



Project acronym: UNICOM

Project full title: Up-scaling the global univocal identification of medicines  
in the context of Digital Single Market strategy

Call identifier: H2020-SC1-DTH-2019

## Deliverable

### D5.2: Guidelines for IDMP-based Cross-Border ePrescription / eDispensation & Patient Summary

Version: 1.0

Status: First draft

Dissemination Level<sup>1</sup>: PU

Due date of deliverable: 30.11.2020

Actual submission date: 08.07.2021

Work Package: WP5: IDMP adoption by eHealth Services

Lead partner for this deliverable: ARIA

Partner(s) contributing: SPMS, DWIZ, IEDOH, ELGA, GNOMON, HL7,  
HZZO, IDIKA, INDRA, IHE, KELA, SEMPA, AGES,  
REGLOMB, SAS

Deliverable type<sup>2</sup>: R

Main author(s):

Marcello Melgara

ARIA

Other author(s):

Anderson Carmo

SPMS

Alexander Berler

GNOMON

Vanessa Mendes

SPMS

Konstantin Hypponen

KELA

Giorgio Cangioli

HL7

Lotta Fordell

KELA

Karima Bourquard

IHE

Anne Sinkkonen

KELA

José Costa Teixeira

IHE

Ivan Prokrovac

HZZO

Caitriona Wray

IEDOH

Helene Prenner

ELGA

Lilly Walsh

IEDOH

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

<sup>2</sup> Type of the deliverable: R: Document, report; DEM: Demonstrator, pilot, prototype; DEC: Websites, patent filings, videos, etc.; OTHER; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot

## Revision history

Version	Date	Changes made	Author(s)
0.1	03.07.2021	First version of the document.	All authors.
0.9	05.07.2021	Submitted to Coordinator	
1.0	08.07.2021	Upload on portal	EMP

**Statement of originality**

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

## Deliverable abstract

This document intends to elicit a deep analysis on the Business Requirements for the implementation at cross-border level of ISO IDMP. Their scope is relating to the identification of the functional and architectural extensions for eP/eD & PS and a deep analysis on the current business requirements with focus provide guidelines and recommendations for ISO IDMP adoption.

This document presents the possible use cases related with the eP/eD & PS, their business requirements and extension analysis, providing a concrete solution to ISO IDMP adoption in the eHealth systems at cross-border level (CEF eHDSI systems), and their needed extensions to submit a change proposal to CEF eHDSI.

ISO IDMP; ePrescription; eDispensation; Patient Summary, Business Requirements.

This document contains material, which is the copyright of the members of the UNICOM consortium listed above and may not be reproduced or copied without their permission.

The commercial use of any information contained in this document may require a license from the owner of that information.

This document reflects only the views of the authors, and the European Commission is not liable for any use that may be made of its contents. The information in this document is provided “as is”, without warranty of any kind, and accept no liability for loss or damage suffered by any person using this information.

© 2019-2023. The participants of the UNICOM project.

## TABLE OF CONTENTS

Revision history .....	2
Deliverable abstract .....	3
Deliverable review .....	7
List of abbreviations .....	8
Executive summary .....	10
1 Introduction .....	11
1.1 Background .....	11
1.2 Scope of WP5 and T5.2 .....	12
1.3 Document Concepts .....	12
2 Use Cases end-to-end functional workflows extension proposals .....	14
2.1 CEF eHDSI ePrescription/eDispensation process .....	14
2.2 ePrescription scenarios for cross-border identification using IDMP .....	19
2.2.1 Generic prescriptions .....	19
2.2.2 Brand name prescription .....	27
2.3 ePrescription / Patient Summary impact and functional extensions .....	38
2.4 Architectural extensions for eP/eD & PS .....	41
2.4.1 Product Master data exchange .....	43
2.5 Legal Organisational impacts .....	43
2.5.1 Introduction to legal aspects .....	43
2.5.2 Legal requirements on Medicinal Products Databases .....	44
2.5.3 Patient Information Notice and Health Professional Information Notice .....	44
2.5.4 Citizens and Health Professional information and training .....	45
3 Proposals for CEF eHDSI business requirements extensions .....	47
3.1 The CEF eHDSI Business Requirements .....	47
3.2 Proposed Requirements Assessment .....	52
3.2.1 Requirement dependencies .....	52
3.2.2 Business impact & advantages analysis .....	52
3.2.3 Revised list of Attributes from D5.1 .....	53
3.2.4 Suggestions to the “smart substitution/selection function” .....	55
4 Summary of proposed requirements extensions .....	58
4.1 Requirements proposals for extensions .....	58
4.1.1 Compatibility and articulation with IDMP and regulatory data .....	59
4.1.2 Consolidated Product attribute model .....	59
5 Conclusions and next steps .....	61
Annex A – D5.1 Chapter 6 – Use Cases .....	62
Analysis Methodology .....	62
ePrescription .....	64

Patient Summary .....	69
Annex B – eHDSI data set analysis .....	73
Annex C – Attributes for cross-border (D5.1) .....	79
Annex D – Sample DRAFT Change Proposal excerpt on Business Requirements extensions .....	84
Tracking information .....	85
Change Proposal Document history .....	86
Change Proposal Summary information .....	87
Change Proposal Description .....	88

## LIST OF FIGURES

Figure 1: Scheme showing a dispensation of medication to a Finnish citizen in another European country, based on an ePrescription. ....	15
Figure 2: General cross-border services view. A) Functional B) Architectural.....	16
Figure 3: Current eHDSI ePrescription data set.....	17
Figure 4: Current eHDSI ePrescription data set: medicinal product .....	17
Figure 5: Current eHDSI eDispensation data set: dispensed medicine .....	18
Figure 6: eHDSI Patient Summary data set: medication summary .....	18
Figure 7: use case based on INN based prescription. ....	20
Figure 8: use case based on ATC coded prescription. ....	21
Figure 9: Generic prescription, based on a generic prescription and use of PhPID. ....	23
Figure 10: Generic prescription, based on the group of equivalents (matching concepts).....	25
Figure 11: use case based on the group of equivalents (no matching concepts).....	26
Figure 12: use case based on the medicine brand name (common MPID).....	28
Figure 13: use case based on the medicine brand name (no common MPID).....	30
Figure 14: use case based on the medicine brand name (similar name) .....	32
Figure 15: use case based on the medicine brand name (substitution) .....	34
Figure 16: Prescription with attribute mapping Brand name .....	37
Figure 17: Uses of Products in different scopes, implying different levels of product specification. ....	39
Figure 18: Categories of Prescribed Product .....	39
Figure 19: Categories of Dispensed and 'Used' (for summaries) Products. ....	40
Figure 20: IDMP and Product Categories .....	40
Figure 21: General cross-border services view. A) Functional B) Architectural with Medicinal Product Dictionaries (MPD).....	42
Figure 22: eHealth actors .....	63
Figure 23: Value Stream Map of ePrescription between countries (Ireland and Portugal).....	65
Figure 24: Value Stream Map of Patient Summary. Ireland and Portugal are examples of countries participating in the exchange. ....	70
Figure 25: How change proposals have been determined.....	73
Figure 26: ePrescription and Prescription data .....	74

Figure 27: “To be” product model (UML).....	76
Figure 28: “To be” product model (HL7 FHIR Logical Model).....	77
Figure 29: Model tracing between the “to be” prescription item and the current eHDSI model.....	78

## LIST OF TABLES

Table 1: Overview of additional product attributes for cross-border identification .....	54
Table 2: Common requirements for ePrescription / eDispensation & Patient Summary extensions ....	58
Table 3: Main actions list on cross-border ePrescription. ....	66
Table 4: Main actions list on cross-border Patient Summary.....	69
Table 5: Attributes for cross-border (from eHDSI), possible changes and impact of IDMP adoption...	79

## Deliverable review

	Internal reviewer: .....			External reviewer: .....		
	Answer	Comments	Type*	Answer	Comments	Type*

Is the deliverable in accordance with

the Description of Action?	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a
the international State of the Art?	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a

Is the quality of the deliverable in a status

that allows it to be sent to European Commission?	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a
that needs improvement of the writing by the originator of the deliverable?	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a
that needs further work by the Partners responsible for the deliverable?	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a

Is the structure and contents of the deliverable

structured, logical and easy to understand?	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a
suitable to meet its intended scope?	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a
Is in conformance with UNICOM deliverable template?	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> M <input type="checkbox"/> m <input type="checkbox"/> a

\* Type of comments: M = Major comment; m = minor comment; a = advice

## List of abbreviations

Abbreviation	Complete form
ATC	Anatomical Therapeutic Chemical Code
CDA	Clinical Document Architecture
CDF	Combined Pharmaceutical Dose Form
CEF	Connecting Europe Facility
CMT	Combined Terms
CP	Change Proposal
EC	European Commission
eD	Electronic Dispensation
EDQM	European Directorate for the Quality of Medicines
eHDSI	Health Digital Service Infrastructure
eHN	eHealth Network
EMA	European Medicines Agency
eP	Electronic Prescription
EU	European Union
GDPR	General Data Protection Regulation
HP	Health Professional
ID	Identification
INN	International Non-proprietary Names
IDMP	Identification of Medicinal Products
ISO	International Organisation for Standardisation
MAH	Marketing authorisation holders
MVC	Master Value Set Catalogue
MPID	Medicinal Product
MPID	Medicinal Product Identifier
NCA	National Competent Agency
NCPeH	National Contact Points for eHealth
PDF	Pharmaceutical Dose Form
PFT	Patient-Friendly Terms
PhP	Pharmaceutical Product



PhPID	Pharmaceutical Product Identifier
PIN	Patient Information Notice
PS	Patient Summary
SPOR	Substance, Product, Organisation and Referential
UCUM	Unified Code for Units of Measure

## Executive summary

This document intends to elicit an in-depth analysis on the Business Requirements for the implementation at cross-border level of ISO IDMP. The *D5.1 - Business requirements for the adoption of IDMP in eHealth Services* was used as a basis for the development of this deliverable that focuses on the description of the ePrescription/eDispensation (eP/eD) & Patient Summary (PS) use cases and their functional extensions and the identification of the elements that should be changed on the current CEF eHDSI structure in order to allow the implementation of IDMP on their systems.

The scope of this document relates to the identification of the functional and architectural extensions for eP/eD & PS including a deep analysis on the current business requirements. This deliverable provides guidelines and recommendations for the ISO IDMP adoption.

This document identifies the possible use cases relating to the eP/eD & PS, their business requirements and extension analysis thus providing a specific solution for ISO IDMP adoption in the eHealth systems at cross-border level (CEF eHDSI systems).

The document chapters analyse the following:

- the different scenarios for product specification, and
- its identification and selection to evaluate the impact of the ISO IDMP adoption on CEF eHDSI systems.
- any gaps and the assessment of the proposed requirements which facilitates the adoption of ISO IDMP.
- a summary of the proposed requirements extensions, in order to provide solid information to base the elaboration of changes proposals to CEF eHDSI.

This document provides information about the key business requirements for the ISO IDMP adoption on CEF eHDSI systems and their needed extensions in order to submit a change proposal to CEF eHDSI.

# 1 Introduction

The ISO IDMP standards ensure the correct identification of the medicinal products among the countries. The data model defined in ISO IDMP establishes definitions and concepts to describe data elements and their structural relationships of products that are required for the identification of medicinal products. It is anticipated that this data model will increase the safety of ePrescriptions/eDispensations (eP/eD) and Patient Summary (PS) in national and cross-border scenarios.

To achieve the implementation of the IDMP on the cross-border level, there is a need to integrate this data model with the Connecting Europe Facility Health Digital Service Infrastructure (CEF eHDSI) and ensure the alignment of the defined requirements (business, semantic and technical).

To provide eP/eD & PS services, the definition of the business requirements is necessary to provide a high-quality service among the EU. In this regard, the CEF eHDSI business requirements<sup>3</sup> were specified to assure the correct provision of the eP/eD & PS services in the countries involved, including the country of affiliation (Country A) and the country of treatment (Country B).

Deliverable D5.1 (Business requirements for the adoption of IDMP in eHealth Services), completed an initial analysis on the current CEF eHDSI business requirements. This analysis highlighted the need for alignment between the CEF eHDSI business requirements and IDMP to ensure the adoption of this data model. This can be achieved by identifying and proposing changes to the current CEF eHDSI requirements.

This document elicits a detailed analysis on the Business Requirements for the implementation at cross-border level of ISO IDMP. It focuses on the description of the eP/eD & PS use cases and their functional extensions and identification of the elements that should be changed on the current CEF eHDSI structure to allow the implementation of IDMP on their systems.

## 1.1 Background

The CEF eHDSI business requirements contain a list of steps that should be fulfilled to ensure the provision of cross-border services, including steps from the identification of the patient and health professional to the conclusion of the service related with eP/eD and PS use cases.

These requirements were developed to support the current CEF eHDSI use cases for eP/eD and PS exchange and are fundamental to providing high-quality services to citizens.

The UNICOM project aims to promote the adoption of the ISO IDMP in CEF eHDSI systems, and thus it is essential that all the requirements are revised and updated to support the adoption of new data.

The deliverable *D5.1 - Business requirements for the adoption of IDMP in eHealth Services* – reports on an analysis conducted on the general business requirements with a focus on the CEF eHDSI eP/eD and PS Use Cases. These requirements were reviewed and updated to reflect current practices in the services among EU.

The approach of identifying the necessary requirements to achieve a minimum dataset informed the analysis and identified improvement opportunities in information flow. A flow analysis was used as the platform to discuss, analyse, and identify the current challenges and business requirements that impact the ISO IDMP implementation.

The outcome of D5.1 informs the deliverable *D5.2 - Guidelines for IDMP-based Cross-Border ePrescription / eDispensation & Patient Summary* – where the goal is to provide an in-depth business requirements analysis reflecting on the use cases workflow. To achieve this goal, a proposal addressing the CEF eHDSI business requirements will be developed where the emphasis will be on the extensions needed to implement the ISO IDMP on the eHDSI systems and on Change Proposals (CP) created and submitted to CEF eHDSI.

---

<sup>3</sup> <https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/1.+eHDSI+Requirements+Catalogue>

The CP submission and its subsequent approval by the CEF eHDSI is fundamental to ensure the adoption of ISO IDMP on their systems and strengthen the alignment between CEF eHDSI and UNICOM. This in turn will support the development of future WP5 deliverables which are intended to provide the semantic and technical specifications required for IDMP adoption.

## 1.2 Scope of WP5 and T5.2

The WP5 (IDMP adoption by eHealth Services) will focus on the implementation of ISO IDMP in the eHealth services, such as eP/eD and PS exchange at the national and cross-border levels. An in-depth analysis of the national and cross-border systems and of the existing diverse range of requirements (business, functional, semantic, technical, among others), which will lead to the development of comprehensive guidelines and recommendations to support ISO IDMP adoption on those systems.

The task *T5.2 Prescribing & dispensation semantic specifications and guidelines in the cross-border domain*, focuses on the ongoing activities of the CEF eHDSI, the business requirements and semantic functional specifications, which will be revised to include the adoption of ISO IDMP. The identification of the functional and architectural extensions for eP/eD & PS and a more detailed analysis on the current business requirements, a first draft of the data set is the focus of this deliverable. From this analysis, a draft change proposal will only be developed for agreed business critical requirements that have an impact the adoption of IDMP. The work conducted in this task will consider the waves of production of CEF eHDSI, so that it can provide a timely support to the ISO IDMP implementation in the CEF eHDSI services.

## 1.3 Document Concepts

In general, this deliverable aims to present the use cases, business requirements and extensions analyses, to provide a specific solution to ISO IDMP adoption in the eHealth systems at the cross-border level.

This deliverable is outlined in three main chapters and is presented in a structured way:

- **The use cases related with eP/eD & PS exchange (chapter 2)**

In this chapter, different scenarios of eP/eD and PS exchange will be designed and analysed to explore different possibilities for product specification, identification and selection. This approach will allow an analysis of the requirements at different levels to evaluate the impact of ISO IDMP implementation in the CEF eHDSI services. In addition, the legal and organisational impact will also be evaluated.

- **The business requirements and their respective extensions with focus on the current CEF eHDSI structure (chapter 3)**

This chapter will build on the analysis conducted in D5.1 to provide a further detailed analysis of the business requirements, with identification of gaps and assessment of the proposed requirements, which will allow the generation of the change proposal to be submitted to the CEF eHDSI to facilitate the adoption of ISO IDMP.

- **A summary of the proposed requirement extensions (chapter 4)**

This chapter will provide a summary of the main proposed requirements, specifying common requirements proposals for extensions, as well as eP/eD and PS specific requirements proposals for extensions. This deliverable expects to provide the knowledge to ensure the correct functionality, including the product specifications, identification and selection.

It is important to also highlight that the focus of this document is the cross-border context, as well as the comparison of the identified requirements with the current international systems, such as SPOR, CEF eHDSI and others. These comparisons will raise the key requirements that should be, somehow, adapted to the further ISO IDMP adoption.

As previously mentioned, the work performed in the deliverable D5.1 resulted in the identification and primary analysis of the business requirements and data elements related to the eHealth services (eP/eD

& PS) that are fundamental to ISO IDMP implementation. During this initial analysis some requirements did not require any changes, while others did in order to support the adoption of the ISO IDMP implementation. In this deliverable, the rationale for change can be found in the detailed analysis of these requirements and data elements.

At the end of this deliverable a summary with all the identified requirements that (according to the performed **analysis**) require extensions to the CEF eHDSI systems is produced. This in turn, will be the basis for the creation of changes proposals to be submitted to CEF eHDSI in order to ensure the adoption of IDMP.

## 2 Use Cases end-to-end functional workflows extension proposals

This chapter describes the ePrescription/eDispensation & Patient Summary at cross-border scenario considering the CEF eHDSI systems, including the overall process and several scenarios where the ISO IDMP can support the current process and the legal organisational impacts that this data model can let to the current cross-border services managed by eHDSI.

The first part of this chapter identifies the existing processes as they are operational or planned today, followed by some details of the data content in these processes.

After this, a normal analytical methodology is followed: A set of representative scenarios are explored, and these scenarios reveal functional requirements and data elements. Each scenario represents a different set of data requirements and while this list is not exhaustive, it is sufficient to facilitate an analysis using the primary criterium outlined below:

Each scenario is identified and developed building an overall set of requirements until the addition of further scenarios does not identify any additional ones. This indicates that the cumulative requirements (functionalities and data elements) are complete.

This approach supports several scenarios with the same set of requirements without having to analyse each of them.

For example, the scenarios identify that in a prescription we may have a national product code. This national product code may or may not (depending on the granularity) have a corresponding EU IDMP identifier. This may imply that such an EU IDMP identifier needs to be added to the ePrescription document. This requirement is the same across several scenarios.

The result is a list of data elements to be added to existing interoperability mechanisms, and any new mechanisms that may be needed.

### 2.1 CEF eHDSI ePrescription/eDispensation process

The CEF eHDSI ePrescription/eDispensation process is described in their confluence page<sup>4</sup>.

This process presents two types of requirements: 1 - The foundational requirements of eHDSI, and 2 - the IDMP-related expansion defined in UNICOM Deliverable D5.1 “Business requirements for the adoption of IDMP in eHealth Services”. The latter presents the needed expansion for the same eHDSI foundation to support IDMP attributes to enable better product identification in cross border services.

Recalling the fundamental goal of eHDSI and the target of UNICOM, Figure 1 exemplifies a citizen obtaining an eP in Finland (Country A – country of affiliation) and dispensing (eD) in another European country (Country B – country of treatment). In this process, the citizen requires the respective personal identity code, and must have given in advance his / her permission to share his / her prescription information with the pharmacy of the other European country. This permission is given through the My Kanta<sup>5</sup> website, which produces digital services for the social welfare and healthcare sector, including access to medical records and prescriptions. The data of the Finnish prescription is then transferred from the Prescription Centre of the Kanta Services to the pharmacy of the other European country via National Contact Points.

It is in this step that the product identification aspects become relevant: During this process, citizens and pharmacists may encounter different situations, such as the medicine not being available in the other country, the name of medicinal product and pack sizes may be different and a substitution may be required, among different scenarios.

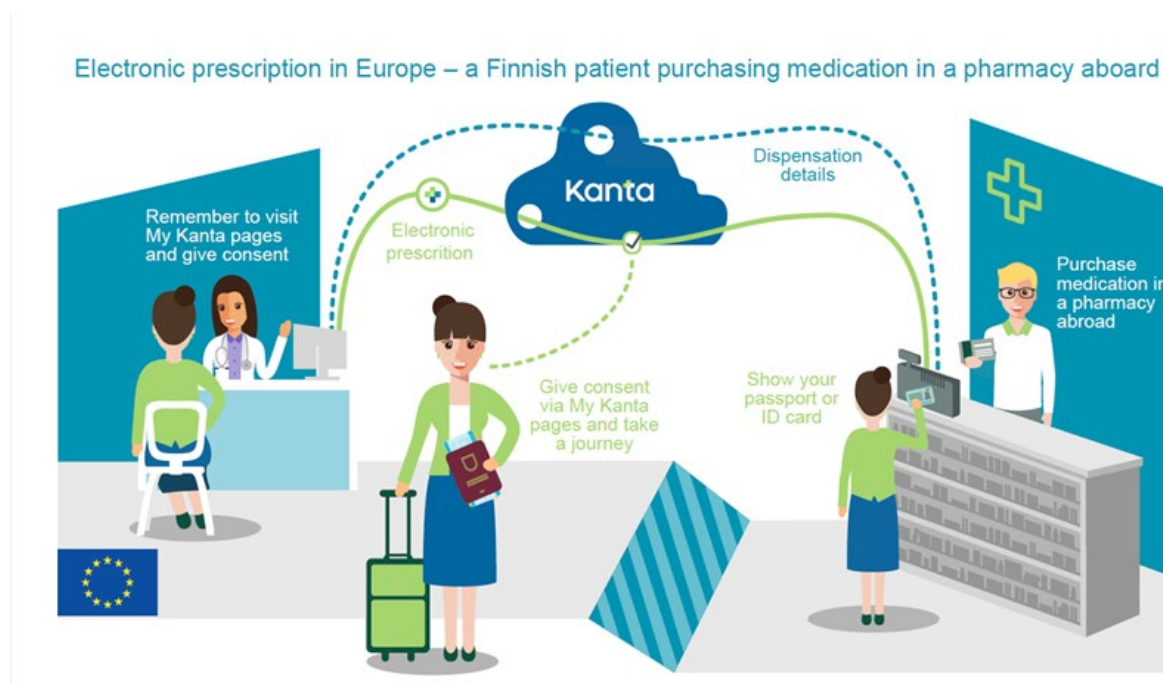
---

<sup>4</sup> <https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pagelId=280625752>

<sup>5</sup> <https://www.kanta.fi/en/my-kanta-pages>

UNICOM deliverable D5.1 provided the key business requirements for this, and the current document, D5.2, informs the functional analysis and guidelines of what is necessary for IDMP to support it.

In the next chapters, several scenarios will be explored to analyse the different gaps and the impact of ISO IDMP adoption in the CEF eHDSI services.



