Extended EHR@EU Data Space for Primary Use - Xt-EHR

Proposal number: 101128085

Stakeholder Consultation

DRAFT

D6.2 Electronic prescription and electronic dispensation: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

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EXECUTIVE SUMMARY

The aim of this deliverable is to establish the requirements and specifications for Electronic Health Record (EHR) systems to support the exchange and interoperability of electronic prescriptions and electronic dispensations across the European Union. This document is part of the broader initiative under the European Health Data Space (EHDS) regulation, which seeks to enhance healthcare quality, ensure patient safety, and facilitate the seamless and secure exchange of health data across healthcare institutions and borders as well as accessibility of EHR for patients.

The use of medicinal products for therapy and diagnostics is prevalent in healthcare. Member states often have electronic systems in place to support electronic prescription and dispensation to enhance quality of care. Furthermore, electronic prescriptions are increasingly used to dispense a patient's medications while they are in a member state other than their country of affiliation, through the cross-border services of MyHealth@EU.

This deliverable builds upon existing eHealth Network guidelines and the MyHealth@EU infrastructure, expanding their scope to include both national and cross-border use cases. It addresses the need for harmonized data models and semantic interoperability to ensure that electronic prescriptions and dispensations can be accurately interpreted and acted upon across different healthcare systems and jurisdictions. The specifications are designed to support a wide range of scenarios, including physical and online pharmacies, and both single- and multi-item prescriptions.

The document introduces detailed use cases for prescribing and dispensing, including variations such as cancellation, substitution, emergency dispensing, and online pharmacy workflows. It provides logical models and HL7 FHIR-based implementation guides that define how data should be structured and exchanged. These resources are provided in some detail in this deliverable, but the full representation is provided externally to this document. These models are informed by previously established European work as well as international standards, such as ISO IDMP, and are designed to be adaptable to local, regional, national and cross-border contexts.

The effort has been done in close collaboration with eHealth Network and its subgroups as well as MyHealth@EU communities and other Xt-EHR work packages (WP4, WP5, WP7 and WP8).

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ABBREVIATIONS

ATC	Anatomical Therapeutic Chemical
CDA	Clinical Document Architecture (HL7)
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European Economic Area
EEHRxF	European Electronic Health Record eXchange Format
EHDS	European Health Data Space
eHN	eHealth Network
EHR	Electronic Health Record
EMA	European Medicines Agency
FHIR	Fast Healthcare Interoperable Resources (HL7)
IDMP	Identification of Medicinal Products (ISO)
IETF	Internet Engineering Task Force
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
PhPID	Pharmaceutical Product Identification (ISO 11616)
SDO	Standards Development Organisation
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
SPOR SMS	Substances Products Organisations Referentials - Substance Management Services
UCUM	Unified Code for Units of Measure
UNICOM	Up-scaling the global univocal identification of medicines
WP	Work Package

TERMS AND DEFINITIONS

ePrescribing	The act of electronically prescribing a medication and issuing a prescription for a patient.
ePrescription	Electronic prescription. A medicinal prescription issued and transmitted electronically [eHealth Network ePrescription/eDispensation guideline]
eDispensing	The act of electronically retrieving a prescription and the subsequent dispensing of the medication to the patient as indicated in the corresponding electronic prescription.
eDispensation	Electronic dispensation. Once the medicine has been dispensed, a report on the items dispensed is made available in a structured format.
Substitution	...it is considered that substitution exists when at least one characteristic of the dispensed product differs from the specified characteristics of the prescribed product [ISO/TS 19293:2018].

1. AIM OF THIS DOCUMENT

The aim of this document is to establish the requirements and specifications for Electronic Health Record (EHR) systems to support the exchange and interoperability of electronic prescriptions and electronic dispensations across the European Union. This document is part of the broader initiative under the European Health Data Space (EHDS) regulation, which seeks to enhance healthcare quality, ensure patient safety, and facilitate the seamless and secure exchange of health data across healthcare institutions and borders as well as accessibility of EHR for patients.

Use of medicinal products for therapy and diagnostics is prevalent in healthcare. Many member states have electronic systems in place to support electronic prescription and dispensation to enhance quality of care and access to medications. Also, electronic prescriptions are increasingly used to dispense a patient's medications, when in a member state which is not their country of affiliation, through the use of the cross-border services of MyHealth@EU.

2. SCOPE AND INTERDEPENDENCIES

2.1. Scope

The scope of this document is to propose a specification of electronic health data related to electronic prescription and electronic dispensation to support the implementing acts on the European EHR exchange Format (EEHRxF) under EHDS. This document builds on previous work including the eHealth Network guidelines and the MyHealth@EU implementation of electronic prescription and electronic dispensation cross-border services but adopts the widened scope in the EHDS, taking local and national as well as cross-border international use into consideration.

The use cases in scope for the specification are:

1. The representation of electronic prescriptions in a standardised form to support interoperable and secure sharing of such prescriptions. The immediate scope as defined by the EHDS regulation, is a prescription for a medicinal product issued by an authorised health professional to be dispensed to a patient by a pharmacy.
2. The dispensation of a medication based on an electronic prescription and the standardised representation of electronic dispense records to support interoperable and secure sharing of such dispense records. The immediate scope as defined by the EHDS regulation, is a dispense of a medicinal product by a pharmacy (including online pharmacy) to a natural person and based on a prescription. In addition, a use case for declining a request to dispense is also in scope, allowing sending back a report of not dispensing a prescribed product with a reason.

