 2.0; FHIR (mXDE and QED)
Portugal	HL7 FHIR, SNOMED CT, EDQM, ATC
Spain (Andalusia)	HL7 CDA
Greece	HL7 CDA Release 2, SNOMED, ICD10, ICPC2, ATC, epSOS for PS

Ireland plans to develop a new mobile solution to deliver eP/eD and PS services. Finland currently has no plans to develop a mobile solution, even so, the intention is to use a mobile solution in the future.

Portugal plans to update their current mobile solution to deliver eP/eD or PS services.

Spain, Andalusia plans to update the current mobile solution to deliver eP and PS services. There are no plans to implement mobile solutions for eD.

Blockchain technologies

None of the survey's responders indicated that they are currently investing in blockchain technologies for data integrity.

ISO 27001 Certification

While none of the survey's responders indicated that they are implementing ISO 27001 certification, Ireland plans to implement this standard in the next two years.

The region of Andalusia, Spain, confirmed that their system meets the National security scheme (NHIS) required by the Spanish public administration, which is compatible with ISO 27001.

Sweden has no plans to certify the use of the ISO 27001 standard. If the use of this standard is necessary in the future, then it will be considered.

Prescription/dispensation mechanisms

This section describes the current approaches to eP/eD.

Table 8: Use of a dematerialised prescription/dispensation mechanism by Member States

Country	Prescription /dispensation mechanisms (paper, electronic, both, others)
Spain (Andalusia)	Both electronic and paper prescriptions and dispensations
Ireland	Both electronic and paper prescriptions and dispensations
Finland	Electronic only, no paper
Portugal	Both electronic and paper prescriptions and dispensations
Greece	Both electronic and paper prescriptions and dispensations

Finland is the only country that prescribes and dispenses medicinal products exclusively through electronic transactions.

Spain, Portugal, Greece and Ireland combine electronic and manual prescription and dispensation.

Prescription/Dispensation document storage

This section outlines the current means of storing Prescription/Dispensation documents.

Table 9: Storage of the Prescription/Dispensation documents

Country	Storing of Prescription and Dispensations documents (raw data, persistent doc, others)
Spain (Andalusia)	As raw data in a database
Ireland	Where a prescription is provided using the national electronic prescription transfer system the pharmacy must print a copy of the prescription as transmitted and treat it as an original prescription for the purposes of record-keeping. The strategy which is being worked on now is to store them in an XDS Registry and Repository.
Finland	As persistent documents in a document database
Portugal	As raw data in a database
Greece	As raw data in a database

Spain, Greece and Portugal store documents electronically in machine and human readable format.

Finland stores as persistent documents in a document database.

Ireland reported that Prescriptions are being shared via HealthMail, a secure clinical email solution. Where a prescription is provided using the national electronic prescription transfer system (Healthmail) there is no need to obtain the paper equivalent from the prescriber. The pharmacy must print a copy of the prescription as transmitted and treat it as an original prescription for the purposes of record-keeping and reimbursement.

Prescription workflow

This section outlines the current workflow for prescription/dispensation.

Table 10: eP/eD workflow.

Country	Prescription/dispensation workflow
Spain (Andalusia)	One medication per prescription that allows one or more dispensation of the same or equivalent medicinal product. The prescriptions can be dispensed at any pharmacy within the country.
Ireland	Multiple medications per prescription/dispensations that allows one or more dispensation for each medication (a prescription is closed fully or partially at the same pharmacy during dispensation)

Finland	Prescriptions include one medication per prescription which can include one or more dispensation for it.
Portugal	Multiple medication prescriptions/dispensations (a prescription is closed fully or partially at the same pharmacy during dispensation
Greece	Multiple medication prescriptions/dispensations (a prescription is closed fully or partially at the same pharmacy during dispensation

Currently there are a number of different types of workflows across the Member State and are categorised as follows:

- One medication per prescription, single dispensation
- One medication per prescription, multiple dispensations,
- Multiple medication prescriptions/dispensations (a prescription is closed fully or partially at the same pharmacy during dispensation)

Finland and Spain follow a one medication per prescription to many dispensations approach. Both countries have their own prescription and dispensation rules, for example in Finland the prescription is valid for 2 years and dispensation of the linked medicinal product is limited to 3 months at a time.

In the region of Andalusia, Spain, the prescription and dispensation rules depend on the type of medicinal product. In general, healthcare professionals can prescribe for a maximum period of one year and necessary packages can be dispensed according to the posology of the treatment and dispensation rules.

In Ireland, Greece and Portugal prescriptions might include several medications linked with one or more dispensations, respecting the country validity, so that during the dispensation act, a prescription might be partially or fully closed. In Ireland, dispensation rules are linked to the schedule of medicinal product. It allows multiple dispensations from the same prescription, e.g., a patient with a prescription of two medicines can request the dispensing of each medicine on different days or pharmacies according to their needs.

3.4.2 Semantic specifications

In this section, semantic specifications of the participating countries were analysed with the objective of identifying the use of elements aligned with the eHDSI and, in this case, the coding system that the different countries are using to represent them.

Participation in the eHDSI Cross-border services

Table 11 shows the status of the responders regarding their country's participation and operation in the eHDSI cross-border services.