**Figure 1: Scheme showing a dispensation of medication to a Finnish citizen in another European country, based on an ePrescription<sup>6</sup>.**

Deliverable 5.1 (Business Requirements Specifications for IDMP adoption in eHealth Services)<sup>7</sup> Chapter 6 (Annex A) provides a detailed description of the different roles and responsibilities of country of affiliation (Country A) and country of treatment (Country B), as well as the necessary pre-conditions and steps for the exchange process of the eHDSI services. The reader is advised to revisit Chapter 6 of the deliverable 5.1 where an overview of CEF eHDSI workflow for eP/eD and PS exchange was described.

The above analysis also applies to Patient Summary or ePrescription: Figure 1 and

Figure 2.A illustrates a generic eP/eD service use case, while

Figure 2.B illustrate a generic Patient Summary (PS) service use case.

The eP/eD and PS use cases (and eventually others) should be supported in a similar way, as introduced in D5.1. Wherever possible this document D5.2, identifies the requirements needed to support these different use cases. The overarching objective is to provide a robust solution enabling different scenarios. However, there is no guarantee that the same solution would also support additional scenarios that have slight variations.

<sup>6</sup> Image retrieved from [https://www.kanta.fi/en/professionals/notice/-/asset\\_publisher/HFU2lnkQbmnX/content/suomessa-maaratylla-sahkoisella-reseptilla-voi-ostaa-laakkeita-myos-kroatian-apteekista](https://www.kanta.fi/en/professionals/notice/-/asset_publisher/HFU2lnkQbmnX/content/suomessa-maaratylla-sahkoisella-reseptilla-voi-ostaa-laakkeita-myos-kroatian-apteekista).

<sup>7</sup> This document is available to the UNICOM members in the SharePoint, and will be available to the public access in the end of the project.

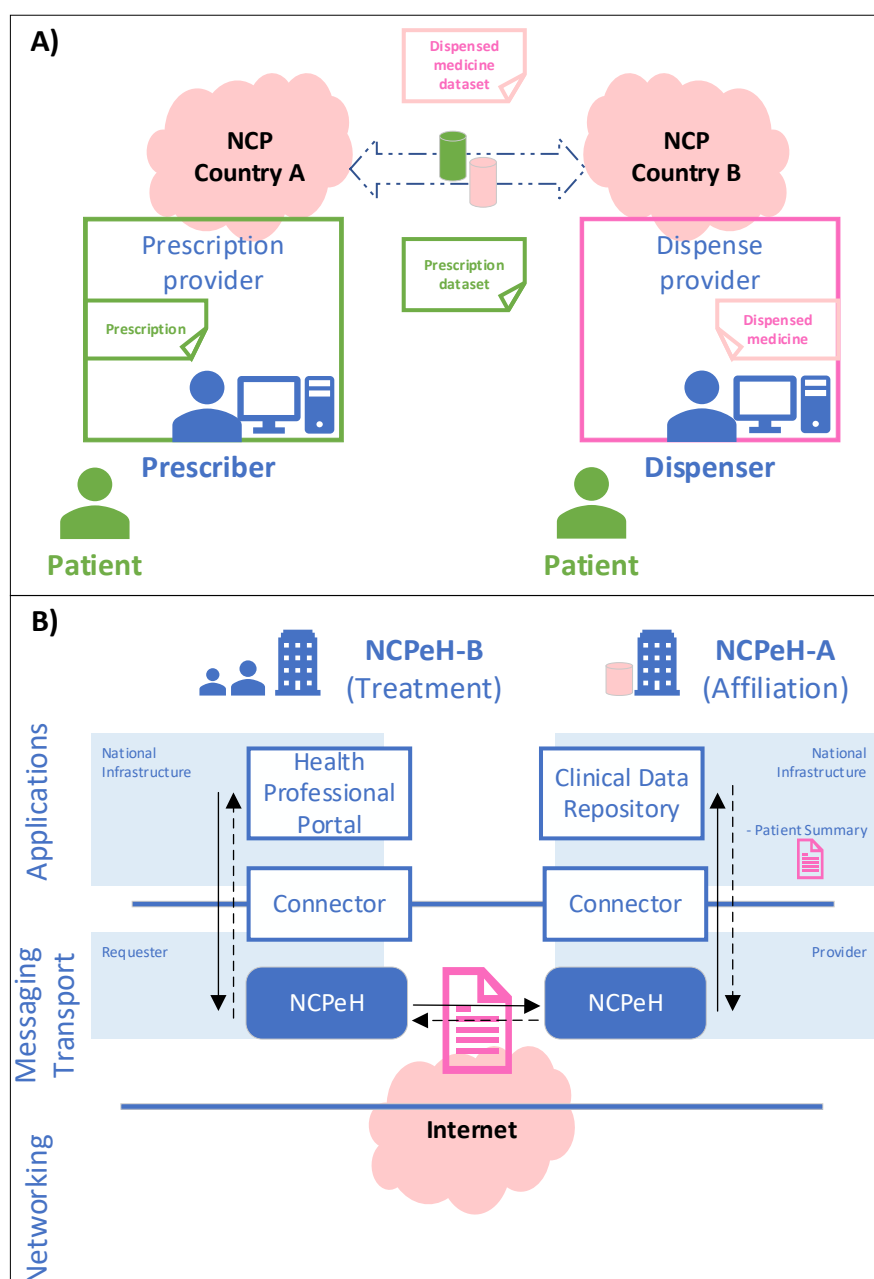


Figure 2: General cross-border services view. A) Functional B) Architectural

The requirements in D5.1 are summarised as follows:

- Backwards compatibility: IDMP adoption should not harm the present interoperability.
- Information sufficiency and cross-border transport: the ability to exchange sufficient information in a prescription or patient summary and make it available to other countries.
- Master data matching or look up: the systems involved with the clinical workflows (including pharmacies) must be able to consult product data (identifiers and attributes).
- Semantic consistency: products must be identified across countries – by providing a common language for attributes and identifiers. This will be technically refined in future deliverables.
- Exchange of product master data: from regulators to the clinical systems, there is a need to provide a standard exchange of product data.



The implementation independent eHDSI content specifications (aka data element / data set) are part of the eHDSI functional requirements described in the [eHDSI Requirements Catalogue](#). Here after the links to the data sets summarised in the following figures have a focus on product related information:

- [ePrescription](#) (Figure 3 and Figure 4)
- [eDispensation](#) (Figure 5)
- [Patient Summary](#) (Figure 6)

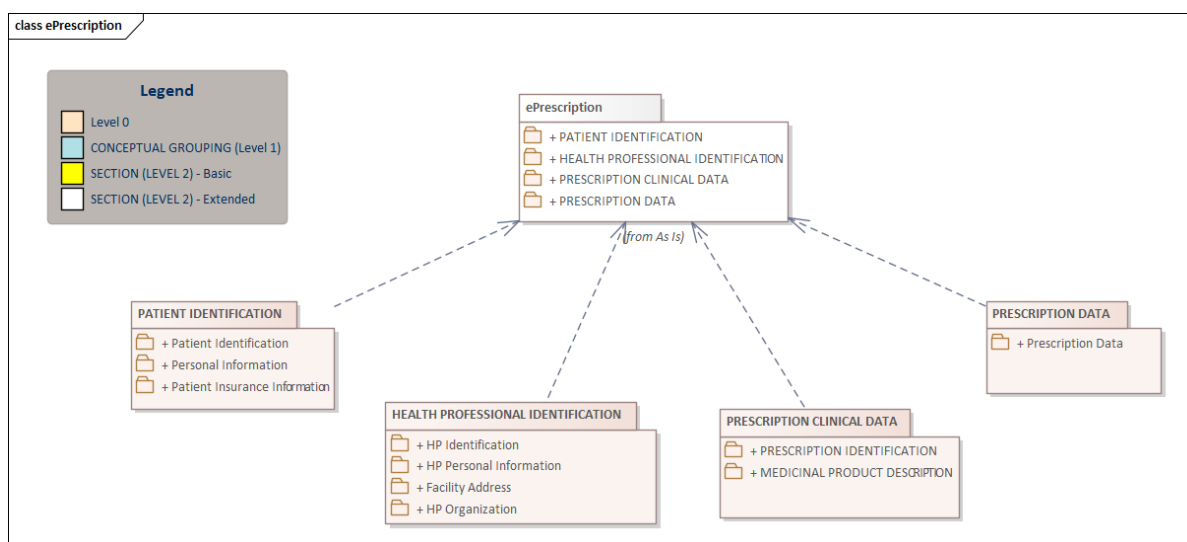


Figure 3: Current eHDSI ePrescription data set

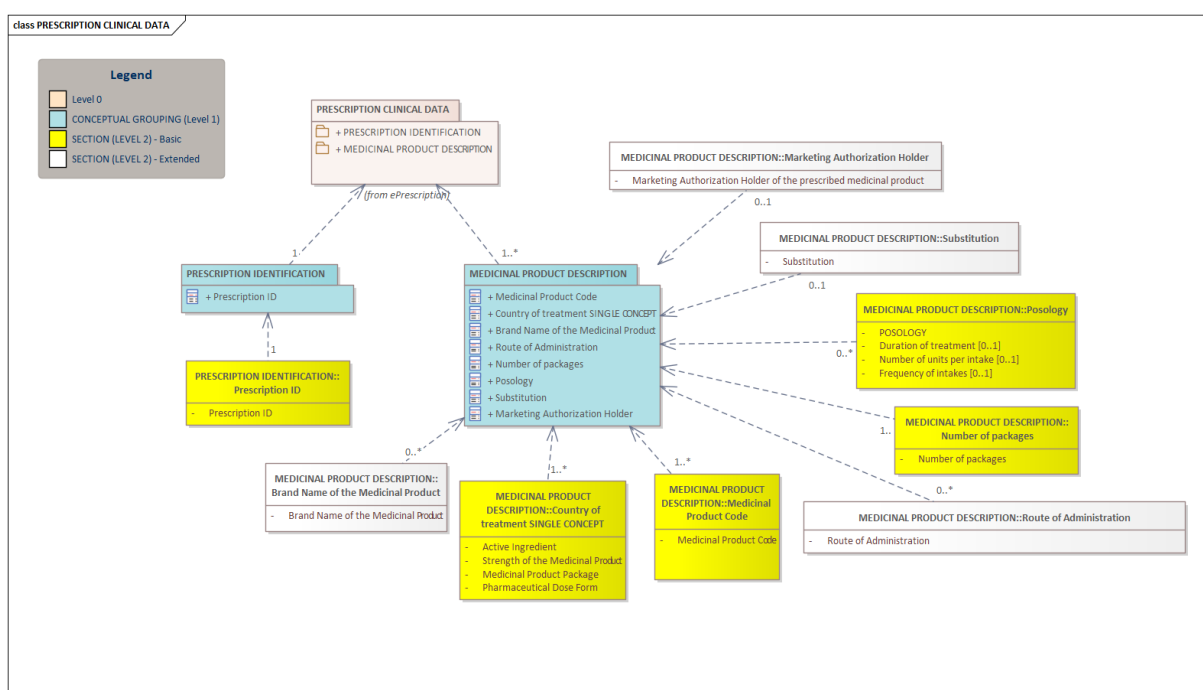


Figure 4: Current eHDSI ePrescription data set: medicinal product

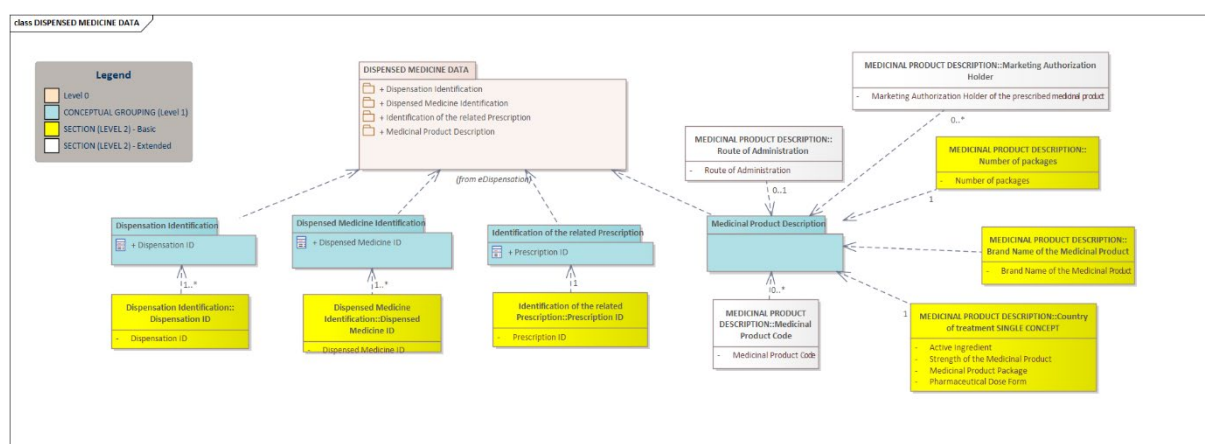


Figure 5: Current eHDSI eDispensation data set: dispensed medicine

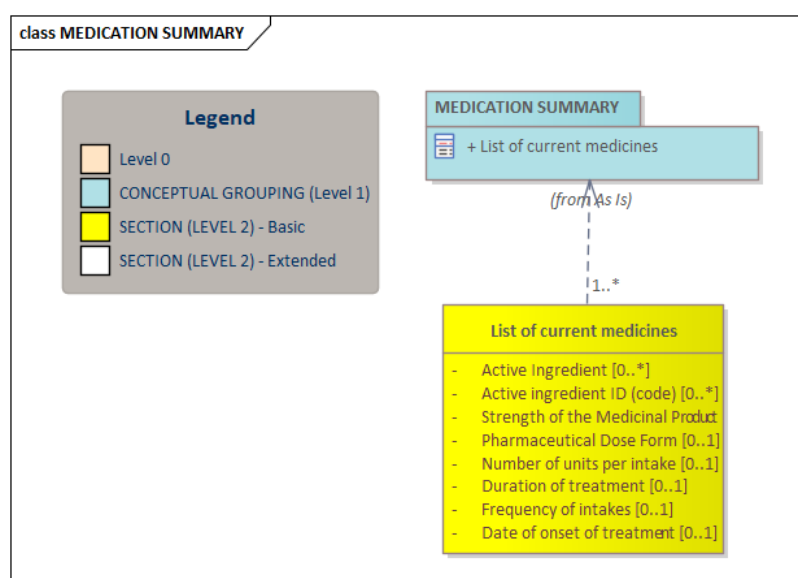


Figure 6: eHDSI Patient Summary data set: medication summary

These data sets are implemented using the HL7 CDA R2 standard. The currently adopted CDA specifications in eHDSI are accessible from these links:

- [eHDSI eDispensation 1.3.6.1.4.1.12559.11.10.1.3.1.1.2](#)
- [eHDSI ePrescription 1.3.6.1.4.1.12559.11.10.1.3.1.1.1](#)
- [eHDSI Patient Summary 1.3.6.1.4.1.12559.11.10.1.3.1.1.3](#)

## 2.2 ePrescription scenarios for cross-border identification using IDMP

In this section, several scenarios, from which the possibilities for robust product specification, identification and selection, were identified. This in turn allows an analysis of the requirements – data and architectural for the cross-border identification of products and these requirements were then compared to adjacent specifications and initiatives, such as SPOR, eHDSI, etc.

The analysis for each use case focuses on the key identification of the problems that are common across the scenarios: the matter of Master Product Data exchange is left implicit (and will need to be addressed in a future version), and in some cases, the identification of the dispensed product is not explicit.

### 2.2.1 Generic prescriptions

In this section, a selected set of scenarios show for the dispensation of generic prescriptions.

A prescription is defined as “Generic” when the medication to be dispensed is indicated as a pharmaceutical product, without making reference to any manufactured product by a specific pharmaceutical company.

While in the same country the complexity is almost the same as for brand name prescription (except for the matters of substitution), the complexity for interoperability across countries increases considerably in this context.

The following use cases will provide a deeper analysis of this context.

#### 2.2.1.1. International Non-proprietary Names (INN) prescription

The first scenario will approach the International Non-proprietary Names (INN), which is a unique name that is globally recognised and is public property, which facilitates the identification of pharmaceutical substances or active pharmaceutical ingredients. A non-proprietary name is also known as a generic name.<sup>8</sup>

This scenario (Figure 7) reveals that one of the most important requirements is that information is coded, and not text-based. A text-based prescription would require manual interpretation which is not the preferred option for a robust framework for sustainable cross-border product identification.

These scenarios are included here specifically to demonstrate how the information available can flow from one country to the other one but remains insufficient to cover a univocal identification of medicinal products across borders.

---

<sup>8</sup> Definition from WHO, retrieved from <https://www.who.int/teams/health-product-and-policy-standards/inn/>.

## Use Case 1: INN Prescription

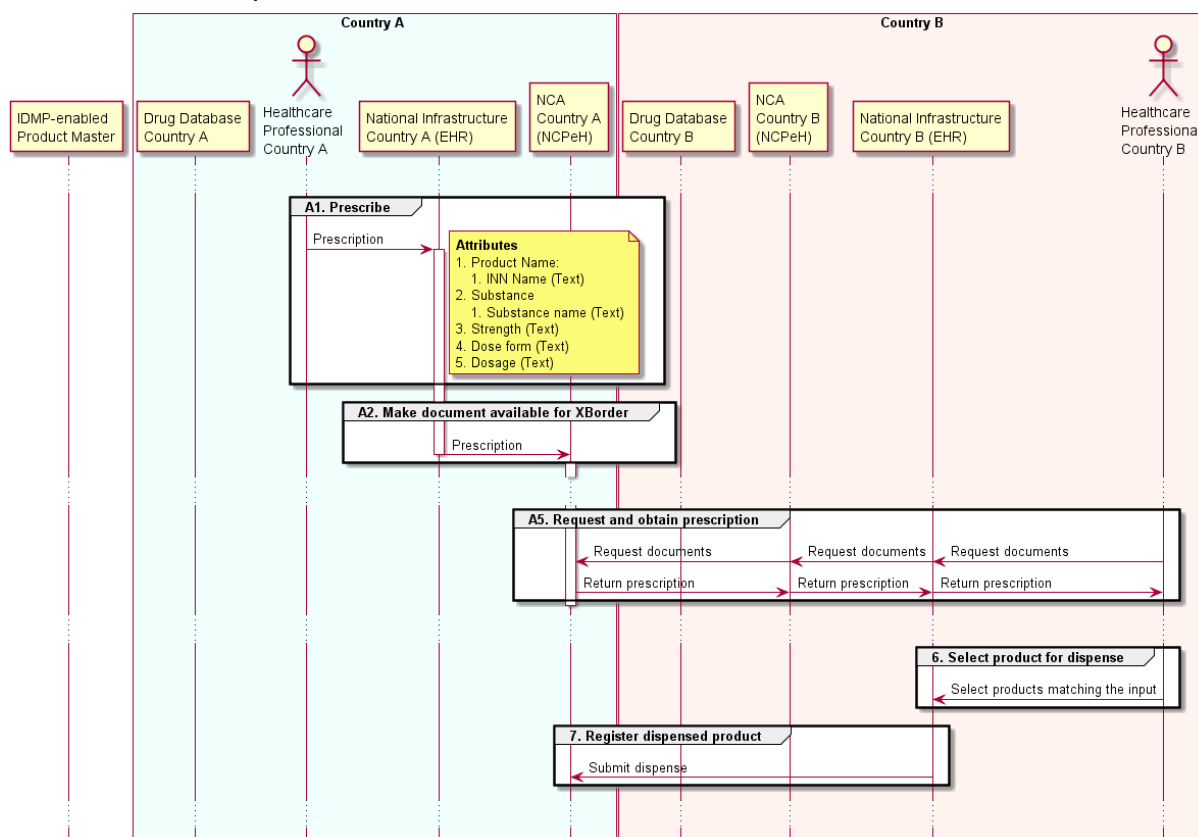


Figure 7: use case based on INN based prescription.

This use case requires a descriptive name for the medication. There are some coding schemes that could be used with INN, but the name is the expected identifier for the substance. In this example, the substances mentioned are active substances.

The following attributes are expected:

- Product Name (INN, Text)
- Substance Name (INN Text)
- Strength (frequently Text)
- Dose form (frequently Text)
- Dosage (frequently text)

The presence of the designators (product name, substance name, dosage) in text format (i.e. unstructured and uncoded), instead of uniform coded information makes automatic transcoding very difficult, requiring human intervention. This consideration applies to all the use cases in this document – when an attribute is exchanged as text, it reduces interoperability.

As shown in Figure 7, and for this simple use case to work correctly, both countries would need to understand the same text language. It is common practice to use Latin in INN prescriptions, however this is not considered a robust interoperability approach.

The Dispensation process is not outlined in this diagram – it will be defined in the next scenarios, where more structured information is available and can better demonstrate the dispensation process.

### 2.2.1.2. ATC-based prescription

The second scenario examines an eP/eD based on the use of the Anatomical Therapeutic Chemical classification (ATC), which is a unique code assigned to a medicine according to the organ or system it acts on and how it works. In this code system, the active substances are classified in a hierarchy with five different levels.<sup>9</sup>

This scenario (Figure 8) identifies a common code like ATC can bring benefits – assuming a shared list of ATC codes across different countries (which is the current practice). This approach means that ATC can be used as a pivot concept.

However, as ATC is a classification and not a unique identifier, therefore it cannot convey all the details about the information and cannot act as a univocal identification of a product.

Use Case 2: ATC Prescription

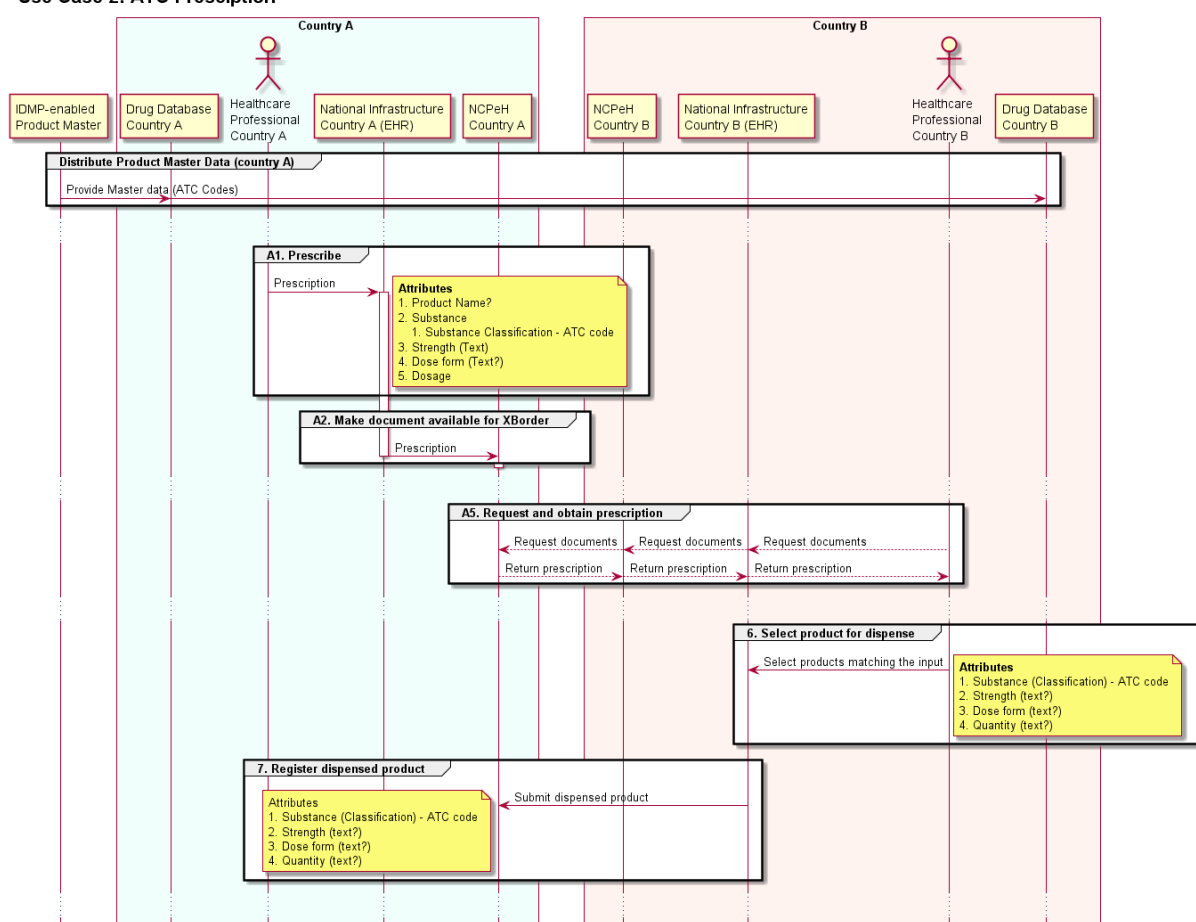


Figure 8: use case based on ATC coded prescription.