While the immediate scope of the EHDS use cases is relatively narrow, and real-life prescription systems often handle more use cases, the specification focuses on the EHDS scope, but also aims to not restrict the parts that might be crucial for adjacent use cases, such as hospital medication or when a device is used to dispense.

This specification also aims to support other use cases through standardised representation of medicinal products in the information present in e.g., the Patient Summaries, Discharge Reports and Medical Imaging reports.

2.2. Out of scope

This deliverable does not include requirements or specifications for the EHR systems with a prescription function or with a dispense function themselves. This deliverable only concerns the sharing of health data in the priority categories of electronic prescription and electronic dispensation from those systems.

The creation of medication summaries based on existing electronic prescriptions and support sharing of such summaries as part of other priority categories of electronic health data is supported but the specifics of medication summaries is out of scope of this deliverable. For details on medication summaries, see Xt-EHR deliverables D6.1 and D7.3 for medication summaries in the Patient Summary and the Discharge report respectively.

This specification does not cover hospital use, detailed workflow issues, reimbursement, prescriptions for devices or other non-medications, and requests to administrating devices. National implementations who need to extend the use case in these areas are allowed to add relevant parts in their national specification or refer to other specifications, such as HL7 FHIR Workflow or IHE Medication Prescription and Dispense profile.

2.3. Interdependencies

There is an overlap between the different prioritised categories of electronic health data listed in the EHDS Regulation. Medication-related health data exist in all parts of the EEHRxF, as defined by the eHealth Network guidelines. Therefore, a significant part of this task's work is to consider the overlap between these categories and to align and adopt the specifications on all levels from functional to technical. This work is done in collaboration with other tasks of Work Package (WP) 5 (*General requirements for EHRs and system interfaces*), WP6 (*Electronic prescriptions and patient summary towards EHDS*), and WP7 (*New services for EHR systems towards EHDS*).

The work in WP 5, 6, and 7 aims to support the concerned implementing acts which will need to include some framework of assessment of conformity of EHR systems. Such frameworks will include, as a basis, detailed criteria on the level of subsets or individual data elements in the harmonised datasets. Those criteria will then be input to and subject to discussions with WP8 (*Certification and Labelling framework*).

3. INTENDED USE

The intended use of this document is to support the development of EEHRxF implementing acts by specifying harmonised data sets, code systems and values, as well as technical specifications. These artefacts are also aimed at providing guidance for the development, implementation, and deployment of EHR systems capable of generating, sharing, and processing electronic prescriptions and electronic dispensations in a standardized format within and across EU Member States. This document is intended for EHR system developers, healthcare providers, policymakers, and other stakeholders involved in the management and exchange of health data. By adhering to the specifications outlined in this document, stakeholders will be able to ensure that electronic prescriptions and electronic dispensations are interoperable, secure, and useful for enhancing patient care and facilitating cross-border healthcare.

4. INTRODUCTION

The Xt-EHR Joint Action (JA09) aligns with the European Commission's commitment to a "Europe fit for the digital age" and further with the objectives of the EU4Health Programme by enhancing health systems. This project aims to develop requirements, guidelines, specifications, and implementation guides to prepare the implementation of the EEHRxF and key assets for primary use data and thus to foster the interoperability and exchange of health data across the European Union, in readiness for the impending EHDS regulation. This work encompasses the comprehensive primary use of health data to achieve several pivotal objectives. Through a concerted effort focused on quality data, robust infrastructure, and capacity building initiatives, the broader agenda for a single market for digital goods and services can be effectively realized while safeguarding data protection and ensuring the free movement of people across borders.

The work package 6 of Xt-EHR aims to develop the EEHRxF for patient summaries and for electronic prescriptions and electronic dispensations. Within WP6, the task 6.2 aims to develop the EEHRxF specifically for electronic prescription and electronic dispensation.

Electronic prescriptions have been used in many of the EU Member States for a decade or more and the infrastructure to support cross-border sharing of electronic prescriptions and dispensations has been available since 2019[1]. Several projects and bodies have performed analysis of the state of play with electronic prescriptions in Europe[2, 3]

[1] https://ec.europa.eu/commission/presscorner/detail/en/ip_18_6808

[2] Bruthans, J., & Jiráková, K. (2023). The current state and usage of European electronic cross-border health services (eHDSI). Journal of Medical Systems, 47(1), 21.

[3] HL7 Europe, IHE. Medication Prescription and Delivery. https://wiki.ihe.net/index.php/MPD_Main_Page

5. METHODOLOGY

The methodology applied in the development of this document has taken into account the vast amount of information related to electronic prescriptions and electronic dispensations available.