For more information, please visit the chapter *National Contact Point for eHealth (NCPeH) overview.*

Table 11: Participation in the eHDSI Cross-border services

Country	Operative in eHDSI Cross-border services
Spain (Andalusia)	The PS is in pre-production environment. Tests have been performed with Andalusia as country B (receiving PS from other countries) using the Spanish node (NCPeH). It is anticipated that the PS will be operational before June 2023. eP/eD services are under implementation. Andalusia should be operative in eP/eD services before June 2023.

Ireland	Wave 5 (PS as country A and eP as country A) Wave 7 (PS B and eP B)
Finland	eP operative, PS-A at the end of 2023, PS-B at the end of 2024
Portugal	Operative for eP/eD and PS as Country A and B
Greece	Pursuing to deploy eP/eD & PS services as country A&B with Wave 4 Specifications in production environment. Currently participating in Formal Pre-Production Testing event with Wave 5 Specifications.
Sweden	Sweden initially participated actively in the preparation of the services however some legal barriers has put this project on hold. Work is currently being undertaken to address this.

Coding system for Medicinal products attributes

Table 12 provides an overview of each countries coding systems used to represent the specific Medicinal Product attributes, in alignment with the eHSDI system.

National systems and National medicinal product dictionaries

Table 12 provides an overview of the use of the specific attributes in the National eHealth services, and the respective coding system to represent each element.

Table 12: Attributes and coding systems among Member States

Atribute	Spain (Andalucia)			Portugal			Ireland			Finland			Sweden		
	In use	Stored	Coding System	In use	Stored	Coding System	In use	Stored	Coding System	In use	Stored	Coding System	In use	Stored	Coding System
Active Ingredient (s)	Yes	Coded	Local coding by group of active ingredients (Compofarma)	Yes	Free Text		Yes	Free Text	Descriptor / Free Text	Yes	Free Text	N/A	Yes	Both	
Active Ingredient ID (code)	Yes	Free Text	N/A	Yes	Coded		Yes	Coded	SNOMED CT	Yes	Coded		-		
Dose form	Yes	Coded	Local codification but mapped to National code of medicinal products.	Yes	Free Text		Yes	Both	SNOMED CT	Yes	Free Text	N/A	Yes	Both	
Route of administration	Yes	Coded	Local codification but related with EDQM (at least for CEF)	Yes	Free Text		Yes	Both	SNOMED CT	Yes	Coded	National	No	-	
Strength	Yes	Coded	Local codification (Compodosis)	Yes	Free Text		Yes	Both	INTEGER (strength) & SNOMED CT (strength unit)	Yes	Both		Yes	Both	
Packsize/Number of Package	Yes	Free Text	N/A	Yes	Free Text		Yes	Free Text	INTEGER	Yes	Free Text	N/A	Yes	Both	
Unit of presentation	Yes	Coded	Own codification but related with EDQM (at least for CEF)	Yes	Free Text		Yes	Coded	SNOMED CT	Yes	Coded		No	-	
Brand Name	Yes	Free Text	N/A	Yes	Free Text		Yes	Free Text	MDP data model expected to also allow coding of 'brand name' via SNOMED CT	Yes	Free Text	N/A	Yes	Free Text	
Marketing Authorization Holder	Not	N/A	N/A	Yes	Free Text		Yes	Both	SNOMED CT (mapped from NCA/SPOR organisation list)	Yes	Free Text		Yes	Both	
Medicinal Product Code	Yes	Free Text	National code of medicinal products	Yes	Free Text		Yes	Both	SNOMED CT	Yes	Coded	VNR	Yes	Coded	

Additional attributes for eP/eD or PS services

Table 13: Additional attributes for support eP/eD & PS

Code	Attribute - EMA IG Section V2.1 (2021-02)[12]	PS	eP	eD	Important for substitution
1.	Medicinal product	FI	FI	FI	ES, FI, IE
1.1.	Product Management Service Identifier (PMS ID)				
1.6.	Combined pharmaceutical dose form		FI	FI	ES, IE
1.10.	Paediatric use indicator		FI		
1.11.	Full indication text		FI		
1.11.1.	Language	FI	FI	FI	IE
1.13.	Product classification		FI	FI	ES, IE
1.13.1.	xEVMPD product type information				ES
1.13.4.	Medicinal product category				IE
1.13.5.	Genetically Modified Organisms (GMO)				
1.14.	Medicinal product name	ES	ES	ES	ES, IE
3.	Therapeutic (product) indication				
3.1.	Indication as "Disease/Symptom/Procedure"				
3.2.	Co-morbidity				
3.3.	Intended effect				
4.	Packaged medicinal product				, IE
4.7.	Package item (container)				
4.7.1.	Package item (container) type				
4.7.2.	Package item reference				
4.9.1.	Type of combination product – Drug/ Device; Biological/ Device				IE
4.10.	Manufactured item				IE
4.10.2.	Manufactured item quantity				IE
4.10.5.	Manufactured item description				IE
4.10.5.1.	Language				IE
4.11.3.	Special precautions for storage				
5 5.	Ingredients				ES, IE
5.1.	Ingredient role				
5.2.	Origin of the substance				
5.3.	Composition grouping description				
5.4.	Manufacturer				IE
5.5.2.	Strength (quantitative composition)				ES, IE
5.5.2.1.	Quantity operator				ES, IE
5.5.2.2.	Strength (Presentation)				ES, IE
5.5.2.2.1.	Quantity operator				ES, IE
5.5.2.2.3.	Strength (Presentation high limit)				ES
5.5.2.3.	Strength (Concentration)				ES, IE
5.5.2.3.1.	Quantity operator				ES
5.5.2.3.3.	Strength (Concentration high limit)				ES
5.5.3.	Reference strength				ES, IE
5.5.3.2.	Quantity operator				ES