This use case is related to the use of ATC as outlined in the current CEF eHDSI specifications. The product classification replaces the use of an identifier.

The following attributes are relevant in this use case:

- Product Name
- Substance
  - Substance Classification - ATC code
- Strength (frequently Text)

<sup>9</sup> Definition from WHO, retrieved from [https://www.whocc.no/atc\\_ddd\\_index/](https://www.whocc.no/atc_ddd_index/)

- Dose form (frequently Text)
- Dosage (frequently Text)

The use of a common code (ATC) in this scenario allows the universal understanding of the product. Even so, it is not frequently sufficient to characterise the prescribed product and certainly not the dispensed product.

Other attributes are available as text and are also therefore not adequate for automated processing.

In addition, this scenario also relies on both countries using a common set of codes, and for that purpose the use of ATC is adequate, because it is centrally governed and made freely available.

While the use of ATC does not support the unequivocal identity the product to prescribe, and even less the dispensed product, it does encourage a minimum of interoperability. This scenario covers some baseline requirements which are met with CEF eHDSI and should be further enhanced:

- Prescription and Dispensation Data sets:
  - Prescribed product dataset shall include (at least) some identification of the product, for example the product's ATC code.
  - Dispensed product dataset shall include (at least) some identification of the product, for example the product's ATC code.

This also recognises some additional requirements which are outside of the eHDSI scope and should be handled by UNICOM going forward:

- Product Master data:
  - Shared codes shall be valid globally, like ATC.
  - Shared codes should be governed centrally or at least have a robust process to manage the correctness (uniqueness, consistency) of the codes, like ATC.
  - Shared codes like ATC should be freely available.
  - The technical and operational mechanisms should be put in place to facilitate the distribution of the ATC classification codes (and respective updates) across all the systems that use it.

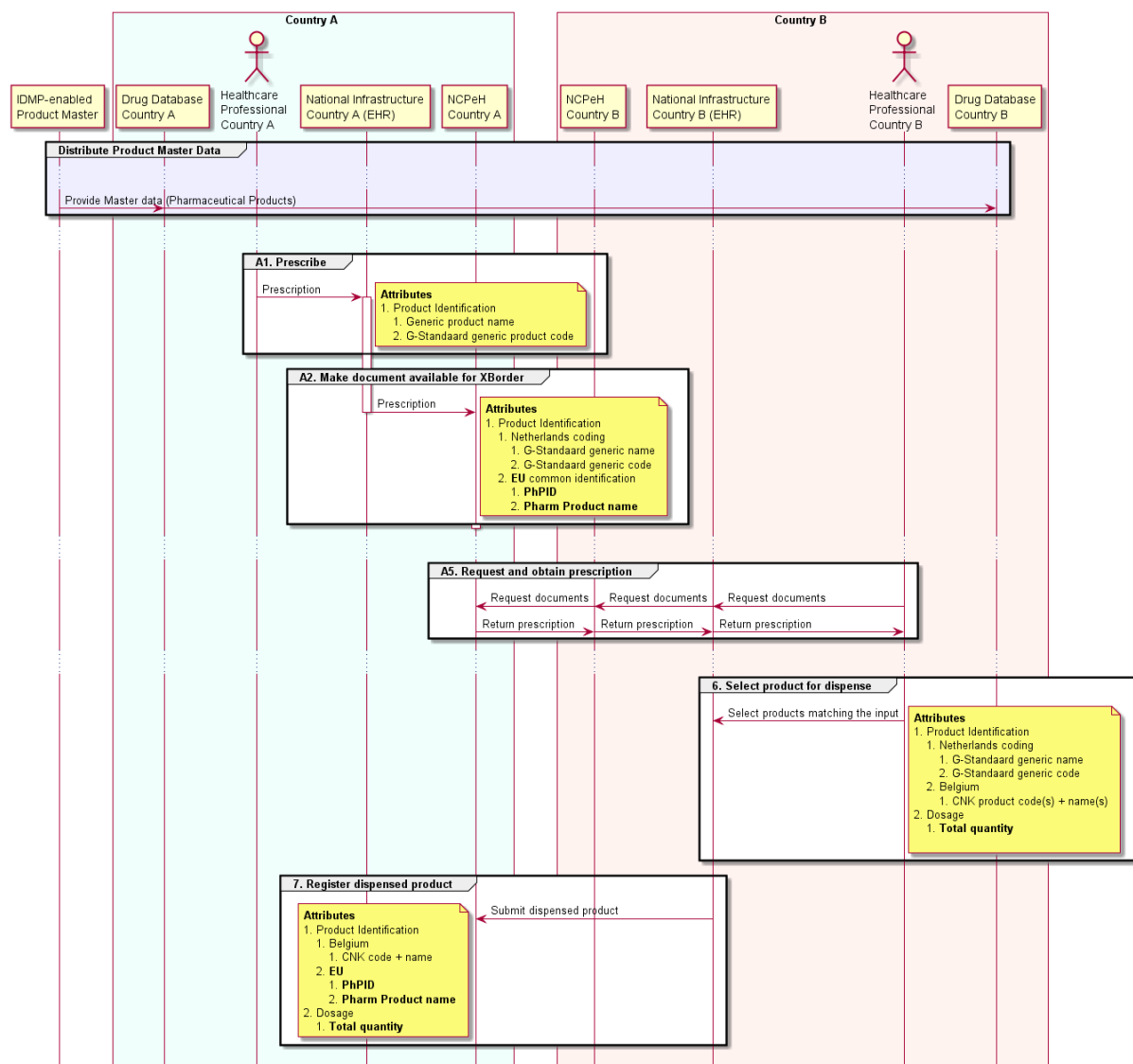
The results from this document, next deliverables, feedback from the pilot implementations and other stakeholder insights will confirm the details of these requirements.

### **2.2.1.3. Generic prescription and use of PhPID**

This scenario is based on the generic prescription. The medicinal product is a generic drug, which is the same in terms of dosage form, safety, strength, route of administration, quality, and performance characteristics of an existing approved brand-name drug. This scenario explores the use of the Pharmaceutical Product Information (PhPID) standard, which uniquely associates medicinal products with the same or similar pharmaceutical composition, based on the substance, strength, reference strength and dosage form data elements.

This use case (Figure 9) demonstrates that the PhPID, similar to ATC, can also be used as a pivot concept and assuming the PhPID is governed in a way that is similar to ATC (i.e. centrally managed, unique, freely available). In this case, it enhances interoperability for those products that do not have a unique ATC code.

### Use Case 3: Netherlands G-Standaard generic prescription



**Figure 9: Generic prescription, based on a generic prescription and use of PhPID.**

In this scenario, the prescription only contains the “generic” product, and this may correspond somewhat to the level of granularity that is defined by the PhPID.

In the figure, as exemplification, an ePrescription from The Netherlands is dispensed in Belgium.

The following attributes are used in the prescription:

- Product Identification
  - Netherlands coding
    - G-Standaard generic name
    - G-Standaard generic code
  - EU common identification
    - PhPID
    - Pharm Product name

The dispense uses the Belgian identifiers:

- Belgian coding
  - CNK product name
  - CNK product code

Only active substances are described in the PhPID and as such, PhPID does not convey all the information to identify the dispensed product as a packed medicinal product (including excipients, market authorisation holder, or other product specific data as lot number, expiry, etc).

The use of a country-specific generic code can help in the transcoding to common codes that are valid across different countries. The PhPID, as defined in IDMP, is expected to be one of these common codes. This requires the exchange of product master data with the synchronisation of PhPIDs and mapping to national codes. This is due to the fact that different PhPID of the same level could be generated for the same pharmaceutical product, if, e.g., slightly different dose forms are used. The total quantity dispensed can also be expressed, possibly in a "common language" – which may require master data synchronisation (units of measurement, etc.).

PhPID does not provide full details of the dispensed product (e.g. dispensed brand name is not understood in the country of origin) and also does not guarantee a country's "generic" product code corresponds to the level of granularity defined in any of the PhPID levels.

Based on this scenario, it is possible to present some baseline requirements:

- Data sets
  - Prescribed product dataset should include the pharmaceutical product identifier.
  - Dispensed product dataset data should include the pharmaceutical product identifier.
- Master data
  - PhPID shall be valid universally.
  - PhPID should be governed centrally or at least have a robust process to manage the correctness (uniqueness, consistency) of the codes.
  - PhPID should be freely available.

The SPOR initiative is responsible for handling the requirements around master data and respective governance for PhPID.

Indications on the Level of PhPID (level 1 - 4) to be adopted for ePrescribing should be agreed. If Level 1, 2 or 3 are adopted, the medicinal product description MUST be complemented with attributes for the missing data elements.

#### **2.2.1.4. Generic “Group of Equivalence” prescription – with matching concepts in country B**

The concept of “Group of Equivalents”, intended as a product classification, is used for prescriptions in some countries. It identifies a group of “equivalent” authorised products with similar characteristics. For example, this allows the prescriber to prescribe a specific packaged product, using a single code, without indicating any specific brand. The Italian code Q2A for “Paracetamol + Codeine sulfate - 16 units (500+30) mg – oral use” for example covers seven different authorised products, including generics (e.g. CODAMOL; COEFFERALGAN; PARACETAMOLO CODEINA TEVA; TACHIDOL; ZEUSEFF).

Sometimes, “Group of Equivalents” prescription is also called “Cluster” prescription.

In some cases, the same non-IDMP concept exists in two countries. This scenario demonstrates what happens when there is a common code for a "cluster" concept, which includes all products with that same (active) substance(s), strength, dose form and package size.

While the codes are different between countries and are therefore not interoperable; these codes can be locally decomposed or matched to specific combinations of attributes.

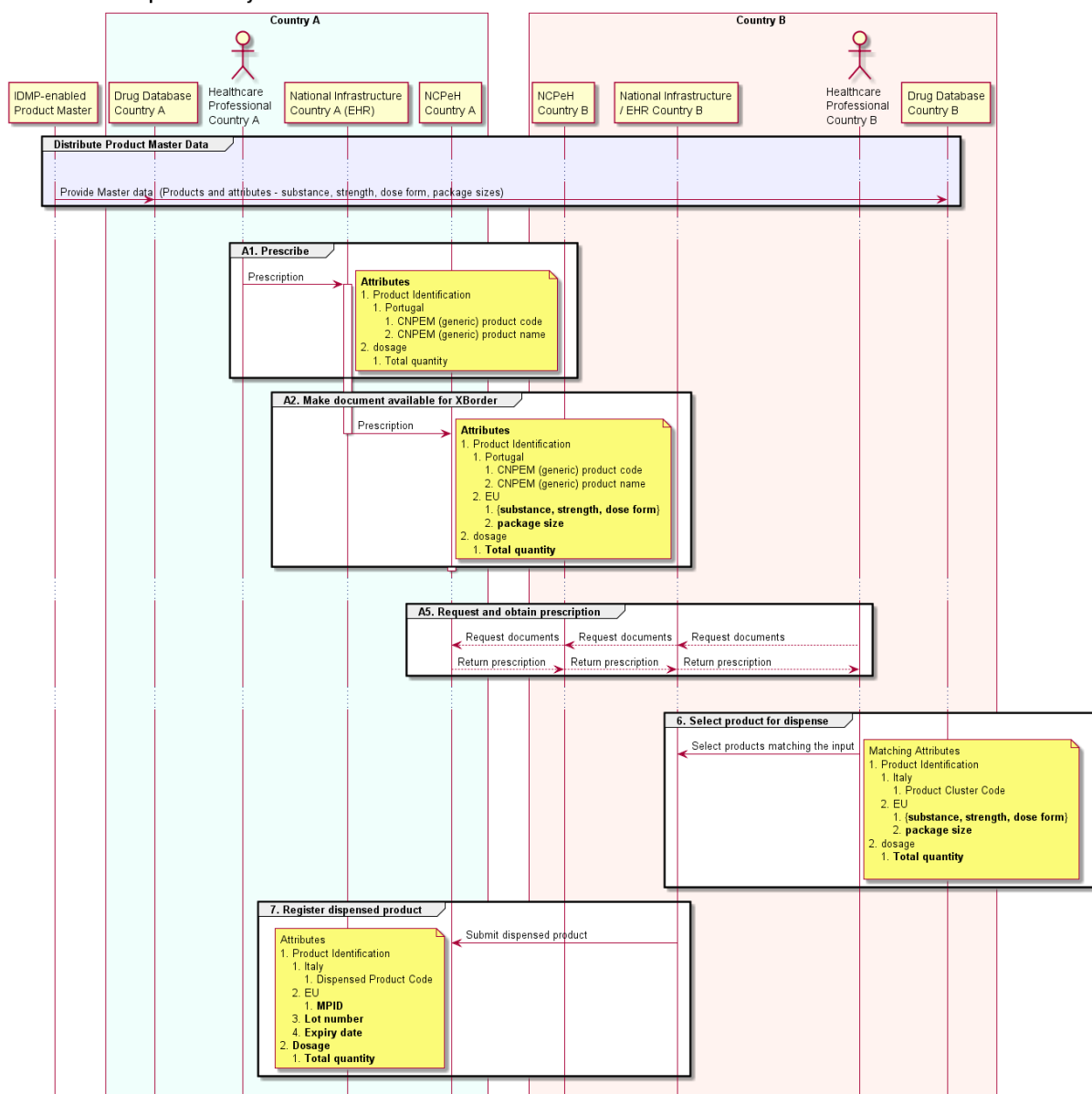
This use case reveals a key aspect of interoperability and IDMP-based product identification: The use of IDMP data attributes which permit interoperability if the elements have compatible values, i.e. the codes for substances and dose forms are compatible, and the expression of quantities is also interoperable.



This places a dependency on master data sharing and is enabled with the efforts of the national authorities and the central regulator (EMA) under the SPOR program.

Based on the above, Figure 10 shows a scenario of a Portuguese prescription with a National Medicinal Hospital Code (CHNM) that is dispensed in Italy. CHNM is a coding system assigned by INFARMED (Portuguese competent authority) to all drugs with marketing authorisation or with special use authorisation and are made available to hospitals so that they can automatically access a set of information relevant to the practice of the hospital pharmacy.

**Use Case 3: Portuguese (Generic) CNPEM-based prescription**  
**Scenario 1 - Dispense in Italy**



**Figure 10: Generic prescription, based on the group of equivalents (matching concepts)**

The following attributes are used:

- Product Identification
  - Portugal
    - CNPEM (generic) product code
    - CNPEM (generic) product name
  - Italy
    - Product cluster code (group of equivalence code)

- Dispensed product code
  - EU
    - Substance, strength, dose form
    - Package size
- Dosage
  - Quantity

### 2.2.1.5. Generic “Group of Equivalence” prescription – no matching concept in country B

Figure 11 displays a use case where the group of equivalence do not have a matching concept.

Use Case 3: Portuguese (Generic) CNPEM-based prescription  
Scenario 2 - Dispense in Belgium

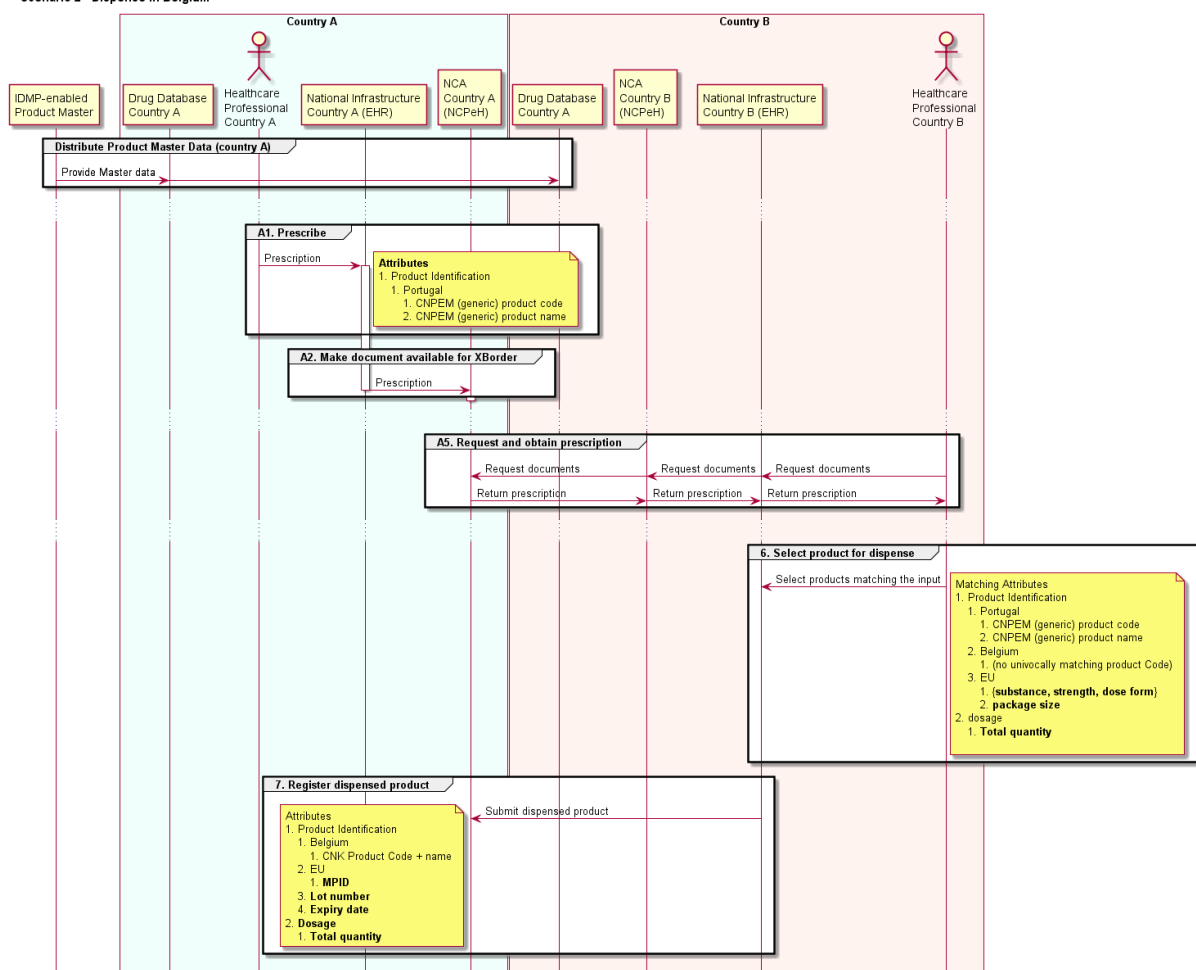


Figure 11: use case based on the group of equivalents (no matching concepts)

The following attributes are used:

- Product Identification
  - Portugal
    - CNPEM (generic) product code
    - CNPEM (generic) product name
  - Belgium

- Product code (in BE referential)
  - Product name
- EU
  - substance, strength, dose form
  - package size
- Dosage
  - Quantity

In cases where the concepts are not corresponding (at least univocally, i.e. 1:1), IDMP can still be used.

By expressing the product characteristics (and related information such as dosage) in a common language, the dispensing system can find products that exist locally that match the product prescribed, or, if not, match some of the attributes that correspond to the prescribed product.

As it can be observed in Figure 11, this scenario shows a change in the operation but without adding new requirements – which gives a first indication that the requirements stated above are sufficient to cover the expected use cases.

## 2.2.2 Brand name prescription

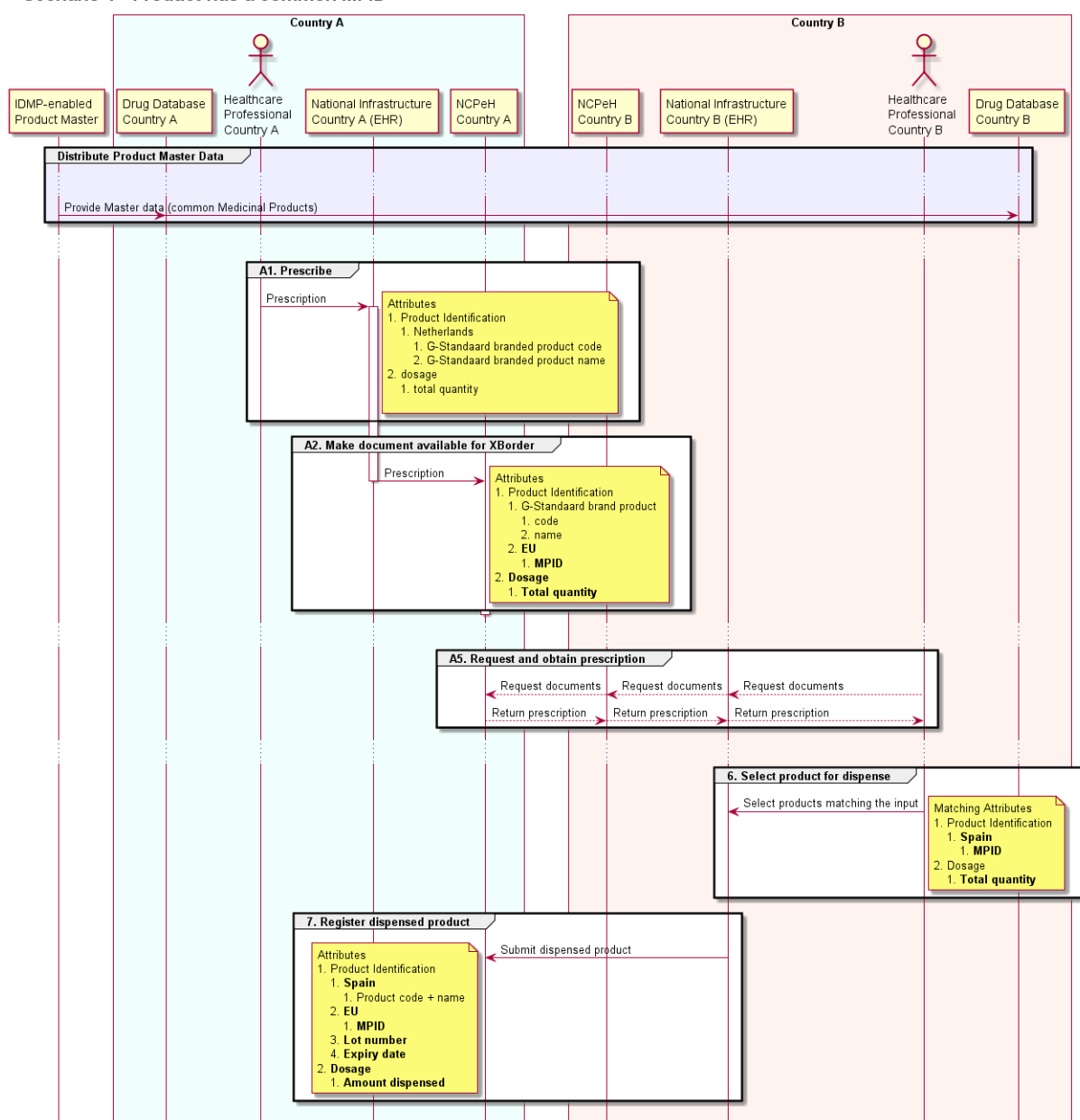
In this section, a selected set of scenarios show the change from generic to brand prescription. While in the same country the complexity is almost the same as for generic prescription (except for the matters of substitution), the complexity for interoperability across countries increases considerably in this context.