The work included the following steps:

- Identification of sources of information regarding electronic prescriptions and dispensations.
- Collaboration with Standards Development Organisations (SDOs) in sharing requirements to support development of implementable specifications, in particular collaboration with HL7 Europe and IHE to support the development of a HL7 FHIR Implementation guide.
- Development and documentation of the electronic prescription/dispensation use cases which are recommended to be supported by the EEHRxF specifications.
- Development of logical models, corresponding to the EHDS dataset level, for medication prescriptions and medication dispensation, as well as medicinal products for reuse in all primary use priority categories of the EHDS, based on available sources and in discussion with Task 6.2 contributors.
- Identification of the source requirement for each data element in the models.

The resources used for this work were:

- eHealth Network guideline on ePrescription and eDispensation of Authorised Medicinal Products, release 3
- Additional eHealth Network guidelines
  - Patient Summary, version 3.3
  - Laboratory Result Reports, version 1.1
  - Hospital Discharge Reports, version 1.0
  - Medical imaging studies and reports, version 1.0
- MyHealth@EU Requirements Catalogue, version 2024-02-23
- MyHealth@EU CDA Implementation Guide, version 8.0.0
- Standards and Standards Development Organizations
  - HL7 Europe Medication Prescription and Dispense (joint project with Xt-EHR)
  - IHE Medication Prescription and Dispense Project
  - ISO/DIS 17523:2024 *Requirements for electronic prescriptions*
  - ISO/TS 19293:2018 *Requirements for a record of a dispense of a medicinal product*
  - ISO/TS 17251:2023 *Business requirements for a syntax to exchange structured dose information for medicinal products*
  - The ISO IDMP suite of standards
  - ISO/DIS 27269:2024 *International Patient Summary*
  - HL7 FHIR Medication and Medication Definition module's resources
- UNICOM deliverables D5.1 and D5.7

The Implementing Directive 2012/52/EU has been central in establishing e.g. the eHealth Network ePrescription and eDispensation guideline and is considered covered by the above resources.

6. ANALYSIS OF RELEVANT GUIDELINES, SPECIFICATIONS AND STANDARDS

6.1. eHealth Network Guidelines

The purpose of an eHealth Network guideline is to describe business requirements for interoperable sharing of health data. The guideline aims to facilitate sharing health data across national borders within the EU/EEA as well as to support all Member States in their respective national eHealth priorities. The guideline also aims to be a single point of strategic-level decision making. The guideline is developed with the aim of being applicable and useful for further elaboration and detailing during implementation activities, such as in setting use-case specific technical requirements or when developing implementation guides.

Use cases supported are developed inside the individual guidelines themselves. Initially, the first two guidelines supported sharing health data of a patient from the country of affiliation (referred to as "Country A") with a healthcare professional in the country of treatment (referred to as "Country B"), with some exceptions, but guideline versions after 2019 aim to support both domestic and cross-border use cases.

Currently, the guideline documents are developed by the eHealth Network subgroups and the decision to adopt a guideline is made by the eHealth Network.

During 2024 the eHealth Network subgroups performed an assessment of the consistency of existing guidelines both regarding the textual sections and the data sets. Changes to improve consistency between guidelines were adopted at the November 2024 meeting of eHealth Network. The analysis of dataset consistency has been provided for use by Xt-EHR in the reuse of the guidelines for developing harmonised data sets.

6.1.1. eHealth Network Guideline on ePrescription and eDispensation of Authorised Medicinal Products

The eHealth Network guideline was first adopted in 2014, developed to support cross-border sharing of electronic prescriptions in the EU. In release 3 of these guidelines, the purpose was widened to include national and regional level use. As other eHealth Network guidelines, this guideline contains two sets of articles, “guidelines” and “supporting information” under the chapters General Considerations, Legal and Regulatory Considerations, Organisational Considerations, Semantic Considerations, and Technical Considerations. As with the other health information domain-specific guidelines, this guideline contains datasets for electronic prescriptions as well as for electronic dispensations.

This guideline is based on the Implementing Directive 2012/52/EU which contains a list of elements which must be included in a prescription. In addition, the standard ISO 17523 *Requirements for electronic prescriptions* (see 6.6.1) was used as a source of data elements.

6.1.2. Other eHealth Network Guidelines

Of the five eHealth Network guidelines corresponding to the six health information domains of the EEHRxF (i.e. priority categories of EHDS), four guidelines explicitly specify representation of information on medication. The ePrescription and eDispensation guideline naturally contains medication information but such information appears also in other eHealth Network guidelines. Patient Summary and Hospital Discharge Report has lists of “relevant” or “recommended” medication as well as vaccinations. The Hospital Discharge Report and Imaging guideline contains administered medication, during the inpatient stay and imaging procedure respectively. The Hospital Discharge Report also contains medication information in the

context of prescription-drug abuse. The guidelines also allow representation of statements of allergies to medicinal products and/or substances.