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

Code	Attribute - EMA IG Section V2.1 (2021-02)[12]	PS	eP	eD	Important for substitution
5.5.3.3.	Reference strength (Presentation)				ES, IE
5.5.3.3.1.	Quantity operator				ES
5.5.3.3.3.	Reference strength (Presentation high limit)				ES
5.5.3.4.	Reference strength (Concentration)				ES, IE
5.5.3.4.1.	Quantity operator				ES
5.5.3.4.2.	Reference strength (Concentration single value or low limit)				ES
5.5.3.4.3.	Reference strength (Concentration high limit)				ES
6 6.	Pharmaceutical product	ES	ES	ES	ES, IE
6.1.	Pharmaceutical product description	ES	ES	ES	IE
6.1.1.	Language	ES	ES	ES	IE

Table 13 identifies other relevant attributes for the implementation of IDMP currently used in the eP/eD and PS services. These attributes are an important feature for the development of the smart substitution component.

From the above information, given the limited amount of information provided by the countries, there is a disparity between all Member States and having a standard approach is preferable.

3.4.3 Substitution specifications

This section presents the primary considerations on how substitution of medicinal products is currently processed in the UNICOM participating countries / regions.

Substitution[13] is defined as the exchange of a medicinal product (MP) by another MP that differs from the original prescribed MP regarding one or several attributes (e.g., name, quantity, dosage form, strength…). Different Member States may have different rules regarding which type of substitution is allowed.

- **Generic substitution:**

  A generic medicine contains the same active substance(s) as the reference medicine (already approved medicine) and it is used at the same dose(s) to treat the same clinical condition. However, the non-active ingredients, name, appearance and package may be different from the reference medicine. Thus, a generic substitution is defined as the dispensing of a generic drug in substitution of the prescribed reference medicine, having the same active ingredient, dosage, strength and dose form.

- **Biosimilar substitution:**

  A biosimilar is a biological medicine highly similar to the reference medicine (already approved biological medicine) in terms of structure, biological activity and efficacy, safety and immunogenicity profile. It is distinguished from the generic medicine, as there is a natural variability and more complex manufacturing process related to the biological medicine, that does not allow an exact replication of the molecular micro-heterogeneity. Thus, a biosimilar substitution is defined as the dispensing of a biosimilar medicine in substitution of the prescribed reference medicine.

[13] For more details, please see the deliverable *D5.2 - Guidelines for IDMP-based Cross-Border ePrescription / eDispensation & Patient Summary*

- **Therapeutic substitution:**

  The dispensed medicine is a chemically different drug than the original prescribed medicine but belongs to the same pharmacological class and / or therapeutic class, meaning the medicines have a similar clinical / treatment effect as the original medication. However, this type of substitution normally needs the permission of the HCP-prescriber and each MS have specific rules for this type of substitution.

It is important to remember that the substitution process cannot remove legal or administrative barriers to dispensing a prescription. Those are governed by the national regulations.

Basic concepts that need to be considered and that need to be detailed in WP5 deliverables:

1. The legal principle is that Country A sets the validity when prescribing and Country B when dispensing.
    a. Country A will do what it does lawfully, and Country B will do things lawfully as well. Prescriptions that are legal in Country A cannot be refused by Country B, notwithstanding the right of the pharmacist to withhold dispensing if they have justifiable concerns about patient safety. So, all the instances will need to be treated on a case-by-case basis.
2. The substitution of a medicinal product needs to follow the single concept approach.

Dispensed medication (substitution) and appropriate pharmaceutical advice.

Spain permits the healthcare professional (pharmacist) to select a substitution for the prescribed medicine. In the Region of Andalusia, Spain, pharmacists can only select the substitution from a specific list of medicinal products according to local and national rules.

Portugal and Finland only permit the healthcare professional (pharmacist) to proceed a substitution at generic level of the medicine.

Finland and Ireland can advise the patient through oral communications; however, it is not registered in the system.

Spain remarks that the eD system does not allow to register advice provided by pharmacists, indeed the prescription (treatment sheet) includes instructions to patients registered by doctors in the prescription act and pharmacists cannot register any advice on the dispensation act. Doctors can also register advice to pharmacists to support substitution, i.e., "do not substitute for excipient lactose".

In Ireland, pharmacists can provide generic substitution (not therapeutic or biosimilar substitution) for a prescribed medicine, along with the appropriate pharmaceutical advice on the medicinal product and the substitution process.