The following use cases will provide a deeper analysis of this context.

### 2.2.2.1. Brand name prescription – Common MPID

A Medicinal Product Identifier (MPID) is a supplementary ID that uniquely identifies a MP, reflecting without replacing, any other authorisation numbers allocated by a regulator. MPID is assigned in accordance with the country code segment, marketing authorisation holder and MP code segment.

Figure 12 represents a use case regarding a prescription from the Netherlands with a brand name registered in the Dutch drug database G-Standaard and the use of the MPID to identify the MP in country B (in this case, Spain).

**Use Case 4: Netherlands G-Standaard brand name prescription****Scenario 1 - Product has a common MPID****Figure 12: use case based on the medicine brand name (common MPID)**

The following attributes are used:

- Product Identification
  - Netherlands
    - G-Standaard branded product code
    - G-Standaard branded product name
  - Belgian
    - CNK code
  - EU
    - MPID + Medicinal Product name
- Dosage
  - Quantity

In the cases where the Medicinal Product Identifier is common, this can be used for a more refined product identification. This requires the exchange of product master data - the synchronisation of Medicinal Product information. This only works for common Medicinal Products and highlights the need to exchange and support another identifier - the MPID.

In this scenario, it is possible to observe that for a few products (those that have the same Medicinal Product ID in country A and country B), the identification of the product can be more detailed and allow a more precise selection for dispensation across borders.

Supporting this use case, it is possible to identify additional requirements:

- As for Data sets:
  - Product dataset (prescribed, dispensed, others) shall include another product identifier - the MPID.
- As for Master data:
  - If MPIDs are not governed centrally, they should have a robust governance process to manage the correctness (uniqueness, consistency) of the identifiers.
  - Identifiers should be freely available.
- As for Architecture:
  - The mechanism to share master data across countries shall include the MPID.

#### **2.2.2.2. Brand name prescription – No common MPID**

This scenario represents a use case where the countries A and B do not have a common MPID to unequivocally identify the same prescribed MP in country B (Figure 13). It represents most of the use cases, since a Common MPID is only available for a few products.

#### Use Case 4: Netherlands G-Standaard brand name prescription Scenario 2 - Product does not have a common MPID

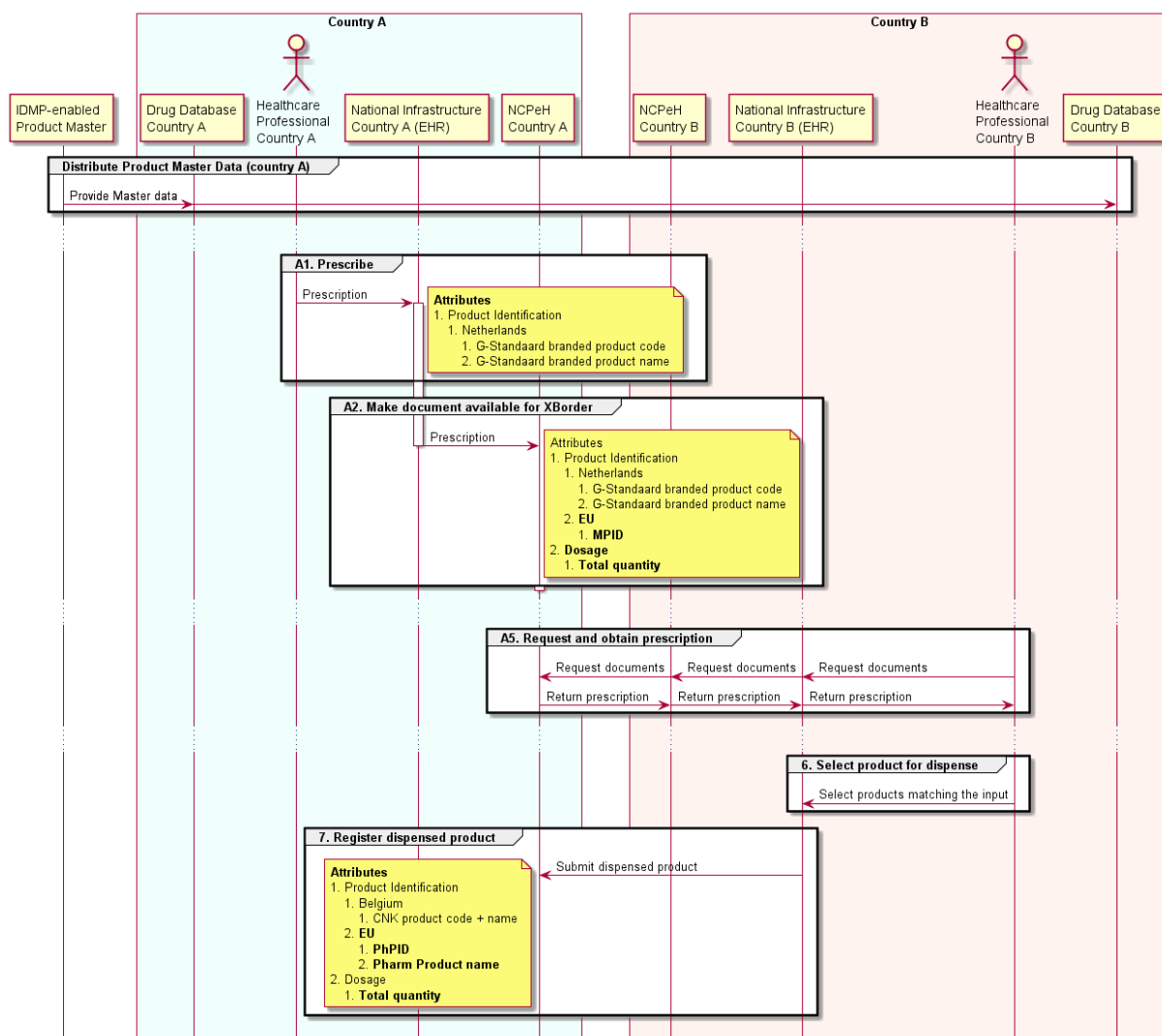


Figure 13: use case based on the medicine brand name (no common MPID)

The following attributes are used:

- Product Identification
  - Prescribed product
    - Netherlands
      - G-Standaard branded product code
      - G-Standaard branded product name
  - Product matching for substitution
    - EU
      - PhPID + Pharm Product name
      - MPID + Pharm Product name
      - Substance + role (e.g. excipient)
    - Belgium
      - CNK product code(s) + name(s)
  - Dispensed product
    - Belgium
      - CNK product code(s) + name(s)
      - MPID + Medicinal Product Name (different from Netherlands MPID)

- EU
    - PhPID + Pharm Product name
- Dosage
  - Quantity

In the cases where the Medicinal Product Identifier is not common, the full product information is no longer immediately available to Country B.

### **2.2.2.3. Brand name prescription – similar name**

This scenario explores a situation where the brand name of the MP in country A is similar to the one found in country B (Figure 14).

This scenario is described to demonstrate two important aspects:

1. The name of the product should not be used as an identifier for lookup in the other country
2. The name of a product in country A may be used for a user in country B to lookup the product in country A.

In other words, there is a risk in using the Country A's product name in country B. The only situation where the Country A's product name may be used is if the country B user wants to lookup the details of the product as it is defined in country A, to make conclusions from the information provided, without ever depending on matching the product name between countries. The name of the product shall only be used in the context of the country where the name was issued - and even then, caution is needed because differences of character set (e.g. Greece to Germany) can cause misunderstanding.

#### Use Case 4: Netherlands G-Standaard brand name prescription Scenario 3 - Product name coincides with another product

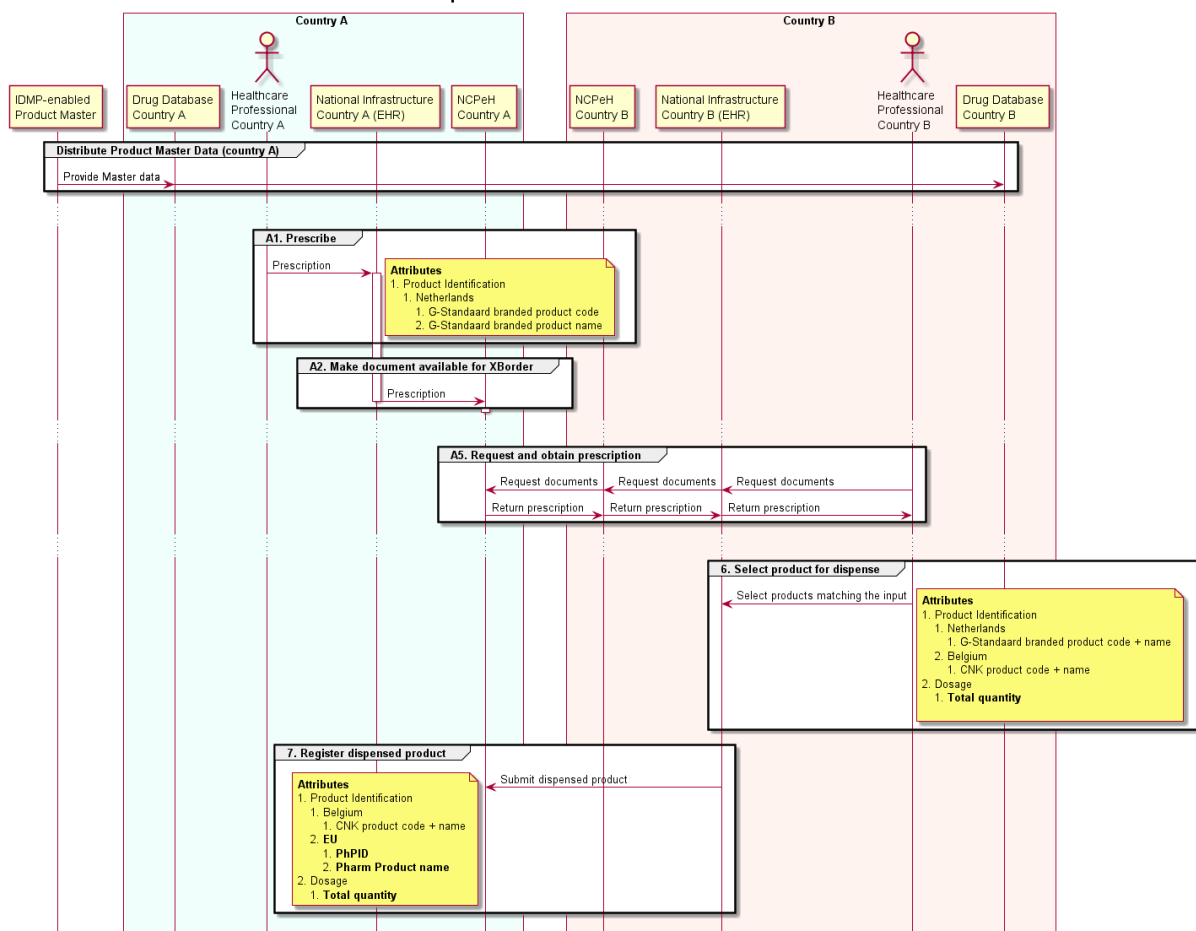


Figure 14: use case based on the medicine brand name (similar name)

The following attributes are used:

- Product Identification
  - Prescribed product
    - Netherlands
      - Generic name
      - G-Standaard code
    - Product matching for substitution
      - EU
        - PhPID + Pharm Product name
        - Substance + role (e.g. excipient)
      - Belgium
        - CNK product code(s) + name(s)
    - Dispensed product
      - Belgium
        - CNK product code(s) + name(s)
        - MPID + Medicinal Product Name (different from Netherlands MPID)
- Dosage
  - Quantity



In the case of a substitution, it is essential to identify the differences between the prescribed product, the product(s) that can be dispensed and capture the actual product that has been dispensed.

This scenario shows that the brand name might in some cases be used to help identify the product across borders, but it should not be a reliable way to identify the product, as it can be misleading. Therefore, the requirement for this scenario is to add the product name to the data set, but only as an adjuvant in identification.

#### **2.2.2.4. Brand name prescription – Substitution**

Substitution does not alter the product identification. It simply implies that the dispensed product may be different from the one intended – “different” here means “missing any characteristic that was implicitly or explicitly described in the original prescription”.

In Figure 15 the following scenario is explored:

A patient is using progesterone (100 mg capsules) and cannot interrupt the treatment. The prescription in country A is for a specific brand (Utrogestan) and substitution is indicated as “not allowed” (note that the meaning of “substitution allowed” may itself vary, but that is out of the scope of this document).

To continue the treatment while on vacation, the patient goes to the pharmacy in country B. However, the specific brand is not available in the country B.

The pharmacist in country B notices that, at the level of Pharmaceutical Product, there is an equivalent product (Progeffik), but one of the excipients in that equivalent is peanut oil, while in the original prescribed product is sunflower oil.

In this case, being substitution indicated as “not allowed” in eHDSI ePrescription and substitution is needed, the pharmacist could not dispense a product, however, the patient could get a prescription from a local doctor<sup>10</sup>.

---

<sup>10</sup> Alternatively, with the Smart substitution, there may be a future evolution where the situation could be handled differently, and a substitution could be considered - if the rules change

#### Use Case 4: Netherlands G-Standaard brand name prescription Scenario 4 - Product can be substituted

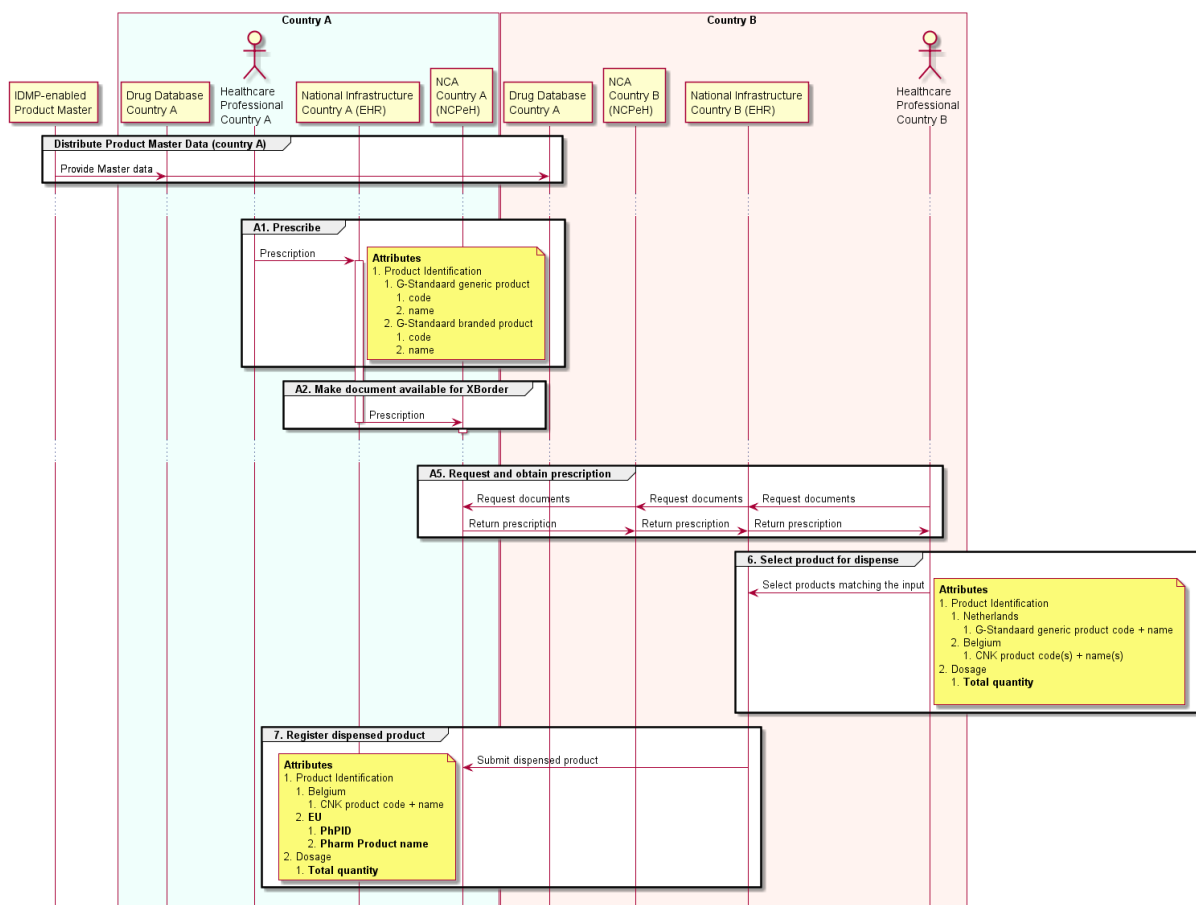


Figure 15: use case based on the medicine brand name (substitution)

The following attributes are used:

- Product Identification
  - Prescribed product
    - Netherlands (in the prescription)
      - Generic name
      - G-Standaard code
    - Product matching for substitution
      - EU
        - PhPID + Pharm Product name
        - Substance + role (e.g. excipient)
      - Belgium
        - CNK product code(s) + name(s)
    - Dispensed product
      - Belgium
        - CNK product code(s) + name(s)
        - MPID + Medicinal Product Name (different from Netherlands MPID)
  - Dosage
    - Quantity

Because of this mismatch of attributes (even if the PhPIDs match and a MPID mismatch is not relevant because it will always happen), the pharmacist asks the patient if they have an allergy and they confirm

they have a strong reaction to peanuts. The pharmacist decides then to replace the capsules with another brand which does not have peanut oil as an excipient.

This is only possible if the composition of the products (for example, excipients) is shared in an interoperable way.

This scenario allows to identify additional requirements:

- Data sets
  - The product ingredients – not only the active ingredients but excipients and others – shall be part of the product data sets – prescription, dispensation, etc.
- Master data and architecture:
  - The mechanisms to govern and distribute product master data shall support the ingredients and their roles, independently of whether they active ingredients.

### **2.2.2.5. Prescription with attribute mapping Brand name**

Based on the possibilities discovered by the use cases above, we can present the possibility of using the attributes (not only the identifiers) to correctly identify the adequate medication to dispense.

In this generic case, the medication is prescribed in country A, using the medicinal product identifiers that are normally used in country A – whether this is a substance, product or package identifier.

There may be a transcoding of the intended product into common coded product attributes. The attributes depend on the prescription –a generic prescription specifies the substance, strength, dose form, and a few other attributes, while a brand-name prescription specifies not only those but also the MAH, authorized medicinal product identifier, etc.

After this transcoding (which can be initiated in the country A or country B – it is not forcefully decided in this document) the professional in country B can observe those attributes and use them to filter the products in country B that match these products.

Once an adequate selection is done (what constitutes an “adequate selection” is the scope of further work), the professional in country B has a matching product, which is identified in country B with an identifier, but also a set of attributes.

The actual dispensed product will match the selected attributes from the prescribed product, but will also have more information such as brand name in the country B, package size, and other optional data, like, e.g. lot number, etc.

This information is sent out to country A in the same way: the dispensed product identifier may be transcoded into a set of common coded attributes. Back in country A, the information of the dispensed product is retained. For reconciliation purposes, there may be some matching to local product codes, but the dispensed product was not a product in country A, so it is important to keep the product identifier in country B.

Use Case: Branded prescription in country A - using attributes to identify products  
Dispensing in country B - identification of dispensed product in country A

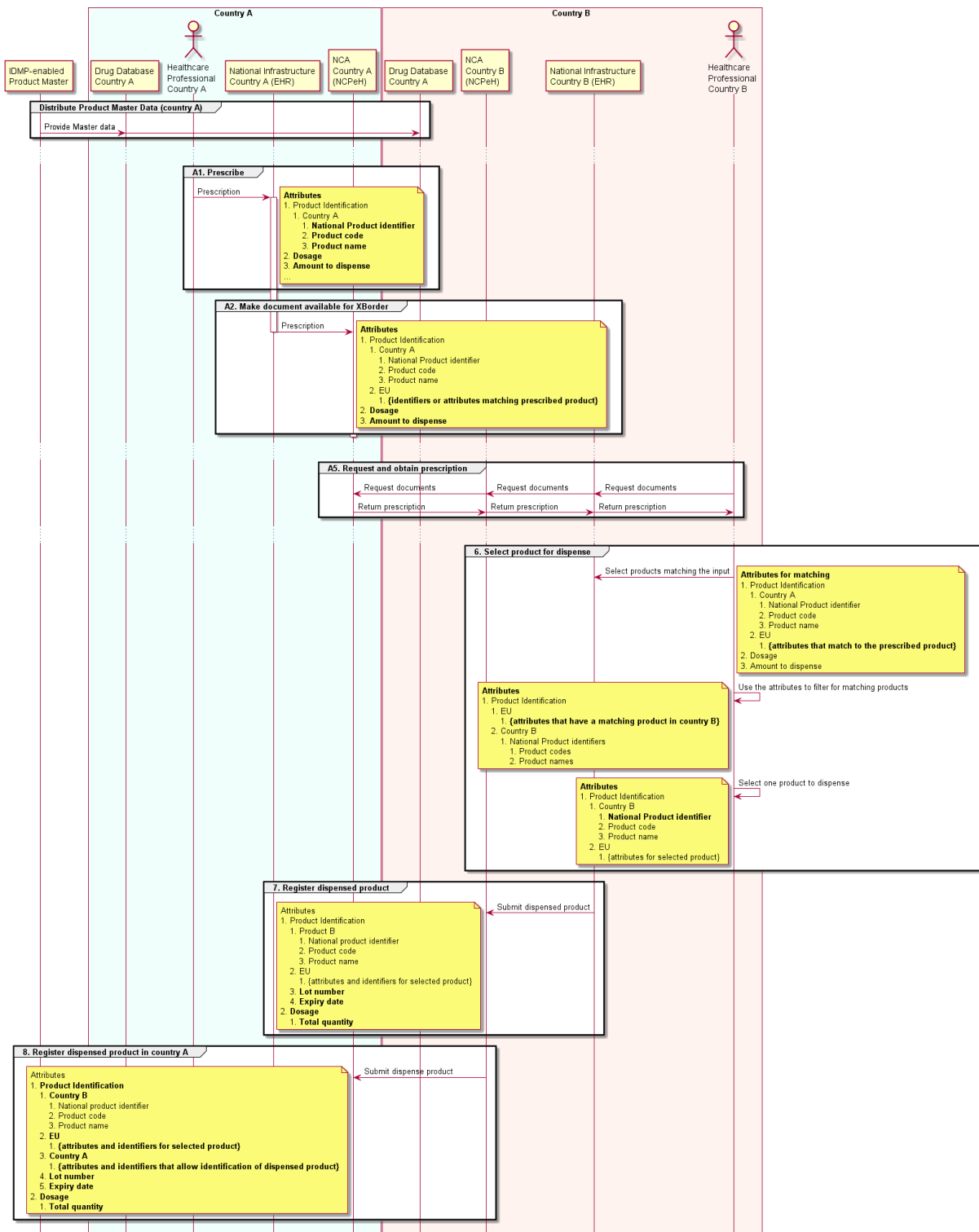


Figure 16: Prescription with attribute mapping Brand name

## 2.3 ePrescription / Patient Summary impact and functional extensions

The previous use cases may imply some extensions to the functionality available for eHDSI. This does not mean that eHDSI must cover these gaps, but eHDSI may require such gaps to be covered for the proper, maintainable support of IDMP-based product identification. These gaps should become part of a roadmap for IDMP adoption.