Table 1. Medication information in eHealth Network guidelines

eHN Guideline	Data element	Content
Hospital Discharge Report	A.2.2.1.10 Agent or Allergen	A specific allergen or other agent/substance (**drug**, food, chemical agent, etc.) to which the patient has an adverse reaction propensity.
	A.2.5.1.4.2 Vaccine/prophylaxis A.2.5.1.4.3 Vaccine medicinal product	Generic description of the **vaccine**/prophylaxis or its component(s) **Medicinal product** name
	A.2.6.5 Pharmacotherapy (Core)	…Medicinal products that were **administered** during hospitalisation…
	A.2.8.2 Medication Summary (Core)	…medication **recommended** for the period after discharge…
	A.2.5.4.3 Drug consumption (Non-core)	**Consumption** of drugs and other-substances (in terms of abuse)
Imaging	A.5.2 Medication	…medication **administered** during the medical imaging examination (contrast, sedation, stress agents), etc.
	A.5.6.1 Description	Narrative description of the **recommended** activities including additional tests, medication etc.
Patient Summary	A.2.1.1.10 Agent or Allergen	A specific allergen or other agent/substance (**drug**, food, chemical agent, etc.) to which the patient has an adverse reaction propensity.
	A.2.2.1.2 Vaccine/prophylaxis A.2.2.1.3 Vaccine medicinal product name	Generic description of the **vaccine**/prophylaxis or its component(s) Brand name of the **vaccine medicinal product**
	A.2.4.1 Current and relevant past medicines	…**prescribed** medicines…or medicines that **influence current**

		health status or are **relevant to a clinical decision**

In addition to the table above, common to all eHealth Network guidelines is that the medications recommended, ordered, prescribed, administered, or otherwise referred to in the EHR need to be consistently identified, most often also further specified with amount, dose form, strength, regimen, route of administration, and/or active ingredients.

Further, the eHN guideline for laboratory reports may represent tests related to medicinal products, such as therapeutic drug monitoring. However, the relationship to medicinal products is through those substances and typically managed by the laboratory test terminology in use. In Xt-EHR task 7.1 use of medication, for example for challenge-test procedures, has been added to EEHRxF medical test results.

6.2. Implementation of cross-border sharing of electronic prescriptions and dispensations

MyHealth@EU is the European eHealth digital service infrastructure that facilitates cross-border health data exchange between Member States. It plays a pivotal role in ensuring that EU citizens can access healthcare services seamlessly across borders, fostering cooperation among health systems in the digital era. The platform is an essential component of the EU's broader agenda to promote a Digital Single Market in health, allowing citizens to receive healthcare services even while traveling or living in other EU countries.

One of the core features of MyHealth@EU is the cross-border electronic prescription and electronic dispensation service. This service allows a patient's electronic prescription issued in one Member State to be dispensed in another one. For example, if a person is prescribed medication in their home country (Member State A), they can have that prescription filled in a different Member State (Member State B) without the need for a new prescription. This ensures continuity of care and convenience for patients who travel within the EU.

The dataset presented by MyHealth@EU includes certain basic elements that must be followed to ensure interoperability. For cross-border electronic prescription/dispensation, basic fields typically include patient identification data, health professional identification data, prescription clinical data (prescription identification, medicinal product description) and prescription data. These standards are crucial in ensuring that healthcare providers across borders can interpret and act on prescriptions from other Member States without ambiguity. Member States are required to adhere to these basic elements to participate in the service effectively, promoting the uniformity and reliability of electronic prescriptions across the EU.

In addition to electronic prescriptions, MyHealth@EU supports the cross-border exchange of Patient Summaries, which provide an overview of a patient's key health information (e.g., allergies, current medications, medical history). This summary can be accessed by healthcare professionals in different Member States, which is particularly valuable in emergency situations when a patient cannot communicate their medical background.

Furthermore, Member States' ability to share data through MyHealth@EU reflects their level of preparedness in terms of digital health infrastructure. Each participating Member State must ensure that its national systems are compatible with the MyHealth@EU platform and meet the regulatory standards set by the EU,

such as General Data Protection Regulation (GDPR) compliance, which governs the security and privacy of personal health data. Member States that have adopted MyHealth@EU benefit from smoother healthcare service provision, greater efficiency, and improved patient outcomes, as the exchange of health data reduces the risk of medical errors and duplication of treatments.

As of now, many EU Member States are either fully integrated or in the process of integrating their national health systems with MyHealth@EU. This growing network between member states enables more seamless cross-border healthcare, by enhancing patient safety, and increases the ability of EU citizens to take control of their own health data, promoting the European Health Union.

The electronic prescription/dispensation services and Patient Summary medication list use CDA for cross-border data exchange. However, the new services in MyHealth@EU being implemented will be using HL7 FHIR, and the existing services will have to migrate to FHIR in the long term. Xt-EHR aims to provide an adoptable/adaptable FHIR specification, from which MyHealth@EU can derive their future implementation guides. The CDA specifications are available from the MyHealth@EU ART-DECOR repository[4].

Xt-EHR implementation guides are not specific to cross-border care and should not be adopted without use case specific adaptation.

6.3. HL7 Europe / IHE collaboration on Medication Prescription and Dispense

IHE International started creating a content and transactions profile on Medication Prescription and Dispense in March 2023[5]. The FHIR implementation guide created by IHE uses FHIR R5 and aims to have an international scope[6]. The project is qualified as a "Gemini" project being a cross-SDO cooperation work between IHE and HL7. IHE project is also closely related to IHE Medication Overview project[7], which is an ongoing work on medication lists and medication treatment planning overview.