Substitution of a prescribed medication

Spain, Ireland, Sweden and Finland permit the substitution of a prescribed medication.

In Spain, substitution is permitted for specific medicinal products according to national and local rules/laws, so that pharmacists are allowed to substitute from a set of medication offered by the eD system. In the region of Andalusia, Spain, the list of medicinal products that can be substituted are coded and based on the national product code (commercial brand). Business rules for substitution are based on the local code (Compofarma): medicinal products with same composition of active ingredients (Paracetamol 1g), pharmaceutical form (e.g., capsules) and packaging units (20) can be substituted. It is also possible to substitute the medicinal product for those with the same composition and pharmaceutical form; in these cases, pharmacists need to inform the reason for substitution (e.g., shortage).

In Ireland, if a prescription has been issued on a non-proprietary basis, the pharmacist can dispense an equivalent medicinal product whether proprietary or non-proprietary, if the medicine is included in the List of Interchangeable Medicinal Products published by the HPRA. If the medicine is not listed on the HPRA interchangeable list, pharmacists can dispense an equivalent medicinal product whether proprietary or non-proprietary, that is the lowest cost to the State or to the patient. In such cases, pharmacists should consult with the patient and exercise their professional judgment. E.g., pharmacists should not substitute medicines with a narrow therapeutic index or those with differing pharmacokinetic profiles likely to impact on efficacy or safety.

In Finland and Sweden, substitution is carried out using substitution groups specified for medicinal products. The prescriber can also forbid substitution in the prescription when necessary.

Organisational or legal constraints for substitution

Primarily all types of Substitution, including Smart Substitution, are only permitted in accordance with National legislation, however there are some exceptions.

Sweden do not have any legal or organisational constraints concerning possible substitution during the dispensation process, however the substitution should follow the countries rules.

In Finland, substitution is subject to legal constraints. The Finnish Medicines Agency Fimea creates and maintains a list of interchangeable drugs that are biologically equivalent and whose active substance and concentration are the same. This list contains innovative and generic products with marketing authorisation that meet the creation criteria. List is published 4 times a year. Biosimilar and therapeutic substitution is not allowed.

The region of Andalusia in Spain permits substitution of medicinal products subject to legal and organisational constraints. For example, restrictions on maximum number of packages or number of days of treatment that can be dispensed.

In Ireland substitution is subject to legal constraints. Therapeutic and biosimilar substitution is not permitted (where this is required to occur the pharmacist is required to consult the prescriber and request a separate prescription). There are also several products that are not permitted for generic substitution such as anti-epileptics, anticoagulants, and lithium products. Both the prescribed and substituted medicines must be part of the same ‘interchangeability list’. The HPRA maintains grouper lists of licensed medicines that are deemed clinically interchangeable. These are grouped by ‘basis of strength substance’ (BoSS e.g., atorvastatin, olanzapine). Each list contains the interchangeable brands for a particular strength. A pharmacist may only substitute products within an individual list. As of 03/03/2022 the HPRA maintains lists for 103 active ingredients, and this is expanding on an ongoing basis.

Smart substitution expectations

Andalusia, Spain has specific expectations which are as follows:

- The component should provide an API for the integration with the current systems
- The component should not penalise the current performance of the systems
- The component should always be updated with the medicinal products allowed by the NCA.
- The component should only provide those medicinal products allowed by the NCA
- The component should facilitate the national codification of the proposed substitution.

Sweden also has specific expectations which are as follows:

- The component must be designed with patient safety as its most important factor.
- Further consideration is required to address particular problems with some products e.g., biosimilar products are not usually substituted.
- The PhPID is not considered suitable for biosimilar substitution.
- An attribute, specifically designed, is needed for prescriptions and generic substitution.

Ireland expectations in the area of smart substitution include:

- Substitution of medicinal products adds risk to overall dispensing process and so patient safety must be the key driver of any smart substitution component (both in terms of system factors and human factors).
- The Irish legislation underpinning generic substitution places the patient at the centre of the decision-making process "*the opportunity to agree to the pharmacist substituting the branded product with one of the substitute medicinal products chosen by the patient, or the person acting on behalf of the patient".* This centricity of the patient would need to be preserved in any smart substitution process.
- It will be required to examine specific medication classes and their considerations at a national level e.g., biosimilar products, antiepileptics and lithium products are not substituted. Specific indicators in this respect are expected to be carried in the National Product Dictionary that is in development. These national limitation attributes would have to be considered.
- In order to ensure an efficient, accurate substitution process the smart substitution component's dataset (if applicable) must be kept up to date with relevant medicinal product interchangeability list information carried by the NCA.
- Where a prescriber does not want a substitution process to be undertaken for a specific medication, they may mark a prescription with the words 'Do Not Substitute' to indicate that although the medicine/brand prescribed is legally allowed to be substituted they deem it subject to a clinical exemption. Any smart substitution component must allow this type of exemption to be clearly and accurately notified.

Acknowledging the process of substitution varies across Member States, further consideration is necessary to ensure synergy.

4 Guidelines for ISO IDMP national implementation

The analysis of the current situation in Member States about product data sharing and clinical document exchange in this document, combined with the functional analysis of eHealth services systems in previous deliverables, and the remaining review throughout UNICOM allows a series of proposed guidelines for enabling or facilitating the adoption of IDMP in Member States.