Continuing from the analysis in D5.1, it is possible to list possible extensions to the functionality available for eHDSI:

1. **Functional need:** Exchange of product information in a way to define a “product” in any part of the process – regulatory, clinical, surveillance.
  - a. This could mean that the eHDSI and other data exchanges shall support the necessary attributes to correctly define a product. This is detailed in the next section, about the data set requirements.
  - b. The attributes provided in the ePrescription shall be correct, and this correctness must be validated by a trusted entity or authority
  - c. This also requires that information to be “understandable”, hence the master product exchange described below, and / or the adoption of appropriate code systems and ValueSets for each attribute.
2. **Data set requirements:** From the analysis in D5.1 and the scenarios described above; the following is required:
  - a. Identify the attributes that should be part of a “standard” document – prescriptions, dispensations, patient summary, etc.
  - b. Define these attributes formally, in terms of cardinalities<sup>11</sup>, constraints, and vocabulary. Note that as a core requirement, the **UNICOM project aims to support the use and evolution of using the EMA SPOR for master vocabularies.**
  - c. Capture the data elements required to enrich the models used in eHDSI, to ensure consistency of the documentation and understandability through mutually adopted international code systems,
  - d. Capture a structured data model formally linked to the IDMP reference data model.
    - i. This work is tightly related to the work done in UNICOM D1.2<sup>12</sup>, about the Logical Data Models – the main purpose here is to make sure that the different data models in prescriptions, dispensations, etc. are mappable to the IDMP reference logical data model.

This model is shown in Annex B of this deliverable.
3. **Master Data exchange:** There is a clear and fundamental functional need to exchange product data across the different systems. While this will not be on the existing eHDSI content, but rather a new functionality, the requirements need to be aligned. For this:
  - a. The interoperability architecture shall be defined.
  - b. There shall be a standard format to exchange this data, from regulators to the clinical systems where this data is used.
  - c. The requirements should be discovered, e.g. Push vs Pull model, differential vs absolute, etc.

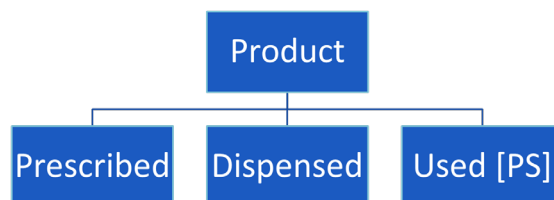
The scenarios described in section 2.2 highlight how a prescription / dispensation can change depending on the usage context; the prescription is however only one of the possible cases to be considered. Starting from the domains in the scope of eHDSI and the European EHRxR recommendation<sup>13</sup> it is

<sup>11</sup> “Cardinality” in this context means the fact the attribute MAY or MUST be indicated, and how many times it can be repeated.

<sup>12</sup> UNICOM D1.2: “Requirements for a new ISO logical model [platform independent]”

<sup>13</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019H0243&from=EN>

possible to identify (at least) three main cases where products are described in the Figure 17, with different needs:



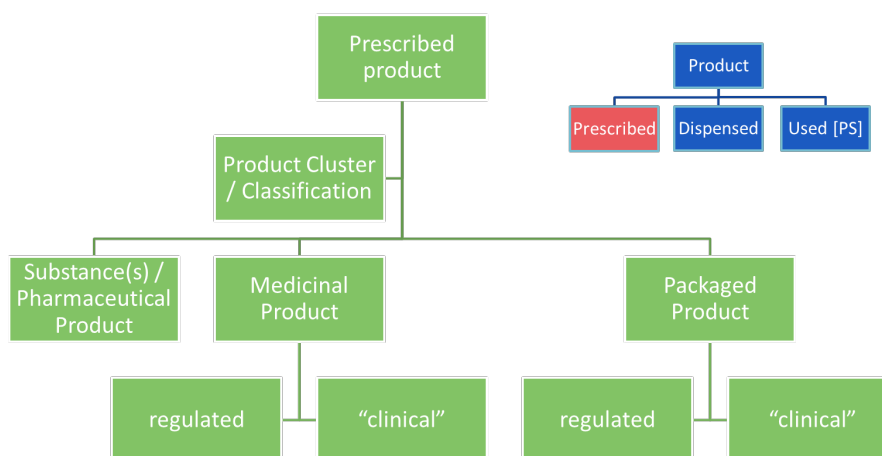
**Figure 17: Uses of Products in different scopes, implying different levels of product specification.**

This brings one conclusion / requirement: given the different scopes to specify a product, a consistent identification procedure needs to exist. The same product may be specified differently in the regulatory, clinical, or monitoring space, and this needs to remain consistent.

From the use cases described before (for products used in prescriptions), the different kinds of product specification can be grouped in the following categories (see Figure 18):

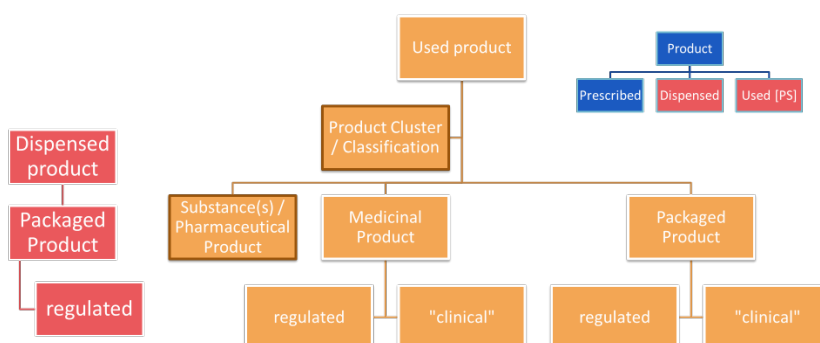
- Per classification. Classifications may be International (e.g. ATC) or local.
- Per cluster or group of products. Often local (e.g. the Italian “gruppi di equivalenza”). Noting prevents that the product cluster is used as a product identifier such as the Portuguese code for CNPEM.
- Per substance / pharmaceutical product, e.g. the INN prescription.
- Per medicinal product
  - Regulated, or
  - Clinical / Virtual. This represents a medicinal product independently on its marketing authorisation. (e.g. the SNOMED Virtual medicinal Product)
- Per packaged product.
  - Regulated, or
  - Clinical / Virtual

Other categorisations, with different granularity levels, are also possible.



**Figure 18: Categories of Prescribed Product**

In the case of the dispensation, with very few exceptions, it is important to note that the focus will be on regulated packaged products, also including information about the actual dispensed package.



**Figure 19: Categories of Dispensed and 'Used' (for summaries) Products.**

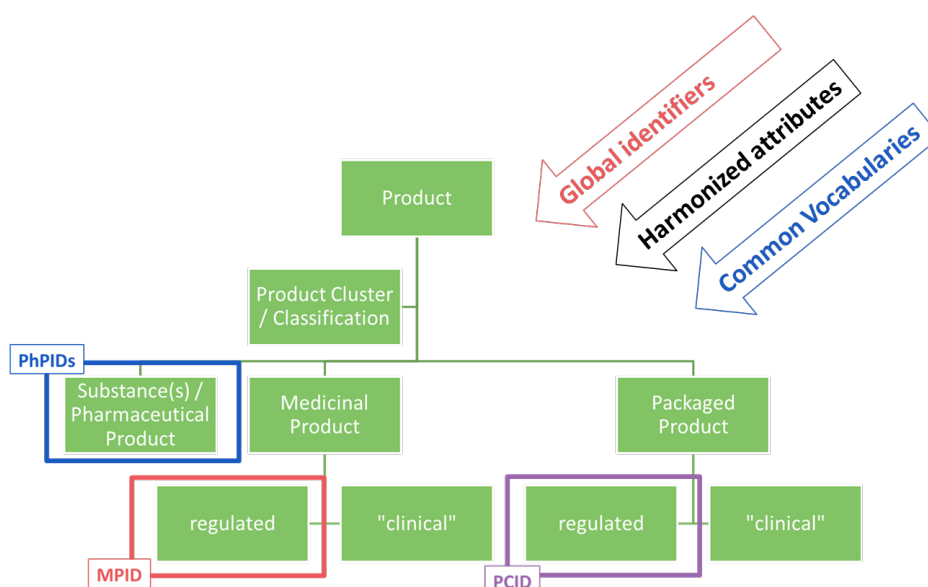
For Patient Summaries, all the product categories identified for prescription are also applied; however, in most cases pharmaceutical product (ingredients, strengths, dose form) and product classification (ATC) may be sufficient for the scope (Figure 19).

To cover all these different needs, IDMP provides support with a set of identifiers (PhPIDs, MPID, PCDID) for specific product categories, however these identifiers are not sufficient to cover all the cases (Figure 20).

As per the scenarios described in this document, this is where IDMP becomes essential, as well as the work in SPOR: More than the standardisation of 3 identifiers (and all the semantic standardisation that is required for that), IDMP enables the interoperability by providing a common vocabulary for each attribute.

The cross-border eHDSI requirement is therefore the inclusion of a set of attributes and additional identifiers/codes describing the products (Annex B).

IDMP and the SPOR work provides support for all the product categories by providing harmonised concepts, standard attributes, and common vocabularies.



**Figure 20: IDMP and Product Categories**

#### Patient Summary note

As described in this section different usage contexts may require different levels of product specification.

In this sense the information requested by the Patient Summary for unplanned care are in general a subset set of those required for the ePrescription, since in that context it is often enough to have a rough



indication of the kind of product that the patient took or is taking. Therefore, no functional extensions are expected other than supporting IDMP identifiers, in particular the PhPID.

In light of this the minimal requirement, they should be reconsidered when dealing with specific conditions (e.g. rare diseases; cancer patients), or when the usage of the Patient Summary components is extended to planned care. In these scenarios at least two aspects should be considered:

- The need of a more detailed description of the treatment and of its associated products.
- The capability of dealing with complex medicinal products (e.g. polychemotherapy) and exceptional situations (including the administration of retired products). Some of those medicines are exclusively used in the hospital environment, prescribed and administered within the hospital and therefore are not available in community pharmacies. Some of these products have a very complex description and do not have an ATC code associated.

While these complex group of medicines are out of scope of the UNICOM project at this time, it is important to recognise the significance of their correct identification in IDMP compliant format for further projects.

## 2.4 Architectural extensions for eP/eD & PS

The scenarios shown so far establish some possible additions to the existing components and data sets in the current architecture. They also indicate a dependency on possible new interactions between systems, which should be addressed<sup>14</sup>:

- Possible interaction between the National Infrastructure of the Country of Affiliation (Country A) and a Medicinal Product Dictionary (MPD) which can be national or European, and therefore must contain national content, with or without EU-wide content.
- Possible interaction between the National Infrastructure / prescribing system / pharmacist Portal and MPD
- Interactions between National Connector of the Country of Affiliation (A) and MPD
- Interactions between National Connector of the Country of Treatment (B) and MPD
- Possible interactions between a European MPD and the National MPDs (to share the data and ensure it is always up to date)

This set of interactions depends on the cases to be considered, for example:

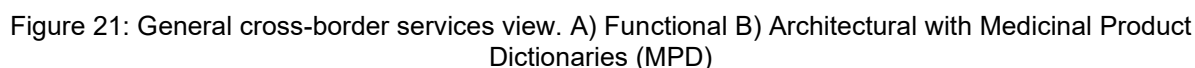
- Country A has fully adopted IDMP in the National Prescribing System
- Country B has fully adopted IDMP in the National Prescribing System
- National NCAs have adopted IDMP in the National Drug Database, but not fully integrated in National Prescribing System
  - Extension of eP can be injected at National Connector A level.
- National NCAs have PARTIALLY adopted IDMP: only some attributes are officially made available, or only some medicinal products have been coded, having a roadmap for implementation with different selection criteria per NCA.
  - Extension of eP can be injected at National Connector A level, limited to the provided attributes, if fulfilling the minimum required set, and limited to the sub-set of medicinal products for which the attributes are defined<sup>15</sup>.
- National NCAs have NOT yet adopted IDMP, but they have coded data compliant with current EMA registration and Pharmacovigilance process.
  - This is already an improvement compared to the unavailability of coded data. The approach described in the previous bullet points can be adopted, anyway,

---

<sup>14</sup> See: Figure 21: General cross-border services view. A) Functional B) Architectural with Medicinal Product Dictionaries (MPD).

<sup>15</sup> Evidence of these limitations should be provided to citizens and prescribers.

The content and format of such standards should be discussed – a few suggestions are given below:



## 2.4.1 Product Master data exchange

The introduction of a product data exchange is essential to ensure that product lookups and semantic consistency are possible. Some functional / technical requirements will need to be defined:

- There **SHOULD** be a central or federated master product data repository. It is expected that the data will be created in different entities (EU-SRS, EDQM vocabularies, PhPIDs, MPIDs). They must all converge or be accessible. Both central and federated approaches require standardisation. A federated approach increases the usefulness of such standardisation since there may be more connectors available.
- The National MPD shall be populated and maintained directly by the National Competent Authority for medicines or the National Competent Authority for eHealth Services or by an entity delegated by either of the previously mentioned ones.
- This master product data **SHALL**, at least, be populated with the IDMP attributes identified in this document for the scenarios considered. In practice, this means that the data used to describe the products must include these common attributes. Other attributes that are not necessary may be available, but they shall not be forced on these consumers. For example, substance details are attributes that are only needed for the regulatory process and should not be forced upon the prescribing and dispensing systems.
- The vocabularies (value sets) used **SHALL** be compatible with the SPOR directives, or univocally mappable to them.
- Besides IDMP concepts (PhP, MP, PP) the master data repository should support the different concepts used locally – i.e., it must contain the identifiers but also the attributes in a way that they can be used by the national dictionaries and cross-border prescription exchange.
- There **SHALL** be a mechanism to exchange product master data – a product “Catalogue” exchange, available for regulatory-originate data, but compatible with the clinical requirements described in this document. It is to be defined which kind of transactions this must support (bulk exchange, lookup, etc).
- Until a central or fully federated product data sharing is available, it is important that the product exchange is done including the common coded attributes, accordingly to SPOR, so that national systems can look up those attributes while find product equivalence. This relies in national databases being based on SPOR coding systems.

## 2.5 Legal Organisational impacts

### 2.5.1 Introduction to legal aspects

The services operated under the Connecting Europe Facility eHealth Digital Service Infrastructure (CEF eHDSI) are governed by the European Commission (EC) regulations and directives related to personal data protection and provision of health care services within and cross-border the Member States.

The UNICOM Deliverable D5.1 “Business requirements for the adoption of IDMP in eHealth Services” section 5: “Legal and Policy Context”, provides the reference and a synthetic analysis of the key directives and regulations was provided. The following list summarises them:

- Commission Recommendation 2008/594/EC of 2nd July 2008 on cross-border interoperability of electronic health record systems<sup>16</sup>
- Regulation (EU) 2016/679 of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)<sup>17</sup>

---

<sup>16</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008H0594&from=EN>

<sup>17</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>

- Cross-border directive 2011/24/EU of 9th March 2011 on the application of patients' rights in cross-border healthcare<sup>18</sup>
- Directive 2012/52/EU of 20th December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State<sup>19</sup>
- Regulation (EU) No 520/2012 of 19th June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council<sup>20</sup>

The last two ones have more impact on the ePrescription service; however, they also influence the Patient Summary service.

## 2.5.2 Legal requirements on Medicinal Products Databases

Marketing authorisation holders (MAHs) are required to submit and maintain information on their MPs to the Article 57 database in accordance with Article 57(2) of Regulation (EC) n° 726/2004, that lays down Community procedures for the authorisation and supervision of MP for human and veterinary use and establishes a EMA<sup>21</sup> database. Then, EMA publishes this information on all authorised medicines in the Article 57 database in the form of an excel document<sup>22</sup>.

EMA has also available a list of national medicine registers in the different MS of the EU and EEA, which contain information on medicines authorised in those countries<sup>23</sup>.

With reference to what was indicated in the previous section, the attributes provided in the ePrescription shall be correct, and this correctness must be validated by a trusted entity or authority"

This implies that each Member State should define rules and procedures to assure the correctness of the data contained in the MPD, by identifying who is responsible to provide and keep updated the common coded attributes associated to each medicinal product.

Furthermore, the security infrastructure and procedures to protect the MPD from undesired breaches SHALL be adopted.

## 2.5.3 Patient Information Notice and Health Professional Information Notice

CEF eHDSI Model Patient Information Notice (PIN) is a template made with the purpose to inform citizens about their rights concerning the protection of their personal data and explain to them how those data are going to be used by the system addressing the requirements found in GDPR<sup>24</sup>. The healthcare provider asks the citizen to access his/her health-related data in the context of the defined session, presenting the PIN and its acceptance (or not) by the citizen. The template provides to MS a simple template containing common information concerning data protection. While the template is voluntary, and MS can choose to build their own PIN itself is a requirement from articles 13 and 14 of GDPR. Article 13 specifies information to be provided where personal data are collected from the data subject,

---

<sup>18</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024&from=EN>

<sup>19</sup> [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=uriserv:OJ.L\\_.2012.356.01.0068.01.ENG](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=uriserv:OJ.L_.2012.356.01.0068.01.ENG)

<sup>20</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0520&from=EN>

<sup>21</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004R0726>

<sup>22</sup> <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/data-medicines-iso-idmp-standards/public-data-article-57-database>

<sup>23</sup> <https://www.ema.europa.eu/en/medicines/national-registers-authorised-medicines>

<sup>24</sup> eHealth DSI Member State Expert Group. Guidance on the Implementation of the Model PIN in W1 Countries. eHMSEG, CEF eHealth DSI, 2018

and article 14 relates to information to be provided where personal data have not been obtained from the data subject<sup>25</sup>.

In the PIN processing, ISO IDMP is unlikely to impact this process in the eHDSI.

However, patients should be informed that the “original ePrescription” will not be just **translated** in the language of the Country of Treatment, but significantly **transformed** by introducing attributes or identifiers not included in the ePrescription he normally knows.

Similar to PIN, the model for the Healthcare Professional Information Notice (HPIN) is used to inform healthcare professionals about the exchange of their personal data in a cross-border setting.<sup>26</sup> The template provides a common model that each eHDSI-participating country can adapt to their national laws, practices and legal context. The HPIN informs healthcare professional about relevant data protection issues applicable to that particular country.

As before, the ISO IDMP is unlikely to impact this process, as the main data is related to the healthcare professional personal information, such as name and contact information.

The ISO IDMP adoption will impact PS and eP/eD, but not the information notice that informs patients and healthcare professionals about the processing of the data information aspects related to their personal information in a cross-border context. Therefore, it does not impact medicinal product-related information. However, existing PINs should be checked as for the evidence of eP and PS Transformations are communicated.

## 2.5.4 Citizens and Health Professional information and training

The digitalisation of health registers and management systems, and the growing use of digital tools to access and manage health data, is leading to the development of new competences, such as eSkills<sup>27</sup> or electronic skills that is present in many different areas, including health-related areas.

The eHAction<sup>28</sup> deliverable “D6.3 - *Report on eSkills for Professionals*”<sup>29</sup> highlights the benefits of competences for a broad group of health stakeholders such as the health professional, healthcare institutions, health science education institutions, policy makers, etc.

Similarly, eHAction deliverable “D4.1 - Policy Framework on People Empowerment” concludes that patients also need to have the skills to access and use eHealth systems appropriately and effectively. The confidence that comes with digital health literacy and encompasses an appreciation of its benefits (such as understanding of maintaining good health and illness prevention) makes healthcare more effective and compassionate for its consumers and all stakeholders in the health ecosystem.

At a minimum, a basic level of digital proficiency is required to access and manage data electronically. Health providers and health related agencies should be able to provide basic training for patients and health professionals to guarantee the proper use of the eHealth systems, or at least, provide users with a detailed “how to” user guide and orientation to access health data. Currently, almost all health data is stored and managed in information systems in each EU Member State. It leads to the need to ensure that the health professionals receive basic training about the eHealth services such as eP/eD and PS to be able to use those systems.

In the same way, patients should also receive basic training to access their own data in eHealth systems, or at least a detailed “how to” user guide to inform them about how to use the systems and how to authorise health professionals to consult or update their information in a cross-border context. Without

<sup>25</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>

<sup>26</sup> Basic MODEL Healthcare Professional Information Notice for cross-border exchange of personal health data. eHMSEG Legal Work group. 2020.

<sup>27</sup> <https://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:E-skills>

<sup>28</sup> The eHAction was a Joint Action to support the eHealth Network developing strategic guidance and tools in the following Priority Areas: Empowering people; Innovative use of health data; Enhancing continuity of care; Overcoming implementation challenges and Integration in national policies & sustainability. Their outcomes can be accessed in: <http://ehaction.eu/>

<sup>29</sup> [http://ehaction.eu/wp-content/uploads/2020/08/03.06.2020\\_eHN-adopted\\_eHAction-D6.3\\_Report-on-eSkills-for-Professionals\\_v1.0.pdf](http://ehaction.eu/wp-content/uploads/2020/08/03.06.2020_eHN-adopted_eHAction-D6.3_Report-on-eSkills-for-Professionals_v1.0.pdf)

the patient's authorisation, health professionals cannot access their data in cross-border context if there is any health encounter.