HL7 Europe decided to create a content profile on Medication Prescription and Dispense in March 2024, planning a cooperation with the IHE Medication Prescription and Dispense working group[8]. The implementation guides created by HL7 Europe use FHIR R4 and R5 and aim to be fully conformant with EEHRxF. The work of HL7 Europe was funded by the XpanDH[9] and xShare[10] projects where HL7 Europe had a task to deliver FHIR Implementation Guides for EHDS use cases. In order to have a better coverage and facilitate cooperation between projects, the work was brought to the wider audience including the technical authors and content experts from Xt-EHR, and xShare, EHR vendors, and other interested parties.

IHE and HL7 Europe joined their working groups, resulting in over 100 participants from over 20 countries (including participants from HL7 Pharmacy, MyHealth@EU, EHR system vendors, etc).

[4] https://art-decor.ehdsi.eu/publication/
[5] https://wiki.ihe.net/index.php/MPD_Main_Page
[6] https://profiles.ihe.net/PHARM/MPD/
[7] https://build.fhir.org/ig/IHE/pharm-meow/
[8] https://confluence.hl7.org/spaces/HEU/pages/227218404/MPD+FHIR+IG+work+proposal
[9] XpanDH Project. https://xpandh-project.iscte-iul.pt/
[10] xShare Project. https://xshare-project.eu/

IHE and HL7 Europe are not in a position to impose any business rules or data requirements on EU Member States. The Joint Action Xt-EHR has an important role here, defining the future requirements of EHDS and bringing additional business requirements to the group. HL7 Europe's implementation guide uses common EHDS profiles for Patient, Practitioner/Prescriber, etc, and follows Xt-EHR proposed logical models. IHE implementation guide, having an international scope, does not have a requirement to follow EHDS, but it would refrain from conflicting with it.

HL7 Europe / IHE working group has conducted a number of surveys and analyses on business requirements and technical solutions used/needed in member states and beyond. This information has been made available for Xt-EHR and is detailed further in the Data Requirements Analysis and Member States State of Play chapters.

HL7 Europe / IHE Medication Prescription and Dispense working group gathered information from participating countries about FHIR implementation in the field of electronic prescription, electronic dispensation and Medication Lists[11]. 15 countries from EEA answered the survey and provided details about their FHIR implementations and related plans in the field (see Figure 1).

11 countries responding to the survey had already started a FHIR project regarding prescribing and dispensing, a majority of them actually focusing on a Medication List/Planning. FHIR facades for prescribing/dispensing services are often created to facilitate creation of new FHIR services. Old prescribing systems continue to operate on the background.

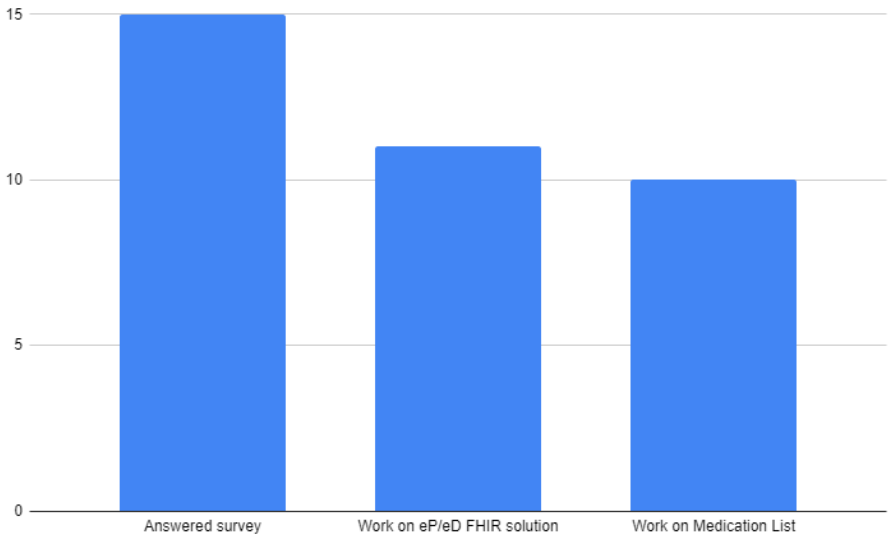


Figure 1. Status of work in member states.

Majority of countries currently implementing FHIR are using FHIR R4 version, several member states having a plan for switching to FHIR R6 in the future. Two countries are using FHIR R5. Almost all

[11] https://docs.google.com/spreadsheets/d/1kjxXq7OIRDBfOhFfpR9bbmrxPzwCN5y_3U1_A2IRk8w/edit?gid=0#gid=0

countries (10 out 11) said their FHIR implementation regarding prescriptions was still in draft status (see Figure 2).

