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Deliverable D6.3: Redesign and implementation of an enhanced IDMP compliant User Portal system and of an IDMP extended CDA display tool.

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1	19.12.2022	Revised final version of the document.	All

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Deliverable abstract

ISO IDMP and HL7 CDA are international standards that promote the cross-border exchange of medical information in Europe. ISO IDMP provides a standardized framework for identifying and communicating information on pharmaceutical products, whereas HL7 CDA standardizes the representation of clinical documents, such as prescriptions, dispensations of prescribed medicines and patient summaries. This task's purpose is to enhance the existing user portal of eHDSI in order to facilitate the usage of ISO IDMP and smart substitution in eDispensation scenarios. This will aid in enhancing interoperability and ensuring that end users see the correct information. In addition, the objective of this work is to improve the user experience of the CDA display tool by showing IDMP information correctly for end-users of electronic prescriptions, electronic dispensations, and patient summaries. This will enhance the overall user experience and make it simpler for end users to get and comprehend the required information.

Keywords: CDA display tool, ISO IDMP, HL7 CDA, eHDSI, wave 6

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List of abbreviations

Abbreviation	Complete form
ATC	Anatomical Therapeutic Chemical
CDA	Clinical Document Architecture
CEF	Connecting Europe Facility
eD	Electronic Dispensation
eHDSI	eHealth Digital Service Infrastructure
eP	Electronic Prescription
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Level 7
IDMP	Identification of Medicinal Products
IG	Implementation Guide
ISO	International Organisation for Standardisation
MAL	Minimum Attribute List
MPID	Medical Product Identifier
PCID	Medicinal Product Package Identifier
PhPID	Pharmaceutical Product Identifier
PS	Patient Summary
WP	Work Package

1 Introduction

In Europe, the HL7 CDA (Clinical Document Architecture) standard facilitates the electronic interchange of medical information, and the ISO IDMP (Identification of Medicinal Products) can support the univocal identification of medicinal products globally. Both standards are intending to promote the international interchange of information, and they play a significant role in enhancing the quality, safety, and effectiveness of health care services in Europe through eHDSI.

The ISO IDMP is a collection of international standards for identifying pharmaceuticals products. The purpose of these guidelines is to establish a consistent and exhaustive method for identifying pharmaceutical items, including their names, contents, and other characteristics. By employing a consistent approach to identification of pharmaceuticals products, health care practitioners in different nations can share and access information about medical items more easily, so contributing to the improvement of the quality and safety of health care services.

The HL7 CDA is a standard format for the electronic transmission of medical data. It is used to organise medical information so that it may be conveniently accessed and shared among various health care practitioners and systems. CDA documents can be used to support care delivery, facilitate communication between health care practitioners, and promote clinical research and other activities. CDA documents can improve the quality, safety, and efficacy of health care services in Europe by facilitating the electronic sharing of clinical information.

Together, ISO IDMP and HL7 CDA are facilitating the interchange of health care information across European Union borders. These standards play a vital role in enhancing the quality and efficacy of health care services in the region by standardizing the identification of medicinal items and the electronic sharing of clinical information.

This task's objective is to improve the existing user portal of the eHDSI to facilitate the use of smart substitution from task 6.2 "Implement the smart substitution components for eD, and ISO IDMP in eDispensation scenarios". The task also intends to enhance the user experience of the CDA display tool by including IDMP and properly displaying it for end users of electronic prescriptions (eP), electronic dispensations (eD), and patient summaries (PS).

2 CDA Display tool enhancement

The eHDSI CDA IGs (electronic Healthcare Data Standards and Interoperability CDA Implementation Guides) are a set of recommendations designed to enhance the interoperability of healthcare data. In the present edition of these IGs, it is possible to insert a variety of identifiers that can aid in the unique identification of pharmaceutical items. These include the MPID (Medical Product Identifier), the PCID (Medical Product Package Identifier), and the PhPID (Pharmaceutical Product Identifier) (Pharmaceutical Product Identifier).