In the specific case of adoption of IDMP attributes, pharmacists in the Country of Treatment, should be trained on the possible way of receiving the description of the prescribed medicinal product:

1. As a full set of minimum attributes to identify the product or
2. As a partial set of attributes, plus additional optional attributes
  - To be used to **identify** the packed medicinal product to be dispensed
3. As IDMP identifiers (PhPID, MPID, PCID), to be used to:
  - either to **pick** to product,
  - or to **select** the product in a list of equivalent one

Specific effort **MUST** be devoted to train the pharmacists on how the **substitution** should be handled for the listed situations, in the case in which "substitution is allowed" or "substitution is not allowed", in line with the indication specified by the prescriber.

This implies that, Substitution / Selection **MUST** be analysed, specified and implemented in dedicated tools, before being able to explain / train pharmacists on how they have to / may behave.

As far as Patients are concerned, as indicated in the PIN section, they should be informed that the ePrescription, as they know, are transformed by the injection of IDMP attributes and identifiers.

Each Member State should consider if it is worth keeping as stable as possible the pre-existing PINs and HPINs, and concentrate the effort on the creation of information material, to explain:

- how the original ePrescription can be transformed
- which are the restrictions (e.g. the current exclusion of some classes of medicinal products, due to lack of coded information) that can be applied to the prescribed medications
- which are the possible rules that can be applied in the selection / substitutions in the Country of Treatment
- As for Country of Treatment PIN, specific restrictions imposed by its legislations or implementations,

## 3 Proposals for CEF eHDSI business requirements extensions

### 3.1 The CEF eHDSI Business Requirements

This section lists the eHealth DSI business requirements that have been identified in D5.1 as those requiring amendments required for the implementation of ISO IDMP.

#### 03.03. Assess and validate the cross-border services

No changes are necessary in the text of the requirement. However, the requirement references the [eHDSI Test Framework](#) and the [eHDSI Audit Framework](#), which in turn use the following underlying artefacts that should be amended:

**Validators (e.g. CDA validators):** should be updated in order to accommodate new data fields.

**CDA Evaluation Form:** should be updated in order to accommodate new data fields.

**Test data:** requirements for test data should be updated in order to include relevant new data elements (attributes and identifiers, data value sets, where applicable).

**Readiness criteria, Semantics Domain:** Member States' translation policies (criterion SI.4) and transcoding policies (SI.5) should be updated in the new audits or follow-up audits.

New ISO IDMP attributes may pose challenges in the creation of eHDSI friendly CDA versions of structured documents (SI.1) and might call for additional measures for ensuring the integrity of data provided to the NCPeH (SI.3).

#### 03.04. Education, training and awareness among citizens of the cross-border services

The awareness of eP/eD minimum dataset specification enriched by IDMP identifier and attributes should be a part of the NCPeH training.

Patients should be informed on how the original ePrescription and Patient Summary could be transformed and displayed to the Health Professionals in the Country of Treatment.

Pharmacists should be trained on what they should do, according to the cases of received enhanced ePrescriptions, with specific indications on how to treat the selection / substitution, based on the indication of "substitution allowed / not allowed" by the prescriber.

#### 04. Ensure lawful processing of personal and health data

No further additions required to this business requirement.

ISO IDMP data is an extension to the data contents available in all prescriptions, dispensations and patient summaries. As personal data is captured, each NCPeH should evaluate whether Patient Information Notices or Healthcare Professional Information Notices provided by them should be updated. The need for updates is unlikely.

#### 05. Make Patient Summary available to HP

No further additions required to this business requirement. The revised eHN PS guideline Release 3, already make reference to ISO IDMP in a high-level way.



### 05.01. Create the eHDSI Patient Summary content

The data sets used for the Medication Summary, ePrescription and eDispensation should be harmonised across the use cases; eP/eD and PS.

The same changes suggested in the requirement “05.01. Create the eHDSI Patient Summary content” are applicable and valid to “06.01. Create the eHDSI ePrescription(s) content”.

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

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

In the event of new code systems and value sets being developed and introduced, additional translations and transcoding might be required. However, no changes are required to the business requirement text itself at this time.

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

### 05.03. Display the Patient Summary to the Health Professional

No further additions are required to the text, however, the reference implementation ([CDA Display Tool Guidelines](#)) should be updated to accommodate new data contents as required.

## 06. Make ePrescription available to HP

Modify the text of the business requirement in the following way:

NCPeH of Country of affiliation must make available to NCPeH of Country of treatment, at least the basic or essential information needed by the HP of Country of treatment to identify the correct medicine to be safely dispensed.

### 06.01. Create the eHDSI ePrescription(s) content

Similar to 05.01. “Create the eHDSI Patient Summary content”, the data sets should be harmonised across the use cases; eP/eD and PS.

#### Medicinal Product Code

- Modify the description of the Medicinal Product Code
  - *from* “National code that identifies the medicinal product description, in that region/country or among some countries <...>”
  - *to* “A product code refers to different ‘kinds’ of products, (e.g.: Packaged Product (regulated or non), Medicinal Product (regulated or non) or Pharmaceutical Product).“, and a set of codes identifies the product in that region/country (e.g. National product code) or among countries (e.g. IDMP IDs).
- Enable provision of ISO IDMP identifiers in addition to the currently supported “national code”: PCID, MPID, PhPIDs; assuring that the type of each IDMP ID is correctly identified, including the multiple levels of PhPID.

#### Ingredients

- Add supporting information, where necessary, to identify any ingredients other than active ingredients (such as adjuvants or additives, e.g. lactose)
- Add additional information to support the description of the use of the ingredient (active ingredient or another ingredient) (see Scenario 3.2.4)
- Add additional information to indicate whether the active ingredient is a salt or a moiety.



### Packaged product description

- Add a text field into the data set specification to provide a sufficiently detailed description of the prescribed medicinal product/package. This information is already supported by the technical specifications, but absent from the business requirements table.
- Enable the description of complex product / packages that include more than one unit of presentations and / or strengths within the same package medicine. For example, within the same package it may include a cream with a specific concentration and a pill with a specific dose (e.g., clotrimazole 100 mg external cream and pessary 100 mg x 6 units, plus the applicator).
  - e.g., some attributes should be repeated where necessary, to ensure the correct understanding on multiple levels (e.g., link to a specific EDQM value set).

### Package size

- Extend the concept of package size, to include more complex packet structures (for example, 10 vials of 35 mL; 2 blisters of 5 ampoules of 3 mL). Up to 3 layers of structure should be considered: immediate, intermediate, and outer package.

### Dose form (Link to WP 3: consider the rules used at the registration phase):

- Update the description to better reflect the dose form concept and highlight the distinction between the manufactured and administrable dose form. Suggest adopting the IDMP description.<sup>30</sup>
- The kind of dose form should clearly distinguish the information it is referring to (e.g. manufactured dose form) (e.g., link to a specific EDQM value set).
- The solution should support different levels of granularity of the dose form (e.g. capsule, hard; capsule).
  - “pharmaceutical dose form” should be repeated where necessary, to ensure the correct understanding of the dose forms on multiple levels.

### Marketing authorisation number:

- Not to be added in this round of changes.

### Information on the last dispensation (optional)

- Date
- Quantity dispensed

The current eHDSI eP Data Set should be improved by indicating "Substitution allowed", not as an attribute of the medicinal product, but as an action the pharmacist is not allowed to perform.

### [06.02. Transcode, translate and exchange cross-border the ePrescription](#)

New translations and transcodings might be required.

### [06.03. Display the ePrescription to the Health Professional](#)

---

<sup>30</sup> According to IDMP (ISO 11239) definitions, administrable dose form is a “pharmaceutical dose form for administration to the patient, after any necessary transformation of the manufactured dose form has been carried out”, while manufactured dose form is “pharmaceutical dose form of a manufactured item as manufactured and, where applicable, before transformation into the pharmaceutical product.” For example, powder for solution for injection (manufactured dose form), solution for injection that has been prepared (administrable form).

No changes needed in the requirement itself, however it references [CDA Display Tool Guidelines](#) which should be updated to include the new data, including ISO IDMP identifiers, that will be adopted.

## [07. Handle Dispensation of medicine and Substitution](#)

The business requirement has a reference to a flag indicating whether substitution was performed as part of the dispensation process.

Make evident that, in the ePrescription, the flag indicated by the Prescriber is:

- “Substitution allowed / not allowed

While in the eDispensation, it should be indicated:

- “Substitution performed / not performed”

The use of the Smart selection/substitution function (to be developed as part of WP6) may provide additional rules that should be linked to the flag to inform the record.

Indications to the pharmacist on how to manage selection / substitution according to the various Use Cases and prescriber indication on “Substitution allowed / not allowed” should be provided. That might call for the creation of a specific business requirement entry on Selection / Substitution, when fully specified in subsequent joint UNICOM / eHDSI eP Cluster activities.

### [07.01. Create the eHDSI eDispensation content](#)

The data sets should be harmonised across the different use case; eP/eD and PS.

Recommendations made in “06.01. Create the eHDSI ePrescription(s) content” should also be applied also to “07.01. Create the eHDSI eDispensation content”, when applicable.

In addition, changes are required to the eDispensation content.

Dispensed medicine data:

- In the section “3. Dispensed medicine data” it should be made clearer that the product described is the one which has been dispensed.
  - “Medicinal Product Description” should read “Dispensed Product Description”.
  - Align the product description with the ePrescription model.

Dispensed Medicine ID:

- This ID may overlap with the Medicinal Product Code concept. If redundancy does exist the possibility of removing this concept should be considered.

Medicinal Product Code

- The dispensed medicine ID is required, if it is a repetition of the prescribed product code then the product code shall be required.
- Align the Product Code description and name with the ePrescription model.

Number of dispensed packages

- In the current eHDSI eD model the “number of dispensed packages” is part of the “Medicinal Product Description” group. This is not however a product attribute, but an attribute of the dispensation act. It is therefore suggested to move this information from the product to the “DISPENSED MEDICINE DATA” level.

#### [07.02. Transcode, translate and exchange cross-border the eDispensation](#)

New translations and transcoding's might be required in the future.

#### [07.03. Inform Country of affiliation about the dispensed medicine](#)

No further additions required.

#### [07.04. Option to discard a previously performed dispensation](#)

No further additions required.

#### [08. Make Original Clinical Documents available to HP](#)

No further additions required.

#### [09. Ensure high quality information \(structured, equivalent, understandable\) is exchanged between countries](#)

- Regarding the context information, the medicinal section should be updated with ISO IDMP information as follows:

The current text is the following:

There are several possibilities to deal with the **unified meanings regarding medicines**:

- Each data field of the minimum data set is translated into a common terminology or nomenclature.
- A subgroup of the minimum data set (e.g. active ingredient + strength + pharmaceutical dose form) has a unique coding in a common language (this subgroup is the data that the doctor cannot break up as they are defined by the commercialised products).

The updated text should more clearly refer to the options provided by ISO IDMP.

There are several possibilities to deal with the **unified meanings regarding medicines**:

- Each data field of the minimum data set is translated into a common terminology or nomenclature.
- Provision of one or multiple unique identifiers, ideally the ISO IDMP identifiers (e.g. PhPIDs), describing a subgroup of the minimum data set (e.g. active ingredient + strength + pharmaceutical dose form).

#### [09.01. Ensure structured and coded information is exchanged between countries](#)

No further additions required. However, any information relating to the medication shall be displayed to the user in proper way.

#### [09.02. Ensure equivalent information is exchanged between countries](#)

No further additions required.

#### [09.03. Ensure understandable information is exchanged between countries](#)

No further additions required.

#### [eP/eD Use Case](#)

Details on the identification of the medicine to be dispensed (Semantic process of the medicinal product) should be updated. The section Details on the Dispensed medicine information to be sent to Country A might also need a revision.

- [eP/eD Use case diagrams](#): No further additions required.
- [eP/eD Example of Use Cases \(Storyboards\)](#): The section *1.2 Issues when dispensing* needs revising. The description of the “single concept” should not include validity date of the prescription or its posology.

### [PS Use Case](#)

There should be consistency between the structure and format of the patient summary document:

- Date for health encounters should be available in the patient summary document.
- PS information should be available in real time or as close as possible to real time.

## 3.2 Proposed Requirements Assessment

### 3.2.1 Requirement dependencies

Interdependencies among interoperability specifications (including requirements) are described in the [eHDSI INTEROPERABILITY SPECIFICATIONS, Requirements and Frameworks](#) and [Matrix of eHDSI Requirements, Functional Specifications and Technical Bindings](#) eHDSI confluence pages.

These dependencies are not affected by the proposals suggested in this deliverable.

### 3.2.2 Business impact & advantages analysis

According to the Change Management process of the eHealth DSI and in order to evaluate the benefits and business impacts of the change, each Change Proposal must provide clear answers to the following three questions:

1. Reason/business justification (WHY this change is needed)
2. Description of the requested change
3. Overview of the expected outcomes/benefits

This section provides answers to these questions, so that they can be included in the Change Proposal (CP).

#### **REASON/BUSINESS JUSTIFICATION (WHY this change is needed)**

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

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

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

The implementation of ISO IDMP is predicted in the Commission Implementing Regulation (EU) N° 520/2012, articles 25 and 26, which obliges EU MS, marketing authorisation holders and EMA to make use of the ISO IDMP standards.

## DESCRIPTION OF THE REQUESTED CHANGE

Modify the Patient Summary, ePrescription and eDispensation data sets; providing support for new ISO IDMP compliant attributes.

Modify the Master Value Set Catalogue (MVC); introducing a number of new code systems and data sets necessary for including coded data for the new attributes.

Modify the medicinal product *selection* phase in the ePrescription/eDispensation use case description; adding a new way of identifying the medicinal product in the Country of Treatment (Country B) based on the information provided as part of the ePrescription document received from the Country of Affiliation (Country A).

## OVERVIEW OF THE EXPECTED OUTCOMES/BENEFITS

The Health Professional in the Country of Treatment will receive more comprehensive and understandable information about the Medicinal Product than what appears on a Patient Summary or an ePrescription document:

- Substances and ingredient roles (coded and translatable)
- Product identifiers (e.g. PhPID, MPID)
- Packages (package content, type, device, coded and translatable)
- Dose form (multiple dose forms of different types, coded and translatable)
- Units (units of presentation as part of strength and package size information, coded and translatable)
- Strength type

This new information enables the Health Professional in the Country of Treatment to better understand the request for a medicinal product in the ePrescription or Patient Summary generated by the Country of Affiliation.

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

When a dispensation is performed abroad, an eDispensation document is sent to the Country of Affiliation supporting better integration into their national infrastructure about dispensations performed abroad.

This consistency in the use of ISO IDMP will help the pharmacist in the Country of Treatment to better assist in the selection of the medicinal product to be dispensed to the patient.

### 3.2.3 Revised list of Attributes from D5.1

The Table 1 presents an overview of the of additional attributes for cross border identification. The list of attributes presented initially in D5.1 (Annex C) was used to generate the data model outlined in this deliverable. The Table 1 can be summarised by indicating the different (types of) attributes that are needed in a prescription (which also applies to dispensation and patient summary):

**Table 1: Overview of additional product attributes for cross-border identification**

Attribute	Requirement: Ability to include the following elements in the product specification of a clinical document like ePrescription	Compatible with SPOR (i.e. vocabulary used should be compatible with SPOR master data)
Substance identification	Substance identifier - according to SPOR requirements	Yes
Product identifier	Product identifier – IDMP identifiers (PhPID, MPID, PCID), national identifiers, other identifiers	Yes, especially in cross-border identifiers
Product Classification	ATC and other classifications in a product specification	Yes, in cross-border classifications like ATC
Package Content	Package Content e.g. quantity and contained products	Yes, for quantity and contained product
Package Type	Package Type e.g. vial, blister...	Yes
Package: Device	Device e.g. pre-filled syringe	Yes, presumed available
Administrable dose form	Administrable dose form	Yes*
Basic dose form	Basic dose form of the product	Yes
Patient friendly dose form	Common-language dose form	Yes, should be available
Pharmaceutical dose form	The dose form of the pharmaceutical product	Yes
State of matter	State of matter, e.g. liquid, powder	Yes
Routes and Methods of Administration	The intended route and method of administration	Yes*
Units of presentation	The unit of presentation of the specified product, e.g. "tablet"	Yes, common code set
Units of measurement	All units of measurement, for strength, dose, etc.	Yes, a common grammar is needed
Strength Type	The type of strength that is indicated (e.g. moiety strength)	Yes, has been proposed by UNICOM to IDMP
Strength units	Common grammar like Units of Measurement	Yes
Ingredient Role	Standard list of possible roles for ingredients (adjuvant, active, excipient, ...)	Yes
Intended site	The intended site of administration	Yes*

Language	The language used to express the product description	Yes
Legal Status of Supply	When needed to assert a status of supply e.g. “prescription-only”	Yes
Marketing Status	Used to differentiate products approved or not, in different jurisdictions	Yes
Quantity Operator	For all quantities expressed	Yes
Release characteristics	When needed to detail the characteristics	Yes
Special Precaution for Storage	????	Yes
Transformation	Indicates the operations used to produce a product, e.g. in magistral preparations	Yes (for structured information). If not, free-text.

\* Note: some attributes in this context (e.g. indication, route, form) refer to the intended use. This may differ from the authorised use in cases requiring an off-label use. For example, tablets can be crushed and dissolved, or administration sites may be different.

The consolidation of the definition of the Minimum Data Set will be the topic of D5.3.

### 3.2.4 Suggestions to the “smart substitution/selection function”

The aim of the ePrescription related requirements has been to strictly focus on the necessary requirements to achieve a minimum, but secure and safe, service and also identify desirable requirements that would improve the service. This might be difficult to implement in eHDSI for all countries. The use case is described in another section of this document, as well as in the eHDSI eP/eD use case wiki page<sup>31</sup>. To refer to a substitution process we need to have at least the following conditions:

1. There is a valid clinically and legally wise prescription available in a country of origin (country A) that is available for dispensation in a country of treatment (country B).
2. There are no legal constraints that do not allow the dispensation of the medicinal product in country B
3. The pharmacist in country B can select any pharmaceutical product that matches the medicinal product (active ingredient)
4. The pharmacists in country B cannot dispense the exact medicinal product as prescribed in country A for example (non-exhaustive)
  - a. The packaging of the pharmaceutical product in country B does not coincide to the prescription in country A
  - b. The dosage cannot be matched exactly in country B
  - c. The pharmaceutical form of the medicinal product (pill, syrup, injection, etc) is not existing in country B
  - d. The clinician in country A has added notes on allergies that may affect the dispensation process (excipients, etc)

<sup>31</sup> <https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pageId=55887070>



Substitution 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 MS may have different rules regarding which type of substitution is allowed.

There are different types of substitution, for instance:

- **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.
- **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 that 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.

The ISO-IDMP enriched database and master value dataset will increase the likelihood that a medicine specified in a cross-border eP can be fully identified and dispensed in country B (country of treatment). Therefore, the introduction of ISO IDMP attributes will contribute to providing the necessary detailed information to ensure a smart selection and substitution, which in turn will promote a safer eD process for the citizen.

Consequently, what we would envision achieving by adding an ISO IDMP enabled smart substitution component are:

1. To provide more attributes to the pharmacist in country B to properly identify the right pharmaceutical drug to the patient.
2. To match an equivalent medicine with the same strength if the packaging is different in country B.
3. To reduce the risk of adverse reactions and allergies for the patient.
4. To provide more guidance to the patient and information concerning the dispensed medication.

From a technical standpoint the smart substitution component needs to:

1. Expand / interact with the CDA display tool for eP/eD.
2. To expand the functionality of the dispensation portal in country B (portal B for example)
3. To reuse the semantic eHDSI components to properly match the prescription into country B language and terminologies.
4. To interact locally with an ISO IDMP database to have access to more medicinal and pharmaceutical product attributes to enhance the dispensation process ensuring patient safety.

Several design points need to be clarified:

1. ISO IDMP enabled prescriptions will increase the possibility of matching a medicinal/pharmaceutical dispensation in country B, so it is important to define in D5.3 the selected ISO IDMP attribute that would be marked as required for a valid cross border prescription.
2. If country B has to process a non-ISO IDMP enabled prescription, it can still use local ISO IDMP attributes to enhance the substitution process if needed on the country of treatment side trying to match the country of treatment clinical requirements.
3. ISO IDMP is only one parameter on the prescriber side that would ensure a better chance for a positive and safe dispensation in country B. Other parameters may affect the judgement of the pharmacist in country B such as
  - a. The diagnosis (ICD-10) related to the prescription.



- b. The prescription protocols that may be in place for specific chronic diseases. In this case additional information can be sent to the pharmacist such as allergies and other patient summary information. For example, prescription protocols are in place in Greece.
4. Taking these points above into account it seems that a distributed architecture where the ISO IDMP data reside at a national level have a better clinical impact than if the service is provided centrally as an eHDSI component. This also simplifies the implementation process leaving more flexibility to the Member State on how to achieve IDMP integration into the eP/eD cycle for cross border or national purposes. As an example, Greece is already envisaging such an approach and a preliminary study for a national catalogue of pharmaceutical substances (EKFO) based on ISO IDMP has already been completed.

This smart substitution process cannot remove legal or administrative barriers to dispensing a prescription. Those are partially governed by the relevant EU Directive and the national regulations.

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

1. The legal principle is that Country A sets the validity when prescribing and Country B when dispensing.
2. 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 he can justify concerns about patient safety. So, all the instances will need to be treated on a case-by-case basis.
3. The substitution needs to follow the single concept approach.

Consequently, the identification of the medicine to be dispensed starts with the selection of the medicine, based on the identifier for the single concept indicated in Country A and is followed by the Substitution process (if this is not prohibited by the prescriber).

- If the prescription includes information about the Brand Name and Substitution is prohibited, in the selection of the medicine process, the same Brand Name must be selected. In this case, the Substitution process must not be commenced.
- If the prescription includes information about the Brand Name and Substitution is allowed, the Brand Name information could be used to help the selection based on the single concept. After the selection process, the Substitution process might be commenced.
- In case of generic prescription, the selection of the medicine process is performed and there is no need for Substitution (if there is no need therapeutic equivalent substitution).

## 4 Summary of proposed requirements extensions

### 4.1 Requirements proposals for extensions

Table 2 below shows a list with the common extensions to eP/eD & PS requirements that have been identified in this document as needed to support the ISO IDMP adoption on CEF eHDSI system. The list of sample draft Change Proposals to eHDSI can be seen on the Annex D.