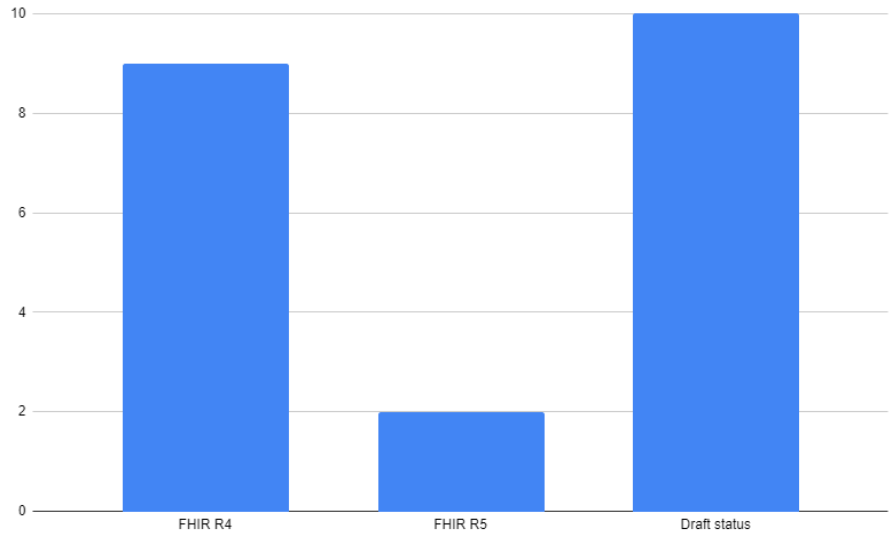


Figure 2. FHIR versions in member states electronic prescription projects.

The fact that most countries are already interested in implementing FHIR but are still in draft status puts Xt-EHR and its cooperation with HL7 Europe / IHE in a good position where all changes can still be easily implemented. However, as most countries have an existing prescription system with its requirements deeply rooted in legislation, breaking changes or imposing FHIR-specific technical solutions should be considered carefully.

6.4. UNICOM

UNICOM project[12], ended in 2024, was a 4-year-project focusing on identification of medicinal products across different use cases, facilitating a consistent data pipeline throughout the life cycle of medication data. From a practical perspective, it significantly improved cooperation and understanding between different organisations on a national and cross-border level. The deliverables included overviews of current status as well as analysis for future services, actual software components and pilot implementations.

Work packages 5 and 7 of UNICOM were closely related to medication data in eHealth services and specifically in services supporting cross-border electronic prescription and dispensation. National implementations and prescriptions using HL7 FHIR standard were out of scope for UNICOM, but some experiments were conducted by WP4 which tested possibilities of providing ISO IDMP-compatible data to eHealth consumers on a national level.

The key achievements of UNICOM WP5 have had a direct impact on several source documents which Xt-EHR Task 6.2 has been using as the basis of work:

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

- Supporting revision of eHealth Network guidelines on electronic prescription and electronic dispensation and Patient Summary, including ISO IDMP[13] compatible data set.
- Co-creating change proposals to MyHealth@EU cross-border specifications (CP-066 "ISO IDMP Adoption by eHDSI – Business requirements" and CP-063 "Medication information representation improvements".
- Supporting alterations to MyHealth@EU CDA specification enabling complex medication package identification.
- Introducing the European Medicines Agency (EMA) SPOR SMS code system to be used for substance identification in cross-border services.
- Creating Minimum Attribute List for eHealth Services (Deliverable D5.7).
- Performing a survey of Member States in relation to state of play of electronic prescriptions.

UNICOM project created awareness and training materials about ISO IDMP. It also briefly investigated usage of PhPIDs in eHealth services, and possibilities to use layered ISO IDMP data model in medicinal product dictionaries (including in the SNOMED CT drug extensions). Work package 4 analysed designing an ISO IDMP and a FHIR-compatible data feed from the regulatory authorities to eHealth users and together with WP6 relevant implementation guide and example data was created.

The UNICOM project also conducted a survey in 2021 to understand the current state of electronic prescriptions and dispensations and their legal frameworks across different Member States. Responses were received from 17 out of 29 EU/EEA Member States[14]. Of the respondents, 14 (82 %) of the Member States had national or regional electronic prescription systems in operation, and some additional states had national or regional systems in the coming 5 year's plan. Of the Member States with a national or regional system, most considered the system mature with more than 80 % of prescriptions being electronic. There is a legal obligation in a majority of Member States for health professionals to use the electronic prescription system.

All public project deliverables are published on UNICOM project web page.

6.5. Pilots for European Digital Identity Wallet (POTENTIAL)

The Xt-EHR Joint Action closely aligns with the goals of the POTENTIAL (PilOTs for EuropeaN digiTal Identity wALlet) project under the DIGITAL Europe Programme, which pilots the European Digital Identity Wallet (EUDI Wallet) for cross-border digital services. Far from being limited to identity credentials, the EUDI Wallet will also support storing and sharing structured health data, such as electronic prescriptions, under the trust, security, and interoperability provisions of the eIDAS 2.0 regulation.

6.5.1. Electronic prescriptions as Qualified Electronic Attestations of Attributes (QEAA)

The EUDI Wallet will enable citizens to carry Qualified Electronic Attestations of Attributes, or QEAAs, for verifiable health-related data. In the context of Xt-EHR and Task 6.2, this means an electronic prescription may be stored and presented as a QR code within the Wallet. This QR code, digitally signed and containing prescribed medicine attributes (e.g., IDMP codes, ATC classifications, dose forms), allows pharmacists to verify the data's authenticity and origin securely, even in offline or low-connectivity scenarios.