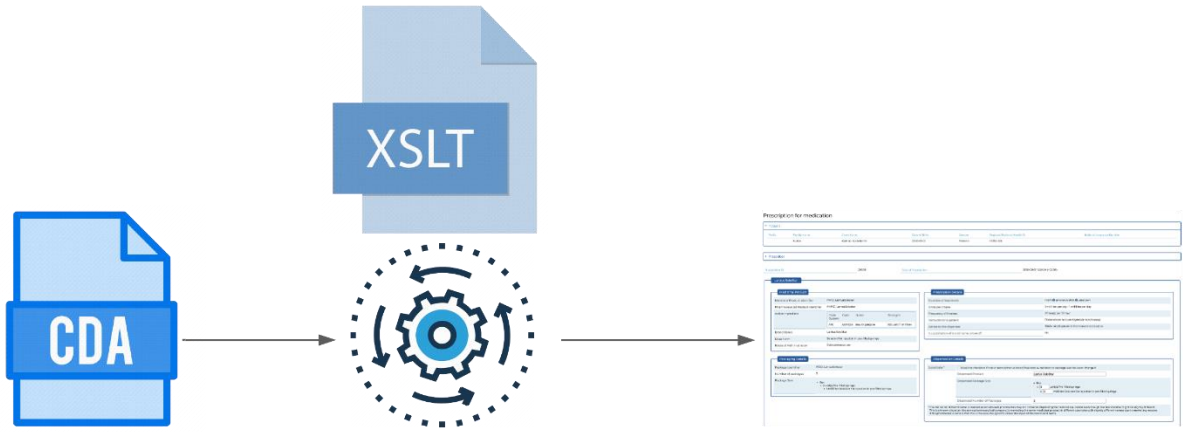

Figure 1: CDA transformation process

2.1 CDA – extended ePrescription display

The extended CDA tool, developed in accordance with deliverable 5.5[i], is now able to provide information about the medicinal product, the prescription, the packaging details and the dispensation details. The reference implementation as depicted in Figure 2: Extended CDA tool and IDMP attributes, is a demonstration of how this tool can be utilized to provide a display for the end users.