**Table 2: Common requirements for ePrescription / eDispensation & Patient Summary extensions**

eHDSI Req. number	eHDSI eP/eD & PS Requirement	Proposed Extension
05.01	Create the eHDSI Patient Summary content	The data sets used for the Medication Summary, ePrescription and eDispensation should be harmonised across the use cases; eP/eD and PS.
05.02	Transcode, translate and exchange cross-border the Patient Summary	Additional translations and transcoding might be required, in the event of new code systems and value sets being developed and introduced. However, no changes are required to the business requirement text itself at this time. The use of ISO IDMP will positively contribute to the implementation of this business requirement in the future by replacing some of the textual elements with coded entries. It is just a suggestion of format to this chapter. It might help to complement the text.
06	Make ePrescription available to HP	Modify the text of the business requirement in the following way: NCPeH of Country of affiliation must make available to NCPeH of Country of treatment, at least the basic or essential information needed by the HP of Country of treatment to identify the correct medicine to be safely dispensed.
06.01	Create the eHDSI ePrescription content	The data sets used for the Medication Summary, ePrescription and eDispensation should be harmonised across the use cases; eP/eD and PS: Medicinal Product Code, Ingredients, Packaged Product Description (including complex package), Package size, Dose form, Marketing authorisation, Information on the last dispensation
06.02	Transcode, translate and exchange cross-border the ePrescription	New translations and transcodings might be required.
07	Handle Dispensation of medicine and substitution	The business requirement has a reference to a flag indicating whether substitution was performed as part of the dispensation process. Make evident if substitution is allowed or not and if the substitution was performed or not. The use of the Smart selection/substitution function may provide additional rules that should be linked to the flag to inform the record. Indications to the pharmacist on how to manage selection / substitution. That might call for the creation of a specific business requirement entry.

07.01	Create the eHDSI eDispensation content	The data sets should be harmonised across the different use case; eP/eD and PS. (see 06.01)
07.02	Transcode, translate and exchange cross-border the eDispensation	New translations and transcodings might be required.
09	Ensure High quality information (structured, equivalent, understandable) is exchanged between countries	Regarding the context information, the medicine part should be updated with ISO IDMP information

Standardise the product model including the new attributes, optionally using it to enrich the eHDSI models

Ensure compatibility and availability between the SPOR data and the data used by clinical systems and clinical interfaces

### 4.1.1 Compatibility and articulation with IDMP and regulatory data

One fundamental requirement in D5.1 has been the minimisation of the impact on operational systems, e.g. eHDSI or national prescription infrastructure. This requirement has a very practical impact here: the adoption of IDMP must avoid a drastic, non-backwards compatible change with eHDSI systems as much as possible. In other words, it must be an incremental change.

While IDMP is expected to cover most of the data elements indicated (except those specific to a treatment, e.g. total quantity for the patient), it is not practical nor needed or possible to reshape the eHDSI model and requirements to be exactly the same as for regulatory information systems.

### 4.1.2 Consolidated Product attribute model

Considering the existing attributes and the proposed additions, a set of common attributes can be consolidated in a single model. This consolidated model contains the attributes that are considered essential for an implementation of cross-border product identification. This model follows the principles:

- Compatibility with IDMP and namely the SPOR data
- Adequate for use in clinical documents (which may differ from regulatory or supply documents)
- Minimising the impact on existing eHDSI

In work package 1, Deliverable D1.2 “Requirements for a new ISO logical model” proposes the use of standardised, functional logical data models as a way to reach a computable, mappable specification.

An analysis of eHDSI, and underlying standards like HL7 and IHE / epSOS profiles, a product attribute model for ePrescription/eDispensation is available in Annex B of this document.

This model presents the attributes that should be exchanged (with varying optionally) in an ePrescription or eDispensation (or others, like Patient Summary) document. The elements in this model are compatible with IDMP, which means that these attributes can be exchanged in a prescription.

This data model is the input to the definition of the minimum data set that will be defined in D5.3 “Guidelines for cross-border semantic interoperability”,

## 5 Conclusions and next steps

The purpose of this document is to provide guidelines on how ePrescription, eDispensation and Patient Summary services can benefit from the adoption of the IDMP.

To achieve this, the methodology is a traditional analysis: It starts with an overview of the cross-border processes to frame the problem. Then a critical analysis of the expected scenarios that demonstrate the possible applicability of IDMP. A few key scenarios are chosen based on their coverage of the requirements: while there are many possible variations of products, attributes, prescription modes, and rules, a limited number of scenarios are chosen to cover the different variations in each dimension (for example prescription mode – generic or brand-name). This allows for the elicitation of the requirements without exhaustively exploring all the possible combinations. For that same reason, the scenarios chosen are for ePrescription and eDispensation – they provide a broader range of requirements than Patient Summary.

In each scenario, the data used and necessary is identified – for example what data elements are present in a generic prescription, or in a dispensation, etc. This approach yields a set of data exchange mechanisms that may be necessary, and the data elements that are used in each of those mechanisms. The data elements considered correspond to IDMP data attributes.

This is then compared to the eHDSI requirements, to identify possible changes to the ePrescription, eDispensation and Patient Summary guidelines. This comparison reveals a gap of some data elements but also architectural changes, such as the availability of centralised or federated Product Master Data, and a mechanism to exchange that data.

This approach reveals that to support cross-border prescription and dispensation, the use of IDMP attributes cannot be limited to only the identifiers such as PhPID, MPID, PCID, and a transcoding of such identifiers to another product code – because that will not be a univocal transcoding. It is also important that some attributes can be available in a cross-border ePrescription and eDispensation. These attributes are identified in this document and will be further detailed in coming deliverables.

Present in this document is one fundamental requirement that was described before: The changes from UNICOM should avoid imposing a radical change in the CEF eHDSI services, and should not present operational challenges to the implementers, especially for those in the field. The main reason is one of impact: A small change in dozens of software vendors will be much harder to achieve than a larger change in a central system. One clear example is that the IDMP data attributes should be added to the CEF eHDSI, not to replace the existing information.

This analysis validates that requirement: it is seen that not many IDMP data elements are needed, and the gap to the eHDSI specifications is not big. However, some minor alignment is recommended. Another important finding is the need for a mechanism to exchange and lookup products based on such attributes. This needs to be based on data aligned with the central agencies, e.g. following the SPOR requirements, but does not require the complexity of the regulatory processes.

As for next steps, it is necessary to describe the data elements that are present and confirm their alignment in IDMP and their coverage by the SPOR and central database regulatory data exchange.

Then, a standard mechanism for that exchange needs to be described and standardised in the next deliverables, and aligned with SDOs.

## Annex A – D5.1 Chapter 6 – Use Cases

### Analysis Methodology

This WP5 concerns the overall orchestration to adopt IDMP in eHealth Services, at national and cross-border levels, with a focus on cross-border on ePrescription (eP) and Patient Summary (PS). Implementing National eP systems for community pharmacies within the same country will be a preparatory step to cross-border eP, without disregarding other scenarios on prescribing (e.g. hospital prescriptions) and making reference to medicinal products (e.g. medication plans, continuity of care documents, hospital discharge letters, etc). These elements will be defined as reusable building blocks for medicinal product identification.

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

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

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

Identifying Actors (Figure 22) is one of the first steps in Use Case analysis. Each type of external entity with which the system must interact is represented by an Actor.

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

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

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

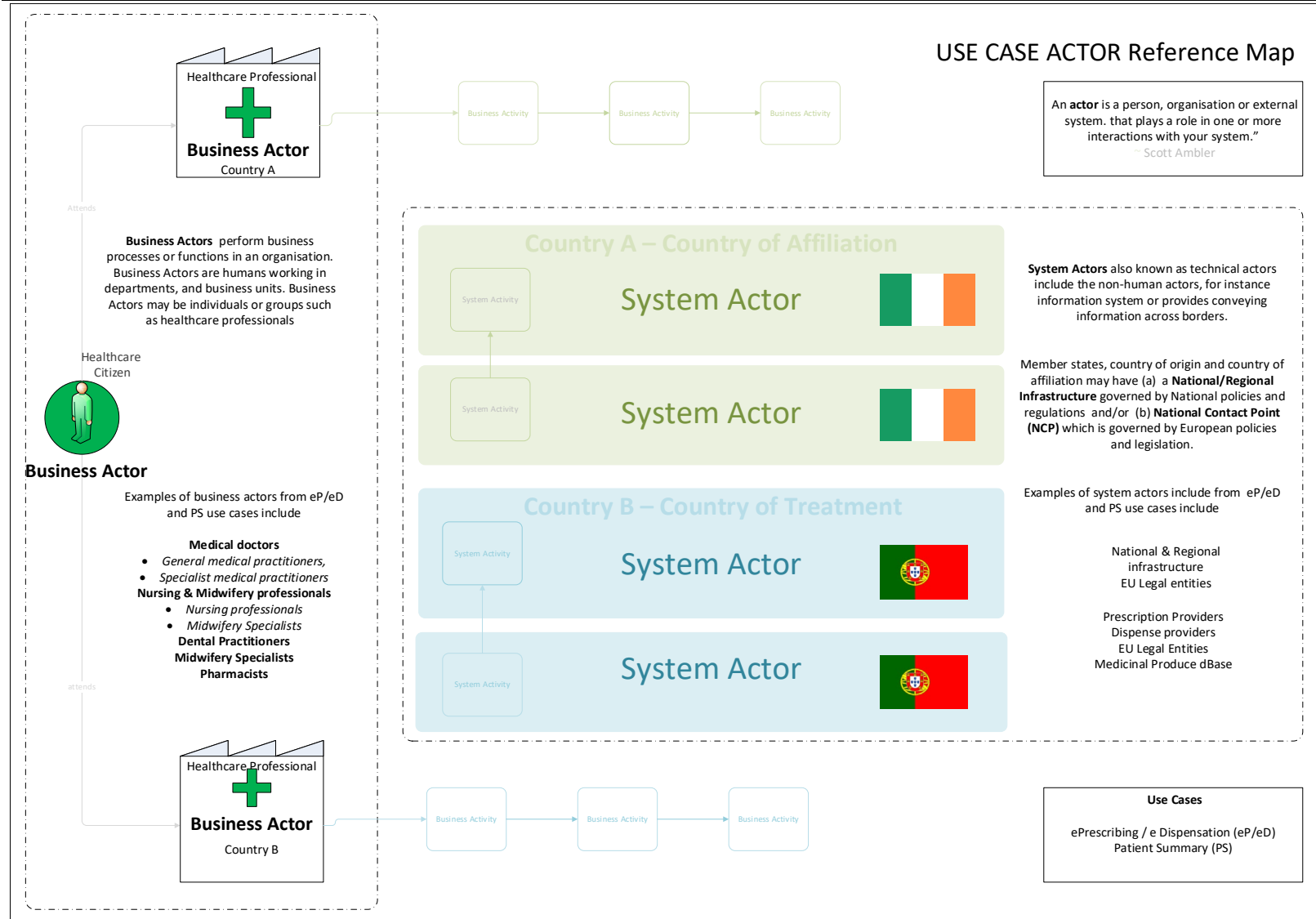


Figure 22: eHealth actors

## ePrescription

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

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

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

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

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





The Figure 23 represents the Value Stream Map for an ePrescription scenario. It identifies the different roles and responsibilities of both Countries in a cross-border exchange. In this, the highlighted (orange) boxes identify the sub-process where there are issues and constraints that may be impacted from IDMP and should therefore be a target for UNICOM, that is, they show where the existing needs can be improved by the UNICOM project.

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

**Table 3:** Main actions list on cross-border ePrescription.

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

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

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

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

#### PRE-CONDITIONS – CEF eHDSI (redeveloped)

4. The patient must have already been electronically prescribed a valid prescription, by an authorised prescriber in Country A.
5. The Health Professional in Country B is assumed to be legally authorised to dispense medicinal products and is identified and authenticated via agreed mechanisms in Country B.
6. In Country B, there has to be a mechanism to validate the identity of the patient and to handle patient GDPR related action (e.g. provision of consent where applicable) and the results to be made available at the pharmacy of country B
7. Dispenser in Country B requests available prescription list.
  - a. In order to obtain the needed information in Country B, the Prescription Provider in Country A must make available the prescriptions to be sent to another country upon their request. Which prescriptions are made available – that is a question that is still open and must be resolved:
  - b. Country A must have the necessary context information or parameters to determine which are the prescriptions that the patient can withdraw from the pharmacy at that specific moment.
8. Country A must provide, maintain and support a logical country node (NCPeH) supporting communication of the information identified in this section with Country B and vice versa (*Ensure traceability and auditability of the exchanged data*<sup>32</sup>)

<sup>32</sup> Note: The Italic text refers to the CEF eHDSI Requirements Catalogue. Along of the text in eP and PS use cases you can find some requirements listed here. For more details visit:

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

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

### **1. Check Patient ID – CEF eHDSI (redeveloped)**

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

### **2. Get available prescription list**

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

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

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

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

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

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

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

**5. Report medicine as dispensed**

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

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

**6. Provide dispensed medicine to patient and secure payment**

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

## Patient Summary

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

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

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

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

Considering the PS flows between cross-border countries, it is possible to analyse different scenarios and the activities within. The Table 4 describes the key activities for the description of the PS use.

The Figure 24 below, represents the Value Stream Map from PS use case. It identifies the different roles and responsibilities of both Countries in a cross-border exchange. Additionally, the pink boxes identify the issues and constraints that could be improved by UNICOM, that is, the existing needs that can be improved with the UNICOM project.

**Table 4:** Main actions list on cross-border Patient Summary.

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



**PRE-CONDITIONS**

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

**1. Check Patient ID**

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

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

**2. Consult Patient Summary of country A**

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

1. The HP requests the Patient Summary from Country A
2. Technical actors from both Country A and B are involved in:
  - a. Processing of the requests.
  - b. Checking patient consent has been provided (where applicable).
  - c. Obtaining patient summary in the agreed eHDSI format. It must contain at least the minimum (could be the maximum) data set
  - d. Transforming the eHDSI format into a suitable format for PS provision in Country B. The PS must be understandable in the Country B's official language, the content of the PS should comply with the usual practice in Country B (format and content, including displaying of information).
  - e. Conveys the PS of Country A to the HP interface of Country B
3. The HP of Country B consults the PS of Country A

### **3. Report treatment received**

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

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

### **4. Secure payment and reimbursement**

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

The use case is terminated.



## Annex B – eHDSI data set analysis

The proposals described in section 3 “Proposals for CEF eHDSI business requirements extensions ” (Figure 25) the results of a long process that starting from the UNICOM D5.1 results and passing through a re-evaluation of the eHDSI ePrescription, eDispensation and Patient Summary - Medication Summary data sets; allowed to identify a set of findings and suggestions for improvement, that have been used as baseline for selecting a minimal core set of changes to propose.

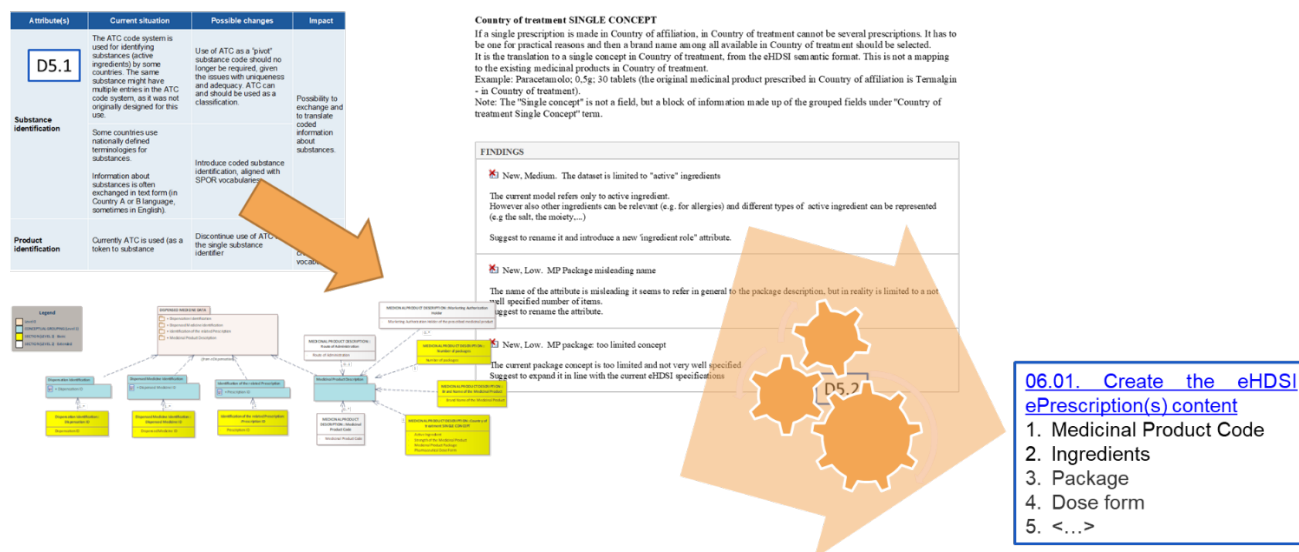


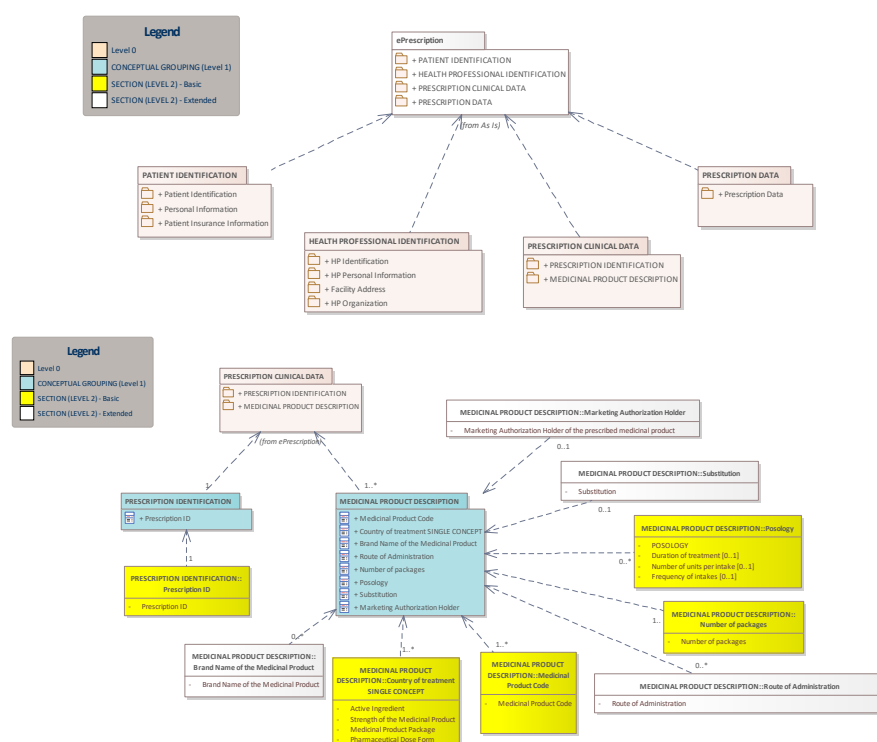
Figure 25: How change proposals have been determined

This annex provides a summary of the eHDSI data set analysis and of the steps accomplished for realising it.

**Step-1 Formalise the "as is" situation**, based on the eHDSI business requirements (e.g. <https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/06.01.+Create+the+eHDSI+ePrescription+%28s%29+content>). The four-levels hierarchy table describing the current data set (even if formally a three levels matrix) has been formalised in a UML as follows:

- Overall data set represented as root UML packages
- Level 0 described as main row heading represented as UML packages
- Level 1 CONCEPTUAL GROUPING represented as nested UML packages
- Level 2 SECTION represented as nested classes
- Level 3 DATA ELEMENTS represented as class attributes.





Hereafter (Figure 26) an example of "as is" eHDSI data set



### Figure 26: ePrescription and Prescription data

**Step-2 Identify potential issues (findings) and suggesting possible changes (suggestions)**

The following tables provide an example of findings and suggestions related to the “Country of treatment SINGLE CONCEPT” heading.


FINDINGS	
 New, Medium. The dataset is limited to “active” ingredients	<p>The current model refers only to active ingredient. However also other ingredients can be relevant (e.g. for allergies) and different types of active ingredient can be represented (e.g the salt, the moiety,...)</p> <p>Suggest to rename it and introduce a new “ingredient role” attribute.</p>
 New, Low. MP Package misleading name	<p>The name of the attribute is misleading it seems to refer in general to the package description, but in reality, is limited to a not well specified number of items. Suggest to rename the attribute.</p>
 New, Low. MP package: too limited concept	<p>The current package concept is too limited and not very well specified. Suggest to expand it in line with the current eHDSI specifications</p>
 New, Low. Dose form: this concept needs further elaboration	<p>The dose form is referred in the current dataset as "The form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablets, syrup)."</p>

This description seems to be closer to the *unit of presentation* ("term describing the discrete countable entity in which a pharmaceutical product or manufactured item is presented") rather than to the *dose form* ("physical manifestation of a Medicinal Product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient").

Both these concepts are relevant.

Suggest to further elaborate and clarify this concept.

## SUGGESTIONS

 New, Medium priority. Add ingredient role and rename active ingredient

Rename Active ingredient as just ingredient (substance ?)

Add a new 'ingredient role' attribute.

 New, Low priority. Rename the MP Package attribute

rename the element to reflect its real concept.


Suggest to have this as part of the task "Expand the Package concept"


 New, Low priority. Expand the Package concept

Provide a more precise description of the package data to be considered:

- package nesting
- textual package description
- ...

In line also with the current eHDSI specifications

 New, Low priority. Expand the dose form concept

 New, Low priority. Elaborate the current dose form concept

Clarify which type of information we should deal with (unit of presentation; dose form; both)

Clarify the type of dose forms we should consider: administrable dose form ; manufactured dose form ; combined dose form)

Add as distinct concepts those that are needed.

## Step-3 Create "to be" data sets

In the following figures a representation of the "to be" product model, abstracting Prescribed, Dispensed and Patient Summary products either as UML model (Figure 27) and as HL7 FHIR logical model (Figure 28).

This model has been used as starting point for determining the set of changes to be proposed.