Group 1 (G1): Articulated integration with Member State frameworks and procedures / business continuity

The first group of guidelines is about supporting Member States current laws, frameworks, systems, and practice. An example from previous documents in UNICOM is that IDMP adoption should not require drastic or isolated changes to the way products are defined in a Member State, because that would misalign with the Member State's regulation. While regulatory changes may be triggered by IDMP, that is not the intent and should not be a consequence of IDMP adoption; at most, it could be supported by the Member States who shall retain their legal autonomy.

G1.1 - For MPDs: ensure support for IDMP in addition to the national product identifications and descriptions

Each Member State should adopt the minimum set of attributes required to support IDMP implementation in the different business processes (regulatory, clinical), but this shall not mean removing support for national product levels and definitions.

G1.1.1 - Member States' MPDs shall retain support for the national product definitions of authorized products

IDMP adoption is not IDMP conversion. Member States' MPDs shall continue to support the description of products in the national vocabulary, as required to maintain the operations based on the Member State's regulation.

G1.1.2 - Member States' MPDs shall implement support for the key IDMP attributes

National MPDs shall adopt IDMP definitions at least to support the common product definitions and identifiers defined by the EMA initiatives.

G1.1.3 - Member States' MPDs may support other products,

Beyond those that are authorised at the national level, e.g., foreign products for substitution and/or for clinical decision support.

G1.2 - For Clinical systems: ensure support for IDMP where needed, maintaining national product identification and description

Similar to MPDs, the clinical systems (ePrescription, eDispensation, Patient Summary, others) will be impacted. For continued compliance with national regulations, the impact of IDMP on clinical systems shall consider the existing services and the and the impact of changes.

G1.2.1 - Member States' clinical systems shall retain support for national product descriptions

As cross-border enablement is important but should not impose on national regulations.

G1.2.2 - Member States' clinical systems shall add support for (at least) minimum IDMP identification and descriptions in the data exchanges, where that is legally or technically required.

IDMP-compliant product description and identification presents minimum requirements. These must be followed in the clinical systems, but only where relevant, and shall not be imposed when the exchange of data does not need to use IDMP product descriptions (for example in tracking medication dispensing and administration strictly within a country or institution), or when that is not possible (for example when assigning rules to national product classifications that are not required by IDMP − typical examples: billing and approval rules).

G1.2.3 - For interoperability: Ensure continued interoperability across all stakeholders by designing and updating systems according to the use cases, requirements, and architecture.

Apps and systems should consider the first 2 principles above, ensuring semantic interoperability as a precondition to technical interoperability:

- Professionals may or not require using IDMP concepts and descriptions, and interoperability shall support both options − IDMP adoption does not need to impose on clinical practices.
- Patients should see the benefits of better data especially when crossing borders − but patient information is a different flow and may or may not be impacted by IDMP in some cases. An analysis should be done for assessing the flow of information and from there evaluate the need and impact of IDMP adoption or conversion.

Group 2: Architecture and governance: Adherence to international standards and eHDSI guidelines

Managing IDMP adoption has a great degree of complexity across the entire architecture layers − legal/business, functional, technical. Alignment in governing the IDMP adoption is important to identify, plan and implement the changes. The eHDSI framework, along with other recommendations and best practices, foresee some architectural patterns and management practices. And the eHDSI has a

fundamental role in maintaining the continuity (over time and across borders) of the specifications that must remain common.

G2.1 - For Member States, IDMP adoption may be phased as per existing conditions and target requirements

IDMP adoption will present change requirements − and those change requirements will vary across Member States, depending on the existing status, national constraints, goals, etc. Some Member States may try to introduce IDMP concepts directly in the clinical systems exchange, others may only align part of the value sets, and others may rely on transcoding between national product identifiers and IDMP identifiers. This variability should be anticipated, instead of expecting a single-shot ("big bang") solution which would probably limit the Member States' autonomy.

G2.2 - Establish a layered architecture for compatible specifications

more than a single specification, ensuring common requirements are clearly separated from local requirements.

G2.2.1 - Maintain common specifications centrally, allow compatible local specifications when needed

While UNICOM presents common requirements (e.g., common value sets, common needs), each country will expect to have their own implementation variants. It is important to allow such variations while maintaining compatibility with central requirements. For example, Member States may have local value sets in local prescriptions, but they must respect the eHDSI value sets for cross-border prescriptions. The common specifications must be maintained centrally as is currently being done by eHDSI, and IDMP adoption shall remain compatible with such specifications.

G2.3 - Document (and coordinate) the system design and planning for IDMP adoption

To ensure cross-border alignment as they plan and implement their IDMP adoption − and provide precious insight to EU-level guidance − Member States should document their design and capture their planning in a consistent way.

G2.3.1 - Capture the requirements, use cases, specifications, and target architecture

possibly in a shared and/or public manner, for cross-checking, scope and gap analysis, feedback, etc.

G2.3.2 - Follow the European Interoperability Framework

and its principles and artifacts for governed, evolving architecture.