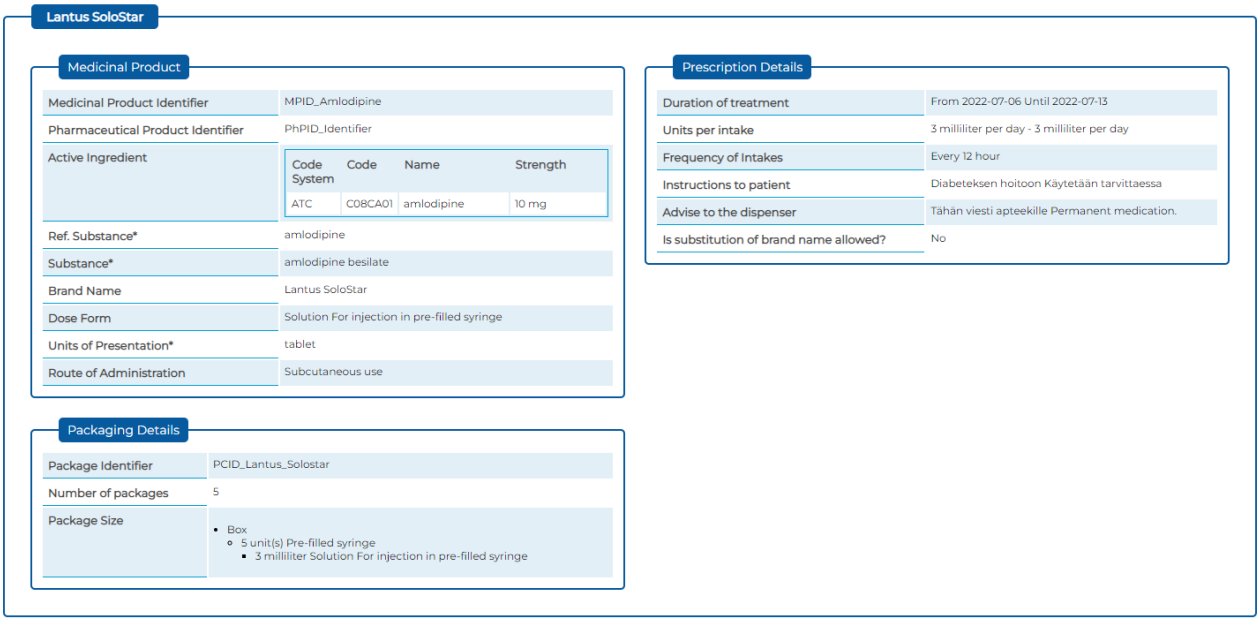

Figure 2: Extended CDA tool and IDMP attributes

2.1.1 Medicinal Product display

The first section on the top left corner of the extended CDA tool contains information about the medicinal product, as shown in Figure 3: CDA Medicinal product information. This section includes two new identifiers that have been added to facilitate the requirements of ISO IDMP in eHDSI Wave 6[ii]. These identifiers are the MPID (Medicinal Product Identifier) and the PhPID (Pharmaceutical Product Identifier), and they are represented on the document as follows:

1) MPID_LantusSolostar: This identifier uniquely identifies the medicinal product, in this case Lantus Solostar.
2) PhPID_Identifier: This identifier uniquely identifies the pharmaceutical product that contains the medicinal product, in this case the specific packaging and formulation of Lantus Solostar.

These identifiers are not yet in place, but the CDA display tool has included them in its implementation to ensure that they can be presented once they are available.