[13] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview

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

6.5.2. Security and trust framework integration

Xt-EHR contributes to the foundational work required for secure implementation by ensuring that electronic prescription data is structured, codified, and traceable to trusted sources. When paired with the EUDI Wallet, this enables high-assurance exchange under MyHealth@EU workflows. Pharmacists in different Member States shall be able to verify a prescription through:

- QR code scanning,
- validation of digital signatures,
- and if necessary, fallback to manual identity verification.

The infrastructure reuses existing 2D barcode reader technology where feasible and supports business continuity through printed or digital Wallet-based credentials.

6.5.3. Architectural synergy with MyHealth@EU and EHDS

POTENTIAL deliverables do not replace current MyHealth@EU workflows but enhance them by introducing Wallet-enabled alternatives for citizen control and secure data portability. Through this architectural synergy, the Wallet acts as a complementary interface for identity and data sharing, maintaining the language translation and document validation capabilities of the MyHealth@EU platform.

6.5.4. Empowering citizens with full data control

At the heart of this integration is citizen empowerment: individuals can access and share their health records—including electronic prescriptions—via the EUDI Wallet in a manner that is privacy-preserving, interoperable, and reliable across borders. This addresses long-standing fragmentation challenges and directly supports EHDS goals for trusted, secure access to health data.

6.6. ISO standards on prescription and dispense

ISO has published two specifications specifically for electronic prescription and dispense: ISO 17523 *Requirements for electronic prescriptions*, and the technical specification ISO/TS 19293 *Requirements for a record of a dispense of a medicinal product*. Both documents at the time were used as references when developing the eHealth Network guideline on ePrescription and eDispensation, however a new version of ISO 17523 was in ballot during the Xt-EHR project, and this version was used as a reference for prescription requirements.

ISO also publishes other health information standards related to prescription and dispense. They include the ISO IDMP suite of standards as well as the ISO/DIS 27269:2024 *International Patient Summary*. The ISO IDMP suite supports the identification of medicinal products and provides high-level terminology and information models to support representation of medicinal products in health information systems. The ISO IDMP suite of standards does not contain any code system to support identification of medicinal products.

The ISO/DIS 27269:2024 was reviewed but did not contain additional requirements compared to the eHN Patient Summary guideline for information related to medication.

6.6.1. ISO/DIS 17523:2024 Requirements for electronic prescriptions

ISO 17523 was first adopted in 2016. A draft of the standard, ISO/DIS 17523:2024, was balloted during fall of 2024 and comments were made by Xt-EHR in response to the ballot. Also, the draft was used for comparison with the Xt-EHR electronic prescription requirements during development.

The scope of the standard is the content of the electronic prescription, i.e. it specifies the requirements that are considered important for all electronic prescriptions.

Particularly, the ISO 17523 includes support for multi-item prescriptions, i.e. prescriptions containing more than one medicinal product per prescription. This is allowed practice in some but not all Member States. In describing dosaging the ISO 17523 refers to the ISO technical specification ISO/TS 17251:2023.

ISO 17523 includes requirements for data elements which are not in any existing European models, including reimbursement information, patient address, and some patient clinical data.

In spring 2025 the final draft ISO/FDIS 17523:2025 was made available, including changes proposed by Xt-EHR.

6.6.2. ISO/TS 19293:2018 Requirements for a record of a dispense of a medicinal product

The technical specification ISO/TS 19293 was first adopted in 2018. The scope of the technical specification is requirements for a record of a dispense of a medicinal product. The specification lists individual requirements for relevant data elements of a dispense record. The specification also describes a wide range of dispensation use cases including national and cross-border use cases.

6.6.3. ISO/TS 17251:2023 Business requirements for a syntax to exchange structured dose information for medicinal products

The technical specification ISO/TS 17251:2023 outlines the business requirements for a syntax to exchange structured dose information for medicinal products but does not aim to provide a detailed information model for dose information.

7. USE CASES

This chapter describes the use cases considered for the proposed EEHRxF electronic prescription and electronic dispensation specifications.

7.1. Actors

This section presents business level and technical level actors relevant to the electronic prescription and electronic dispensation use cases.

7.1.1. Business level actors

Prescriber: a member of a regulated health profession who is legally entitled to prescribe medicinal products as a part of provision of health care for a patient.

Dispenser: a member of a regulated health profession who is legally entitled to dispense medicinal products to a patient as indicated in a prescription and according to national regulation. Note: medicinal products can be dispensed through Automated Dose Dispensing but different rules apply in different member states[15].

7.1.2. Technical level actors

To support the expected functionalities without mandating specific architectures, a set of specific technical actors are defined. These actors are focused on the data exchange and interoperability – they represent atomic functionalities that may be implemented in different configurations depending on the situation and architecture – for cross-border, national or internal EHR system exchange.

The actors for prescription are:

Prescription Producer: This actor is responsible for submitting a prescription, or an update of an existing prescription, or similar uses.

Prescription Consumer: This actor represents an entity that handles or processes the order, typically for dispensing, but can also be for further authorization, verification, etc. For example, a prescription system may be a prescription consumer, to read prescriptions for validation, or checking previous prescriptions.