G2.4 - Establish coordination across Member States for IDMP adoption roadmap

This is being initiated in several aspects by and within UNICOM but should continue even after the closure of the UNICOM project, by establishing common references and making the best use of coordination mechanisms.

G2.5 - Ensure IDMP adoption is part of an expandable architecture

IDMP adoption will require a solid integration among systems. In addition, IDMP adoption will likely have a progressive nature, which in itself benefits from an expandable architecture. Member States should not be locked to a fixed architecture. The architecture shall accommodate expansion to accommodate for IDMP adoption, and allow further expansion − to new use cases, to new types of systems, and to the evolution of IDMP itself, when applicable.

G2.5.1 - IDMP adoption shall itself use standards as much as required for the challenges defined by IDMP

Such as interoperability, semantic standards, etc. As seen in this deliverable, there is a strong appetite for using standards in national implementations − which is favourable to successful implementation across borders. The use of standards − and the common use of the same standards − should be encouraged throughout the implementation, even after the UNICOM project has ended, namely by a central and continued governance of semantic specifications and common criteria. One example of this would be standardizing the mechanisms for brokerage of MVC data (i.e., the technical interface for an NCA to update the Value Sets from eHDSI).

G2.6 - Testing of cross-border product identification should be based on common, managed test cases, test criteria, test data.

Besides the UNICOM coverage of the testing for cross-border exchange, it is expected that different testing will be done as Member States adopt IDMP and the UNICOM recommendations in different phases. To ensure continuous interoperability, UNICOM is expected to produce the necessary testing artifacts, and Member States (and any systems involved with IDMP adoption) should make use of common test artifacts − test cases, test criteria, test data − which should be maintained and always kept in line with the specifications.

G2.7 - Implementation and maintenance

G2.7.1 - IDMP adoption shall complement, but not forcefully alter or override, existing national architecture

This is a reflection of Guideline 1 above. The operational implementation of IDMP should not negatively affect the existing national architecture and operations.

G2.7.2 - Establish and document Release Management (including data sharing and brokerage) for the IDMP adoption and especially for its common dependencies

As seen in this document, most Member States make explicit their release cycles − when the value sets and product catalogues are updated and how they are synchronized. This becomes fundamental as it impacts semantic interoperability. While a single, common mechanism may not be achieved (or even important), the key activities related to the Release Management − when master or reference data is updated, how to synchronize, etc.) should be formally established for comparison and dependency analysis − and possibly for optimization.

G2.7.3 - Progress of implementations should be monitored

As Member States implement their IDMP compliance in different parts of their architecture, these implementations should be monitored to support cross-border planning based on updated and realistic information.

G2.7.4 - Define criteria for operational success and monitor the implementations according to such requirements.

Implementations at each Member State will have their own scope, and therefore their own measure for success. However, common criteria can be defined for safe, interoperable data exchange, and that criteria may be monitored by Member States. Examples: system uptime for MPDs and respective interfaces, data quality indicators, etc. Such criteria should be defined centrally and monitored when applicable to a specific Member State.

Group 3: Clinical and societal impact

The promise of IDMP adoption can only be fulfilled when patient safety or operational efficiency are enhanced. A few specific guidelines can be important in attaining and monitoring the real impact.

G3.1 - Support and monitor the effect of IDMP on effective, safe drug substitution across countries − centrally and locally

The present monitoring at eHDSI provides a good indication of how many prescriptions have been produced, shared, etc. After IDMP adoption, it is important to monitor how much this has effectively impacted patients, by monitoring the prescriptions dispensed, refused, or substituted.

G3.2 - Use IDMP in decision support

Starting with different types of prescription and substitution support, assess the potential of these rules in defining different types of substitution, different rules, and new decision support categories.

G3.3 - Evaluate the other impacts of cross-border treatment − from billing, to supply chain shortages, to legal limitations

As example of the eHDSI monitoring, Member States should evaluate criteria (from billing, to supply chain shortages, legal limitations, etc.) related to the eP/eD & PS services in order to identify the results of the IDMP implementation in their system, accordingly with the Member State implementation strategy.

Annexes

Annex 1 – Survey questions

UNICOM – Survey 2 (Technical questions) – WP 5

Analysis on the current state of Medicinal product databases of eHealth Services at the National level for IDMP adoption

Introduction

UNICOM[14] – an EC supported Innovation Action - focuses on implementing the International Organization for Standardization (ISO) suite of IDMP (**ID**entification 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), electronic Dispensation (eD) and Patient Summary (PS)) aims to gather information about the current state of Medicinal product databases of National Competent Authorities (NCAs) and national eHealth services at national/regional level. The results of this survey will be used to develop the UNICOM guidelines for the adoption of ISO IDMP eHealth services at the national level and their connection to de Medicinal Product databases both from NCAs and from private providers.

This survey is intended to be answered by the eHealth Agencies and national drug agencies representatives.

For the purpose of this survey, the definitions of ePrescription and Patient Summary was extracted from the UNICOM Glossary[15].

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.

The concept of **eDispensation** is understood as 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.

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

[14] https://unicom-project.eu/

[15] https://glossary.ramit.be/public/index.cfm

target groups of survey respondents, but please note that any response you provide in this Survey will be fully anonymised.