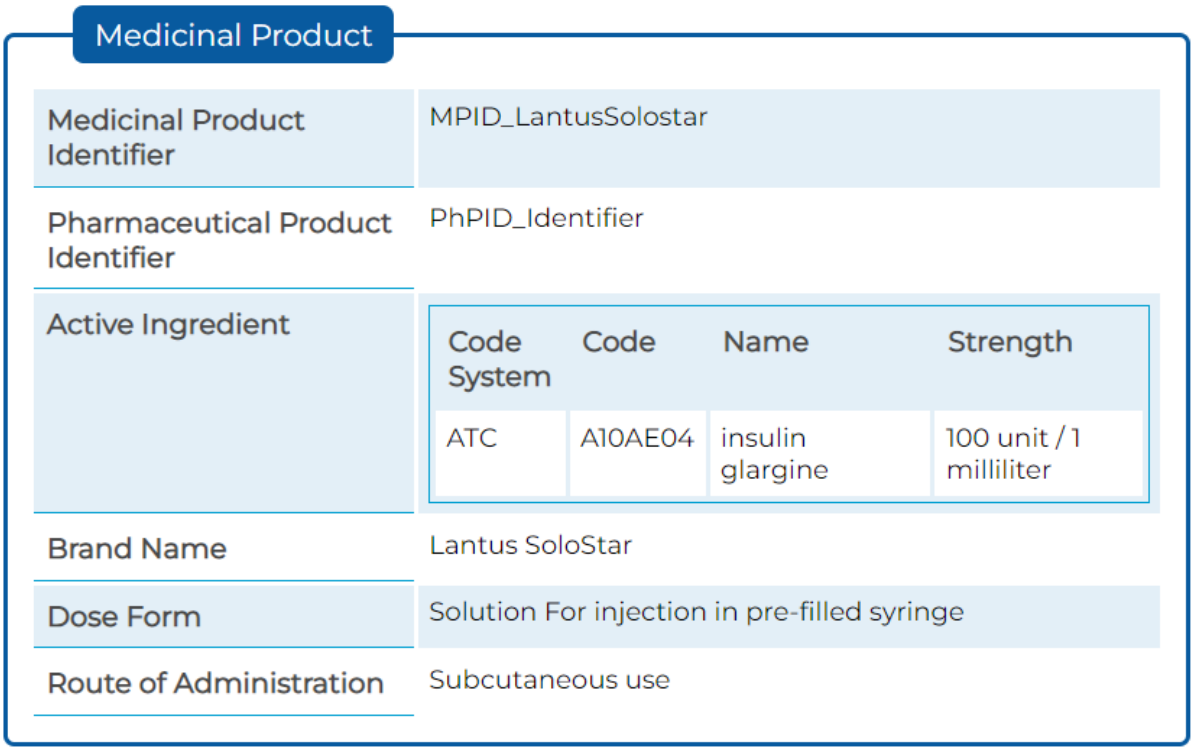

Figure 3: CDA Medicinal product information

2.1.2 Prescription details display

The extended CDA tool includes a section that provides specific information about a prescription, as shown in (Figure 4: CDA Prescription details). This section is designed to meet the requirements and specifications outlined in deliverable 5.5. The table below (Table 1: CDA Prescription details mapping) and Figure 4: CDA Prescription details, shows how these fields are coded in the CDA document and represented in the extended CDA Display Tool. This section includes information such as the duration of treatment, instructions to patient and details on the frequency of intakes and the unites required per intake, and finally information to the dispenser. This information is important for ensuring that the correct medication is being dispensed, and that it is being used according to the prescribed instructions.

Table 1: CDA Prescription details mapping

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

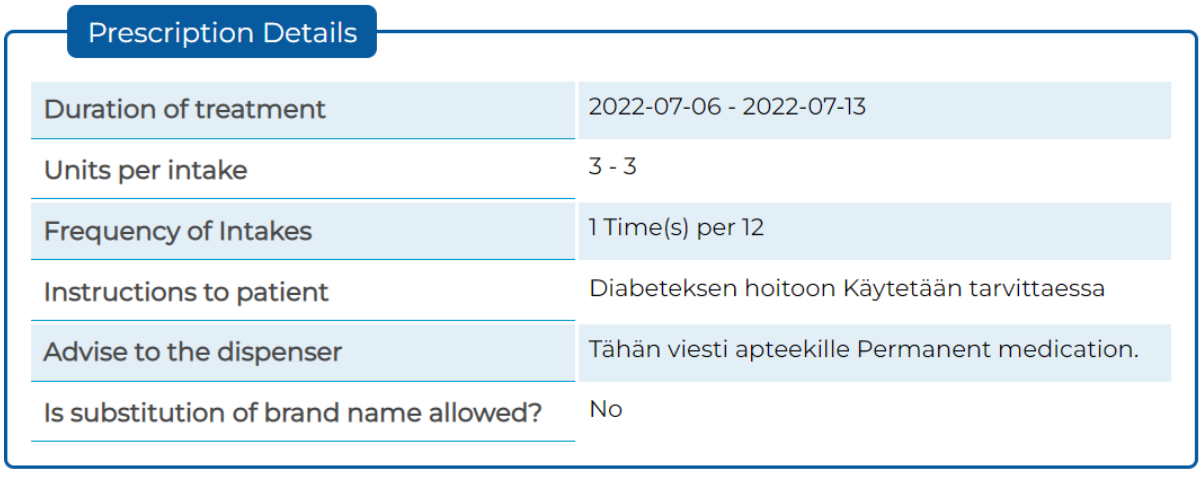

Figure 4: CDA Prescription details

2.1.2 Packaging details

The packaging details view of the extended CDA display tool has been updated to include the PCID and support for multilevel package sizes. This adheres to the guidelines listed in the deliverable 5.5. Previously, the packaging details were shown in a single line presentation, as shown in Figure 6: Old CDA packaging details. However, this limited the amount of information that could be displayed and made it difficult to accurately represent the packaging details of a medicinal product. With the new design, as shown in Figure 5: CDA new packaging details, the packaging details are presented in a more structured and informative way. The inclusion of the PCID identifier allows for more accurate identification of the medicinal product, and the multilevel package size presentation allows for more detailed information to be displayed. This improves the usefulness of the CDA for end users, who can now easily access the information they need.