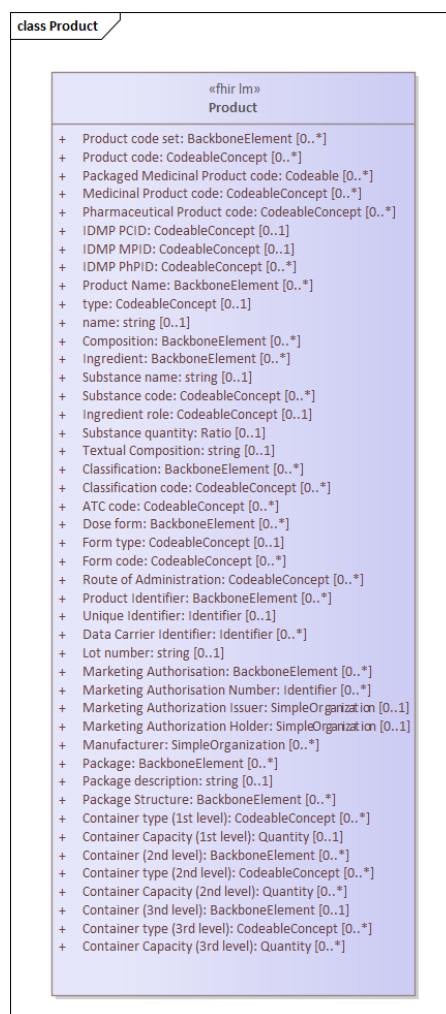


Figure 27: “To be” product model (UML)

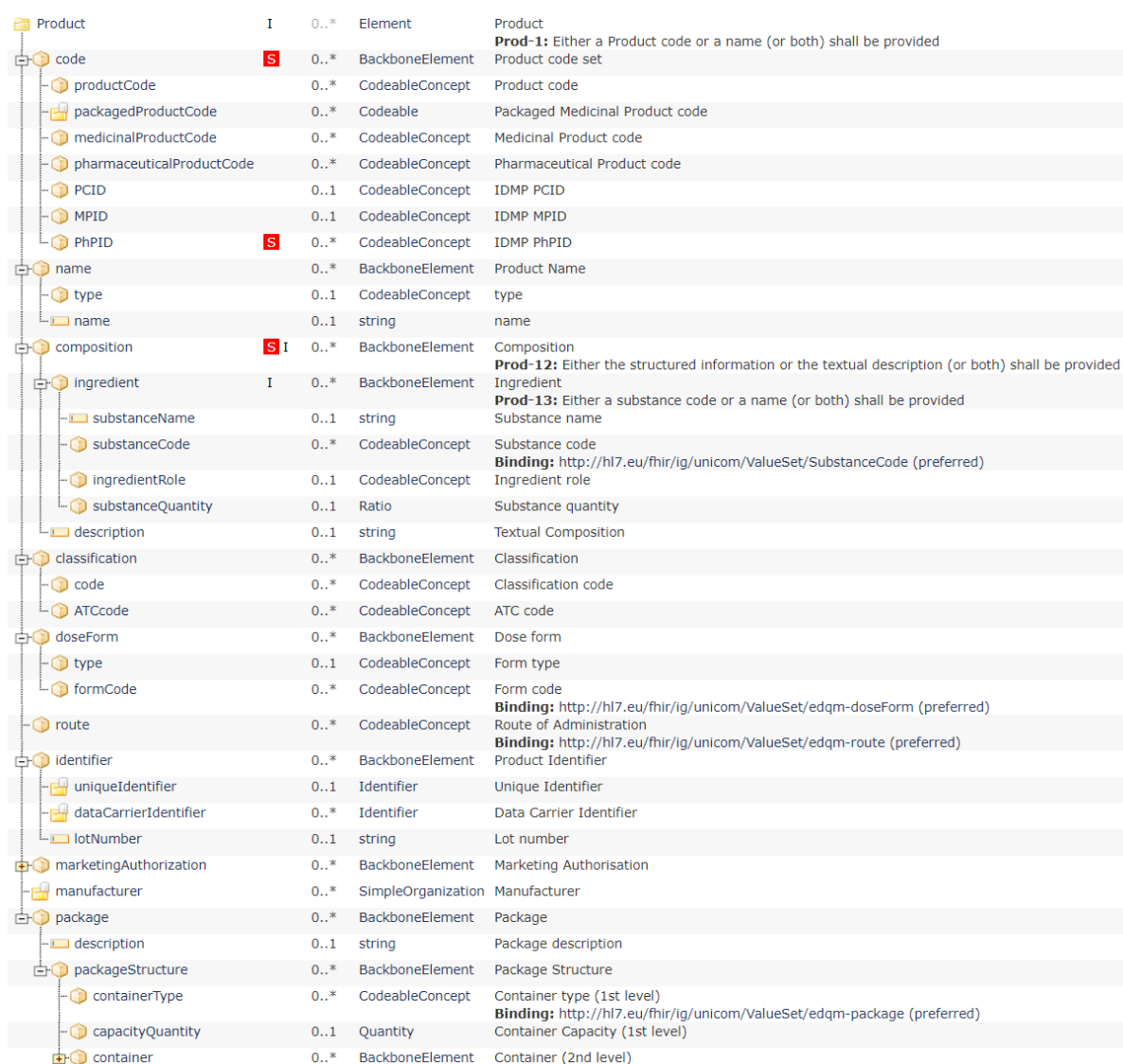
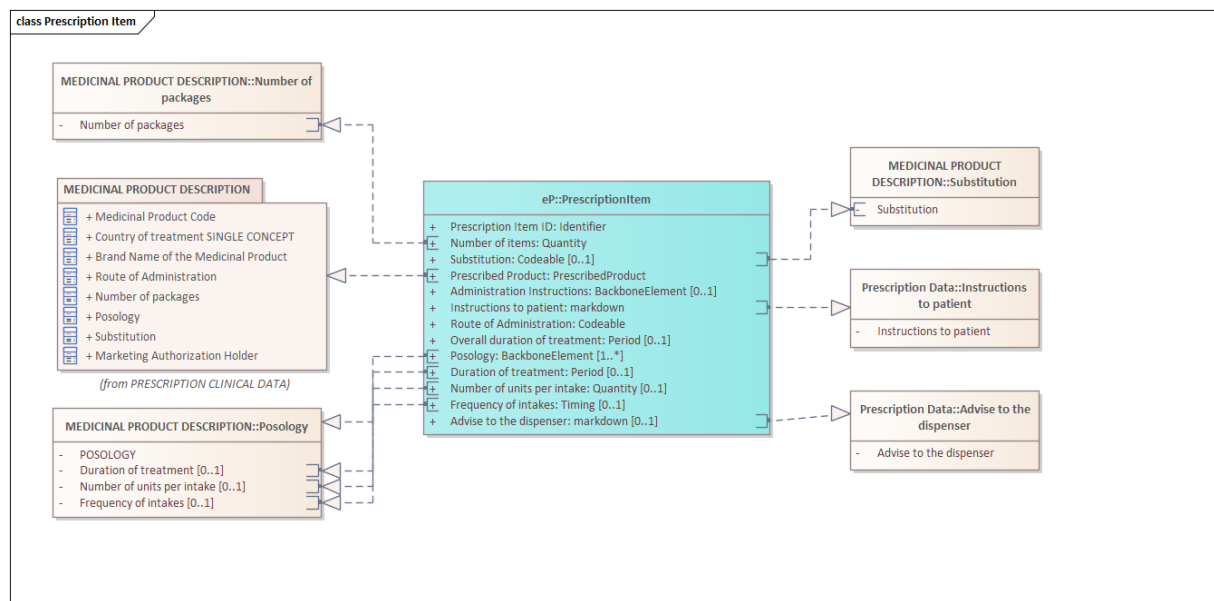


Figure 28: “To be” product model (HL7 FHIR Logical Model)

#### Step-4 Formalise the model tracing from the “to be” models and to the current eHDSI data sets (“as is”)

In the Figure 29 an example related to the “to be” Prescription item heading.



**Figure 29: Model tracing between the “to be” prescription item and the current eHDSI model**

## Annex C – Attributes for cross-border (D5.1)

In Table 5 is possible to see the complete attributes table from the deliverable 5.1.

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

Attribute(s)	Current situation	Possible changes	Impact
Substance identification	The ATC code system is used for identifying substances (active ingredients) by some countries. The same substance might have multiple entries in the ATC code system, as it was not originally designed for this use.	Use of ATC as a “pivot” substance code should no longer be required, given the issues with uniqueness and adequacy. ATC can and should be used as a classification.  SPOR ATC codeset 100000093533	Possibility to exchange and to translate coded information about substances.
	Some countries use nationally defined terminologies for substances.	Introduce coded substance identification, aligned with SPOR vocabularies.	
	Information about substances is often exchanged in text form (in Country A or B language, sometimes in English).		
Product identification	Currently ATC is used (as a token to substance).	Discontinue use of ATC as the single substance identifier.	Uniquely identify products in a cross-border vocabulary
	Use IDMP and/ or other identifiers e.g. PhPID, MPID, etc.	Support new product identification: In an ePrescription, depending on how the prescription is specified, the product code can be substance code, a PhPID, MPID, or a national code.	
		Any product code used should clearly identify the code system – when using a PhPID, indicate that the code is a PhPID (including version, if adequate).	
		It is conceivable that more than one product code would be used, for example a national product code, and a common (IDMP) code such as the PhPID.	

Product	ATC		ATC code(s) can and should still be used as a classification	Add product classifications in a common way across borders
	Other classification(s)		To be added when available and needed. When using any classification, the classification system should be clearly identified – for example a drug prescribed in Sweden could indicate that it is classified as a narcotic – in this case, the “narcotic” classification would be clearly identified as <i>the Swedish narcotics schedule</i> (and point to the version of that schedule).	
Package	Package Content	Combination packages are currently not supported	Needs discussion on the potential support.  Consider recursive packaging description (e.g. boxes which contain kits which contain different products).	Possibility to exchange prescriptions for combination packages that are currently excluded from the service by an MS decision.
	Package Type	One field for representing the package type. The value set based on EDQM values describing Administration devices, Closures and Containers. Closures might be removed from the value set after a change proposal.	Information about administration device, closure, and container to be separated.	More detailed description of packaging might be possible, but no significant impact is foreseen.
	Device		Support adding Device information to the product description when needed.	
Dose		One field for representing the pharmaceutical dose form. The value set based on EDQM values from PDF (Pharmaceutical Dose Forms), PFT (Patient-Friendly Terms), CMT (Combined Terms), and CDF (Combined Pharmaceutical Dose Forms) are included.	Consider the possibility to add several dose forms (of different types).  Ensure alignment of Dose Form Types (Administrable, Basic, etc) with the corresponding IDMP attributes.	Possibility to provide context-specific information on the dose form. Improved database searches and matching of products as part of the



				product selection step performed in the pharmacy.
		Nationally defined dose forms cannot be always mapped to their EDQM equivalents, preventing the exchange of certain ePrescriptions across borders	Common vocabulary: Nationally defined dose forms can be replaced or complemented by IDMP- and SPOR-compatible vocabularies. Find IDMP terms and SPOR vocabularies (handled in WP2, WP3 and WP4)	Prescriptions currently excluded from cross-border exchange due to the use of incompatible dose forms can be exchanged.
			Common / specific hierarchies – consider defining “hierarchies of Dose Forms” to allow considering products with different but related dose forms as belonging to the same Cluster.	
	Administrable dose form		Consider adding support for Administrable dose form in ePrescription; Common vocabulary	
	Basic dose form		Consider the use of “Basic dose forms”	
	Patient friendly dose form		Consider the use of “Patient friendly dose form”, Common vocabulary	
	Pharmaceutical dose form		Common vocabulary	
	State of matter		Consider adding support for State of matter and Administrable dose form.	
Routes and Methods of Administration		Currently used. No significant challenges identified.	No changes required.	No changes foreseen.
Units	Units of presentation	UCUM is used for representing units in package sizes and strengths. Units of presentation are not used. The meaning of the UCUM unit “1” (unity) is	Add support for exchanging information on Units of presentation, to improve representation of package sizes and strength.	Possibility to translate information about units of presentation and provide more

		not always clear and is sometimes complemented with the curly braces' notation such as "1 {ampoule}".	Harmonise units with SPOR vocabularies	understandable information on package size and strength.
	<b>Units of measurement</b>			
<b>Strength</b>	<b>Strength Type</b>	Meaning of "Strength" is not unambiguous; When strength is used, it should be unambiguous.	Identify Strength type when necessary (see WP1 D1.1)	
	<b>Strength units</b>		Express units consistently; Harmonise units with SPOR vocabularies	
<b>Other attributes not currently used</b>	<b>Ingredient Role</b>	Not currently used	Consider adding Role: When describing product compositions, the role is an important attribute, like active vs excipient (SPOR Ingredient role 100000072050)	
	<b>European Regulatory Authorisation: Country, Domain, Procedure ID, Regulatory Entitlement Status</b>		This is part of IDMP, and therefore should be accommodated by the inclusion of IDMP identifiers	
	<b>Intended site</b>		Part of the description of the treatment; investigate if useful.	
	<b>Language</b>		All language-specific or language-sensitive attributes must be tagged with the language used.	
	<b>Legal Status of Supply</b>	This is an important attribute when identifying the equivalence across borders – whether a product needs a prescription or not.		

	<b>Marketing Status</b>			
	<b>Quantity Operator</b>			
	<b>Release characteristics</b>	Useful to define a product		
	<b>Special Precaution for Storage</b>	Useful when describing a product		
	<b>Transformation</b>	Transformation procedures may be relevant in describing a product		

## Annex D – Sample DRAFT Change Proposal excerpt on Business Requirements extensions

[https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pageId=74092560&preview=/74092560/78551321/CP%20FORM%20TEMPLATE\\_CP-eHealthDSI-000\\_CP%20Title\\_vX.X\\_20190228.doc](https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pageId=74092560&preview=/74092560/78551321/CP%20FORM%20TEMPLATE_CP-eHealthDSI-000_CP%20Title_vX.X_20190228.doc)

The list of the intended change proposals that will be produced in UNICOM WP5:

1. Business Requirements
2. Functional Specifications for Patient Summary
3. Functional Specifications for ePrescription / eDispensation
4. Implementation Guide for Patient Summary
5. Implementation Guide for ePrescription / eDispensation

### eHDSI – Change Proposal (CP) form

#### Instructions

This is the template to propose changes to eHealth DSI (eHDSI) artefacts (Requirements, Specifications and/or Frameworks). The Change Proposal provides the description of what must be done (for changed or newly implemented services).

CPs should be submitted to the eHDSI Change Manager until a tool will be put in place to follow the Change Proposal Status and they will be managed according to the eHDSI Change Management Procedure.

---

## Tracking information

Change Proposal ID:	CP-eHealthDSI-
Change Proposal Status <sup>33</sup> :	New
Date of last update:	
Person assigned: (Diogo or Marcello???)	
Version of Change Proposal:	V0.1

---

<sup>33</sup> Status options: New, In Registration, Under Distribution, Under Assessment, In Consolidation, In Consultation, For Information, For Approval, For Publishing, Closed

## Change Proposal Document history

Version	Date	Person	Short description of changes
V0.1		WP5 UNICOM	First version of the change proposal prepared by WP5 UNICOM analysis on the eHDSI business requirements to adopt ISO IDMP, submitted as input to eHMSEG eP Cluster and Semantic Task Force for subsequent joint activities.

## Change Proposal Summary information

Change Proposal Title:	ISO IDMP Adoption by eHDSI – Business Requirements
Submitter's Name(s) and e-mail address(es):	To be defined with eHMSEG eP Cluster and Semantic Task Force
Submission Date:	
Component(s) or Configuration item(s) to be changed <sup>34</sup> :	eHDSI Business requirements
Actor(s) affected:	
<b>Business and Solution Requirements impacted:</b>	<a href="#">05.01. Create the eHDSI Patient Summary content</a> <a href="#">05.02. Transcode, translate and exchange cross-border the Patient Summary</a> <a href="#">06. Make ePrescription available to HP</a> <a href="#">06.01. Create the eHDSI ePrescription(s) content</a> <a href="#">06.02. Transcode, translate and exchange cross-border the ePrescription</a> <a href="#">07. Handle Dispensation of medicine and Substitution</a> <a href="#">07.01. Create the eHDSI eDispensation content</a> <a href="#">07.02. Transcode, translate and exchange cross-border the eDispensation</a> <a href="#">09. Ensure high quality information (structured, equivalent, understandable) is exchanged between countries</a>
<b>Specifications/documentation impacted:</b>	<a href="#">eHDSI Specifications documents</a>
Change estimated impact <sup>35</sup> (minor, major):	Minor

<sup>34</sup> Component examples: Client connector, WS server, OpenNCP Portal, epSOSWeb, OpenATNA, TRC-STs, Security Manager, TSL-Sync, TSL-Editor, TSL-Util, Protocol Terminators, TSAM Sync, Stork Plugin, CDA display tool, xslttransformer, tsamexporter, cdautils, epsos-util, configuration manager, epsos-common-components, e-SENS eID richclient, e-SENS eID design-main...

<sup>35</sup> Change estimated impact is the estimated order of magnitude of the change: a change will be qualified as major if it introduces for instance a component that already exists or a new component, impacting the architecture; it will be qualified as minor if it improves the existing behavior without impacting the architecture.

## Change Proposal Description

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

### REASON/BUSINESS JUSTIFICATION (WHY this change is needed)

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

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

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

The implementation of ISO IDMP is predicted in the Commission Implementing Regulation (EU) N° 520/2012, articles 25 and 26, which obliges EU MS, marketing authorisation holders and EMA to make use of the ISO IDMP standards.

### DESCRIPTION OF THE REQUESTED CHANGE

#### 05.01 Create the eHDSI Patient Summary content

The data sets used for the Medication Summary, ePrescription and eDispensation should be harmonised across the use cases; eP/eD and PS.

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

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

Additional translations and transcoding might be required, in the event of new code systems and value sets being developed and introduced. However, no changes are required to the business requirement text itself at this time.

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

It is just a suggestion of format to this chapter. It might help to complement the text.

#### 06 Make ePrescription available to HP.

Modify the text of the business requirement in the following way:

NCPeH of Country of affiliation must make available to NCPeH of Country of treatment, at least the basic or essential information needed by the HP of Country of treatment to identify the correct medicine to be safely dispensed.

#### 06.01 Create the eHDSI ePrescription content.

The data sets used for the Medication Summary, ePrescription and eDispensation should be harmonised across the use cases; eP/eD and PS:

Medicinal Product Code

- Modify the description of the Medicinal Product Code
  - *from* “National code that identifies the medicinal product description, in that region/country or among some countries <...>”
  - *to* “A product code refers to different ‘kinds’ of products, (e.g.,: Packaged Product (regulated or non), Medicinal Product (regulated or non) or Pharmaceutical Product).“, and a set of codes identifies the product in that region/country (e.g. National product code) or among countries (e.g. IDMP IDs).



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

#### Ingredients

- Add supporting information, where necessary, to identify any ingredients other than active ingredients (such as adjuvants or additives, e.g. lactose)
- Add additional information to support the description of the use of the ingredient (active ingredient or another ingredient) (see Scenario 3.2.4)
- Add additional information to indicate whether the active ingredient is a salt or a moiety.

#### Packaged product description

- Add a text field into the data set specification to provide a sufficiently detailed description of the prescribed medicinal product/package. This information is already supported by the technical specifications, but absent from the business requirements table.
- Enable the description of complex product / packages that include more than one unit of presentations and / or strengths within the same package medicine. For example, within the same package it may include a cream with a specific concentration and a pill with a specific dose (e.g., clotrimazole 100 mg external cream and pessary 100 mg x 6 units, plus the applicator).
  - e.g., some attributes should be repeated where necessary, to ensure the correct understanding on multiple levels (e.g., link to a specific EDQM value set).

#### Package size

- Extend the concept of package size, to include more complex packet structures (for example, 10 vials of 35 mL; 2 blisters of 5 ampoules of 3 mL). Up to 3 layers of structure should be considered: immediate, intermediate, and outer package.

#### Dose form (Link to WP 3: consider the rules used at the registration phase):

- Update the description to better reflect the dose form concept and highlight the distinction between the manufactured and administrable dose form. Suggest adopting the IDMP description.<sup>36</sup>
- The kind of dose form should clearly distinguish the information it is referring to (e.g. manufactured dose form) (e.g., link to a specific EDQM value set).
- The solution should support different levels of granularity of the dose form (e.g. capsule, hard; capsule).
  - “pharmaceutical dose form” should be repeated where necessary, to ensure the correct understanding of the dose forms on multiple levels.

#### Marketing authorisation number:

- Not to be added in this round of changes.

#### Information on the last dispensation (optional)

- Date
- Quantity dispensed

The current eHDSI eP Data Set should be improved by indicating "Substitution allowed", not as an attribute of the medicinal product, but as an action the pharmacist is not allowed to perform.

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

New translations and transcodings might be required.

### 07 Handle Dispensation of medicine and substitution

The business requirement has a reference to a flag indicating whether substitution was performed as part of the dispensation process.

<sup>36</sup> According to IDMP (ISO 11239) definitions, administrable dose form is a “pharmaceutical dose form for administration to the patient, after any necessary transformation of the manufactured dose form has been carried out”, while manufactured dose form is “pharmaceutical dose form of a manufactured item as manufactured and, where applicable, before transformation into the pharmaceutical product.” For example, powder for solution for injection (manufactured dose form), solution for injection that has been prepared (administrable form).

Make evident that, in the ePrescription, the flag indicated by the Prescriber is:

- “Substitution allowed / not allowed

While in the eDispensation, it should be indicated:

- “Substitution performed / not performed”

The use of the Smart selection/substitution function (to be developed as part of WP6) may provide additional rules that should be linked to the flag to inform the record.

Indications to the pharmacist on how to manage selection / substitution according to the various Use Cases and prescriber indication on “Substitution allowed / not allowed” should be provided. That might call for the creation of a specific business requirement entry on Selection / Substitution, when fully specified in subsequent joint UNICOM / eHDSI eP Cluster activities.

#### **07.01 Create the eHDSI eDispensation content.**

The data sets should be harmonised across the different use case; eP/eD and PS.

Recommendations made in “06.01. Create the eHDSI ePrescription(s) content” should also be applied also to “07.01. Create the eHDSI eDispensation content”, when applicable.

In addition, changes are required to the eDispensation content.

Dispensed medicine data:

- In the section “3. Dispensed medicine data” it should be made clearer that the product described is the one which has been dispensed.
  - “Medicinal Product Description” should read “Dispensed Product Description”.
  - Align the product description with the ePrescription model.

Dispensed Medicine ID:

- This ID may overlap with the Medicinal Product Code concept. If redundancy does exist the possibility of removing this concept should be considered.

Medicinal Product Code

- The dispensed medicine ID is required, if it is a repetition of the prescribed product code then the product code shall be required.
- Align the Product Code description and name with the ePrescription model.

Number of dispensed packages

- In the current eHDSI eD model the “number of dispensed packages” is part of the “Medicinal Product Description” group. This is not however a product attribute, but an attribute of the dispensation act. It is therefore suggested to move this information from the product to the “DISPENSED MEDICINE DATA” level.

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

New translations and transcodings might be required.

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

- Regarding the context information, the medicinal section should be updated with ISO IDMP information as follows:

The current text is the following:

There are several possibilities to deal with the **unified meanings regarding medicines**:

- Each data field of the minimum data set is translated into a common terminology or nomenclature.
- A subgroup of the minimum data set (e.g. active ingredient + strength + pharmaceutical dose form) has a unique coding in a common language (this subgroup is the data that the doctor cannot break up as they are defined by the commercialised products).

The updated text should more clearly refer to the options provided by ISO IDMP.

There are several possibilities to deal with the **unified meanings regarding medicines**:

- Each data field of the minimum data set is translated into a common terminology or nomenclature.
- Provision of one or multiple unique identifiers, ideally the ISO IDMP identifiers (e.g. PhPIDs), describing a subgroup of the minimum data set (e.g. active ingredient + strength + pharmaceutical dose form).

#### OVERVIEW OF THE EXPECTED OUTCOMES/BENEFITS

The Health Professional in the Country of Treatment will receive more detailed and understandable information about the Medicinal Product that appears on a Patient Summary or an ePrescription document:

- Substances and ingredient roles (coded and translatable)
- Product identifiers (e.g. PhPID, MPID)
- Packages (package content, type, device, coded and translatable)
- Dose form (multiple dose forms of different types, coded and translatable)
- Units (units of presentation as part of strength and package size information, coded and translatable)
- Strength type

This new information enables the Health Professional in the Country of Treatment to better understand the medicinal product that appears in the ePrescription or Patient Summary provided by the Country of Affiliation.

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

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

This consistency in the use of ISO IDMP will help the pharmacist in the Country of Treatment to better assist in the selection of the medicinal product to be dispensed to the patient.