Technical Services Questions

Technical Services

Q1. Are your citizens/Health Professionals able to access a self-service portal to view their health data today?

Citizens:
☐ Yes
☐ No

Health professionals:
☐ Yes
☐ No

If yes, can you confirm which services are available via this self-service portal, mobile app? Specify if is to eP/eD/PS.

Citizens:
☐ eP
☐ eD
☐ PS
☐ Other:_____

Health Professionals:
☐ eP
☐ eD
☐ PS
☐ Other:_____

If No, do you plan to enable self-service access to health data within the next 2 years?

☐ Yes
☐ No

Q2. What standards are currently employed to support eP/eD/PS within your country?

☐ HL7 messaging (i.e. HL7 v2, v3)
☐ HL7 CDA
☐ HL7 FHIR
☐ IHE XDS document exchange
☐ Other please specify, R: _____

a. Can you confirm what standards you plan to adopt/upgrade over the next 2 years?

Q3. Do you plan to use cloud-based applications and services in the deployment of eP / eD or PS within your country?

☐ Yes
☐ No

If yes, can you confirm where your patient data will reside?

☐ Within your Organisation
☐ External but within your country

☐ In your cloud partners ecosystem

Q4. Do you plan to develop mobile solutions to deliver eP / eD and / or PS within your country?

☐ Yes
☐ No

If yes, can you confirm the key standards you plan to adopt?

A.

B.

C.

Q5. Is your organisation investing in blockchain technologies for data?

☐ Yes
☐ No

If yes, can you confirm the use cases and technologies you plan to use?

Q6. With reference to IT security, can you confirm if your organisation has IS0 27001 Certification?

☐ Yes
☐ No

If No, can you confirm if you plan to implement ISO 27001 certification within the next 2 years?

☐ Yes
☐ No

Q7. Any other comments or details that you would like to add to improve technical services and their ability to deliver eP and PS:

Q8. Do you use a dematerialised prescription/dispensation mechanism, thus only electronic transactions or do you still have to print the documents?

☐ Electronic only, no paper
☐ Paper only
☐ Both electronic and paper prescriptions and dispensations
☐ Other please specify, R: _____

Q9. How do you store the Prescription/Dispensation documents?

☐ as raw data in a database
☐ as persistent documents in a document database
☐ Other please specify, R: _____

Q10. How do you handle the prescription workflow?

☐ on medication per prescription, one to one dispensation
☐ multiple medication prescriptions/dispensations (a prescription is closed fully or partially at the same pharmacy during dispensation
☐ Other please specify, R: _____

Substitution Questions

Q11. Are the pharmacists allowed to select the final medication dispensed to the patient and provide pharmaceutical advice to the patient?

☐ Yes
☐ No

Comments: _____

Q12. Are the pharmacists allowed to substitute a prescribed medication?

☐ Yes
☐ No

Comments: _____

If you replied "Yes" to the above question, what are the substitution parameter allowed?

A._____

B._____

C._____

Q13. Are there organisational or legal constraints concerning dispensation and possible substitution of a medical during the dispensation process?

☐ Yes
☐ No

If 'yes', please describe: _____

Q14. If a smart substitution component is implemented by UNICOM, what are your expectations from such a component?

R:_____

THANK YOU VERY MUCH FOR YOUR HELP!

Semantic questions

The purpose of the following questions to NCAs is to understand the current state of their Medicinal product databases to identify possible gaps for the ISO IDMP adoption:

Q1. Is the country you are answering this survey for participating in the operation on the eHDSI Cross-border services?

☐ Yes
☐ No
☐ Planning for: _____(month/year)

Q2. Are the **National systems** linked with the following medicinal product information in your national medicinal product dictionary?

The objective of this question is to identify, in alignment with the eHDSI system, the use of the elements specified in the first column in the national eHealth services, and their respective coding system to represent each element.

The outcomes of those questions will support the UNICOM WP5 to define the minimal attribute list to be used on the implementation of the ISO IDMP on the eHDSI and National structures.

Before filling the table, please consider the following example (blue lines table):

Attributes	**National product coding system**		**Which coding system does your country uses to represent the Medicinal Products attributes?** **R:** *SNOMED CT*
	In use?	**How is the information stored?**	**Does your country use the same coding system for all the attributes?** ☐Yes ☒ No **If not, please specify below:**
Active Ingredient(s)	☒ Yes ☐ No	☒ Free text ☐ Coded ☐ Both	**R:** *SNOMED CT*
Active ingredient ID (code)	☒ Yes ☐ No	☐ Free text ☒ Coded ☐ Both	**R:** *SNOMED CT*
Dose Form	☒ Yes ☐ No	☐ Free text ☒ Coded ☐ Both	**R:** EDQM

Which coding system does your country uses to represent the Medicinal Products attributes?