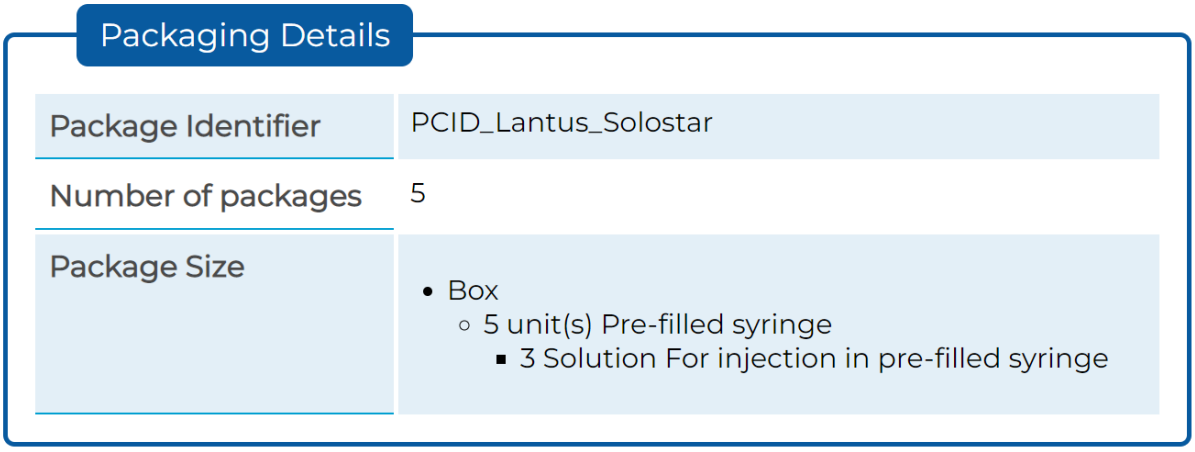

Figure 5: CDA new packaging details

Figure 6: Old CDA packaging details

A characteristic example of the improved packaging details views in the extended CDA display tool can be seen when dealing with medicinal products that have multiple parts to their packaging. An example of such a product is Canesten Thrush Combi Pessary & External Cream, as shown in Figure 7: Medicinal product with multiple parts of packaging, in the CDA display tool it will be displayed as a product with multiple package levels, as depicted in Figure 8: CDA packaging with multiple parts

Figure 7: Medicinal product with multiple parts of packaging

Package Size	◦ Box ▪ 1 unit(s) Cream + pessary
Part 1	• Tube ◦ 1 unit(s) Cream ▪ 20 gram
Part 2	◦ Pessary ▪ 6 unit(s)

Figure 8: CDA packaging with multiple parts

2.1.3 Dispensation details

The extended CDA display tool also includes a dispensation view, which allows for the dispensing of medication. This view is located at the bottom of the document, as shown in Figure 9: CDA Dispensation display. The list of available medicinal products will be populated based on the results of the substitution component provided in D6.2. This list will be presented in the local language of the MS. The dispensation view allows a healthcare provider or dispenser to select the appropriate medication from the list and dispense it to the patient. This ensures that the correct medication is being dispensed and helps to prevent errors or misunderstandings. Figure 10: Smart Substitution and CDA communication, illustrates the communication between the different components of the system, showing how the substitution component provides information to the CDA display tool, which is then used to populate the list of available medicines.

Overall, the extended CDA display tool is a valuable tool for improving interoperability and ensuring that the correct information is being displayed to end users. By including new identifiers and improved views for medicinal product, prescription, packaging, and dispensation details, the tool is better able to facilitate the needs of ISO IDMP in eHDSI Wave 6.