R:_____

Attributes	National product coding system		
	In use?	How is the information stored?	Does your country use the same coding system for all the attributes? ☐Yes ☐ No If not, please specify below:
Active Ingredient(s)	☐ Yes ☐ No	☐ Free text ☐ Coded ☐ Both	**R:_____**
Active ingredient ID (code)	☐ Yes ☐ No	☐ Free text ☐ Coded ☐ Both	**R:_____**
Dose Form	☐ Yes ☐ No	☐ Free text ☐ Coded ☐ Both	**R:_____**
Route of administration	☐ Yes ☐ No	☐ Free text ☐ Coded ☐ Both	**R:_____**
Strength	☐ Yes ☐ No	☐ Free text ☐ Coded ☐ Both	**R:_____**
Packs size / Number of Packages	☐ Yes ☐ No	☐ Free text ☐ Coded ☐ Both	**R:_____**
Unit of presentation	☐ Yes ☐ No	☐ Free text ☐ Coded ☐ Both	**R:_____**
Brand Name	☐ Yes ☐ No	☐ Free text	**R:_____**
Marketing Authorization Holder	☐ Yes ☐ No	☐ Free text ☐ Coded ☐ Both	**R:_____**
Medicinal Product Code	☐ Yes ☐ No	☐ Free text ☐ Coded ☐ Both	**R:_____**

Q3. Does your country use any additional attribute to perform the eP/eD or PS services? Please select all relevant attributes on table below (for more information, please consult the EMA IG V2.1). Also, please mention which attribute UNICOM should use for the smart substitution component.

EMA IG Section V2.1 (2021-02)		In Use on the National System?			This attribute is important to substitution.
Code	Attribute	PS	eP	eD	
1.	Medicinal product	☐	☐	☐	☐
1.1.	Product Management Service Identifier (PMS ID)	☐	☐	☐	☐
1.6.	Combined pharmaceutical dose form	☐	☐	☐	☐
1.10.	Paediatric use indicator	☐	☐	☐	☐
1.11.	Full indication text	☐	☐	☐	☐
1.11.1.	Language	☐	☐	☐	☐
1.13.	Product classification	☐	☐	☐	☐
1.13.1.	xEVMPD product type information	☐	☐	☐	☐
1.13.4.	Medicinal product category	☐	☐	☐	☐
1.13.5.	Genetically Modified Organisms (GMO)	☐	☐	☐	☐
1.14.	Medicinal product name	☐	☐	☐	☐
3.	Therapeutic (product) indication	☐	☐	☐	☐
3.1.	Indication as "Disease/Symptom/Procedure"	☐	☐	☐	☐
3.2.	Co-morbidity	☐	☐	☐	☐
3.3.	Intended effect	☐	☐	☐	☐
4.	Packaged medicinal product	☐	☐	☐	☐
4.7.	Package item (container)	☐	☐	☐	☐
4.7.1.	Package item (container) type	☐	☐	☐	☐
4.7.2.	Package item reference	☐	☐	☐	☐
4.9.1.	Type of combination product – Drug/ Device; Biological/ Device	☐	☐	☐	☐
4.10.	Manufactured item	☐	☐	☐	☐
4.10.2.	Manufactured item quantity	☐	☐	☐	☐
4.10.5.	Manufactured item description	☐	☐	☐	☐
4.10.5.1.	Language	☐	☐	☐	☐
4.11.3.	Special precautions for storage	☐	☐	☐	☐
5 5.	Ingredients	☐	☐	☐	☐
5.1.	Ingredient role	☐	☐	☐	☐
5.2.	Origin of the substance	☐	☐	☐	☐
5.3.	Composition grouping description	☐	☐	☐	☐

EMA IG Section V2.1 (2021-02)		In Use on the National System?			This attribute is important to substitution.
Code	Attribute	PS	eP	eD	
5.4.	Manufacturer	☐	☐	☐	☐
5.5.2.	Strength (quantitative composition)	☐	☐	☐	☐
5.5.2.1.	Quantity operator	☐	☐	☐	☐
5.5.2.2.	Strength (Presentation)	☐	☐	☐	☐
5.5.2.2.1.	Quantity operator	☐	☐	☐	☐
5.5.2.2.3.	Strength (Presentation high limit)	☐	☐	☐	☐
5.5.2.3.	Strength (Concentration)	☐	☐	☐	☐
5.5.2.3.1.	Quantity operator	☐	☐	☐	☐
5.5.2.3.3.	Strength (Concentration high limit)	☐	☐	☐	☐
5.5.3.	Reference strength	☐	☐	☐	☐
5.5.3.2.	Quantity operator	☐	☐	☐	☐
5.5.3.3.	Reference strength (Presentation)	☐	☐	☐	☐
5.5.3.3.1.	Quantity operator	☐	☐	☐	☐
5.5.3.3.3.	Reference strength (Presentation high limit)	☐	☐	☐	☐
5.5.3.4.	Reference strength (Concentration)	☐	☐	☐	☐
5.5.3.4.1.	Quantity operator	☐	☐	☐	☐
5.5.3.4.2.	Reference strength (Concentration single value or low limit)	☐	☐	☐	☐
5.5.3.4.3.	Reference strength (Concentration high limit)	☐	☐	☐	☐
6 6.	Pharmaceutical product	☐	☐	☐	☐
6.1.	Pharmaceutical product description	☐	☐	☐	☐
6.1.1.	Language	☐	☐	☐	☐

Comments: _____

References:

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