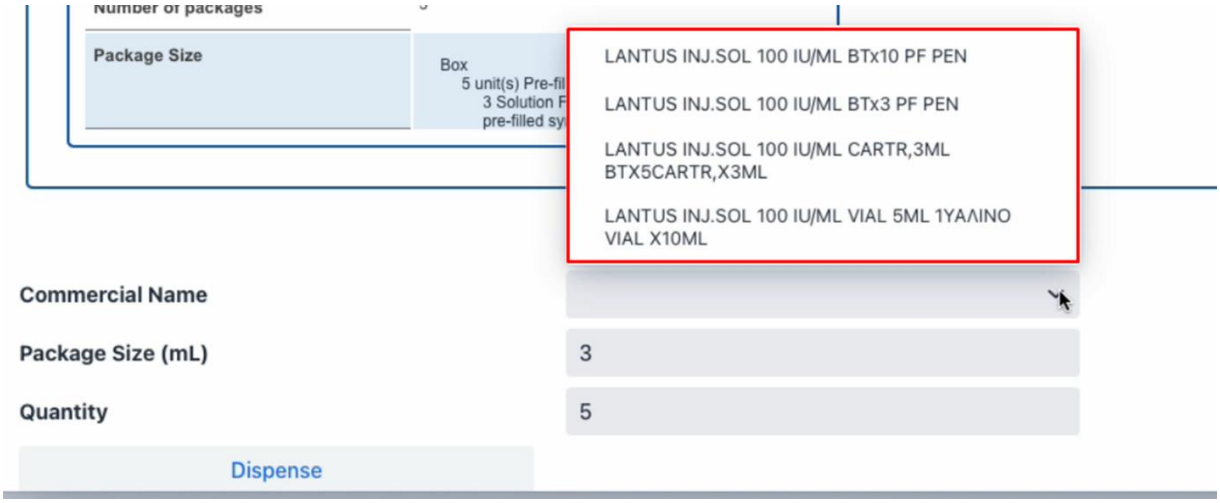

Figure 9: CDA Dispensation display

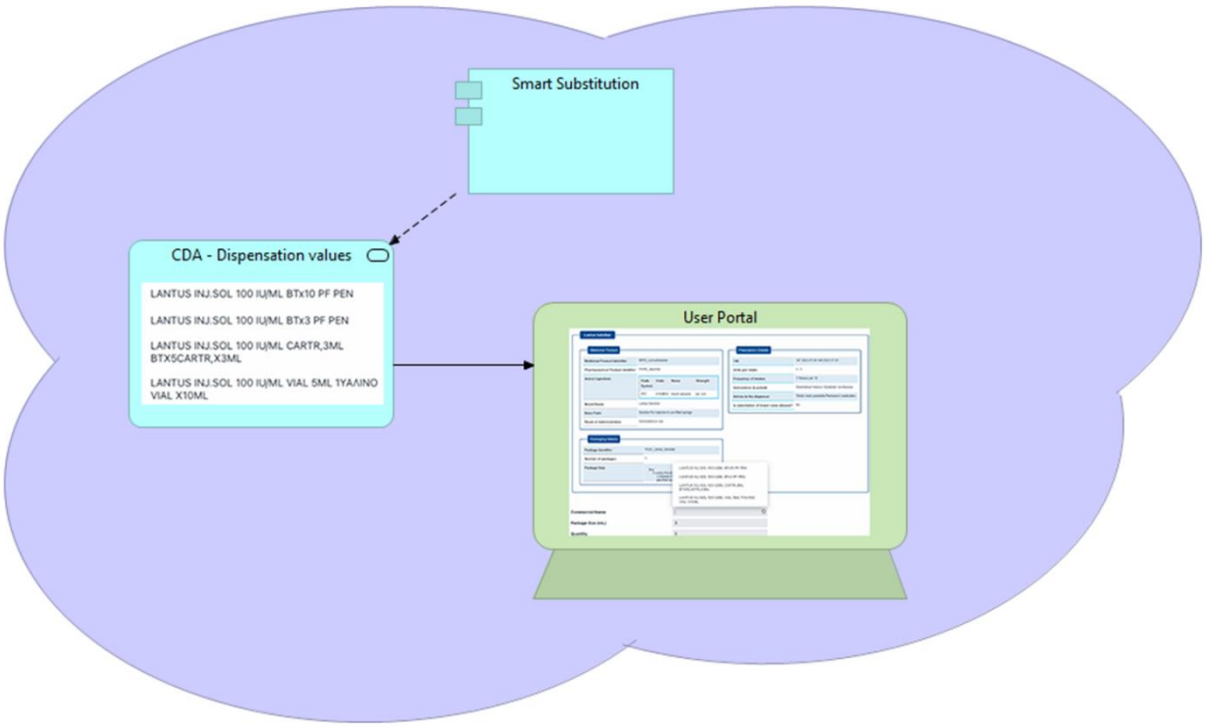

Figure 10: Smart Substitution and CDA communication

3 Resources

All the content that was developed along with the related technical documentation can be found on GitHub on the following link:

unicom-project-eu/wp6-NCPeH-dispensation: UNICOM NCPeH user portal reference implementation for eP/eD and PS (github.com)

[i] D5.5 was not yet publicly accessible at the time of this deliverable submission. All public deliverables will be made available on the following website: https://unicom-project.eu/public-deliverables/
[ii] The eHDSI Wave 6 is scheduled to start in September 2022 and finishes in August 2023.