Another actor that may be required depending on the architecture is a "Prescription repository" - a system functionality for storing and/or forwarding the prescriptions, without displaying or processing or altering it in any way.

Alternative decomposition of functionality into modular actors could be considered but the pattern of Producer + Consumer + [Repository] allows expression of data rules as is foreseen in the scope of this document.

These same actors apply for the Dispense: Dispense Producer, Consumer, Dispense Repository.

Dispense Producer: This actor is responsible for submitting a dispense report, or an update of an existing dispense report, e.g. when discarding a dispense report.

Dispense Consumer: This actor represents an entity that handles or processes the dispense reports.

7.2. Use case: Prescribing

Title	Prescribing
Purpose	To support the processes of prescription and reuse of prescriptions through the electronic exchange of health data.
Relevance	Prescriptions can be retrieved nationally and across the European Union. Increases potential for having a complete list of a patient's relevant prescriptions which may constitute a large part of a patient's relevant medication treatments.
Scale	Cross-border, national/regional

[15] EDQM. Automated Dose Dispensing (ADD) Guidelines. 2017. Available from: https://freepub.edqm.eu/publications/AUTOPUB_30/detail

Domain	Medication
Situation	Sharing health data between EHR systems, nationally or cross-border
System functional profile	Prescribing system
Context	Prescription: A prescription for a medicinal product or a medical device issued by a member of a regulated health profession within the meaning of Article 3 (1) (a) of Directive 2005/36/EC, who is legally entitled to do so in the Member State in which the prescription is issued. Source: Directive 2011/24/UE
Information	Prescription information necessary to dispense the medication
Participants	Prescriber Patient
Preconditions	A health professional has made the assessment that a patient is to be treated with a medicinal product
Functional process flow	The patient is identified. The health professional is identified and authorised. A health professional using an EHR system with a medication prescription system function uses that system to create a new electronic prescription for an identified patient, recording the prescription in the EHR system. In the prescription, the medicinal products allowed to be dispensed may be described by brand or by the active substance(s).
Cross-border considerations	Due to the current lack of an EU-wide system for identification of medicinal products and variations in the national pharmaceuticals markets, additional information may need to be provided to support identification and/or disambiguation of the products when sharing electronic prescriptions cross-border. For example, this may include dose form and lists of ingredients with strength.
Variations	Cancellation of prescription Changing prescription (Alteration? See below)

7.2.1. Functional requirements

The main functional requirements for prescribing are what is provided in the dataset (see 8.4). In addition, the following requirements are stated:

- During the contact with the health professional, the patient SHALL be identified using methods of identification according to deliverable D5.1, section 5.1.2.
- The prescriber SHALL be identified, authenticated, and authorised to use the EHR system to produce prescriptions for medicinal products, according to D5.1, section 5.1.2.
- The EHR system SHALL have included or have access to prescription and dispense repositories to store prescriptions produced and make the prescriptions available for dispensation services.

7.2.2. Variations of prescribing use case

7.2.2.1. Cancellation of a prescription by a prescriber

A health professional using an EHR system with a medication prescription system function uses that system to recall or cancel an existing electronic prescription. Prescribers have the ability to revoke or cancel an electronic prescription before it has been dispensed to the patient. This ensures that patients do not receive medications that are no longer deemed appropriate.

Important Considerations:

- Timing of Cancellation: electronic prescriptions can only be revoked before they have been dispensed. Once an electronic prescription has been dispensed by a pharmacist, it cannot be canceled through the software of the health professional.
- Communication with Patients: It's advisable to inform patients about the cancellation to prevent confusion during their pharmacy visit.
- System Integration: Ensure that the EHR system is properly integrated with the electronic prescription/electronic dispensation software and supports the revoke functionality.

7.2.2.2. Alteration of a prescription by a prescriber

A health professional using an EHR system with a medication prescription functionality can alter an existing prescription they previously added to the system. Changes may involve modifying the value of any data element within the current prescription or by invalidating it (e.g. by changing the status) and issuing a new prescription.

7.3. Use case: Dispensing

Title	Dispensing
Purpose	To support the processes of dispensing and reuse of dispensation records through the electronic exchange of health data.
Relevance	Dispensation records can be retrieved nationally and across the European Union. Sharing dispensations is a pre-requisite of an electronic prescription system. A dispensation is an indication that a patient has access to the medication and increases likelihood that the patient is in fact consuming the medication.
Domain	Medication
Scale	Cross-border, national/regional
System functional profile	Dispensing system
Context	Electronic dispensation: is defined as the act of electronically retrieving a prescription and reporting on giving out the medicine to the patient as indicated in the corresponding electronic prescription. Source: eHealth Network Guideline
Information	Information about the dispensation
Participants	Dispenser Prescriber Patient or nominated proxy
Preconditions	A health professional has made the assessment that a patient is to be treated with a medicinal product, thus there is - in the normal case - a prescription to dispense.
Process steps	The patient or proxy and the health professional are identified and authorised. A health professional (pharmacy professional or other health professional) uses an EHR system with a medication dispensation function to retrieve a prescription, validate the prescription, possibly in contact with the prescribing health professional, give out the medicinal products to the patient (or proxy) in question, and

	create a record of the dispensation in the EHR system. Can be repeated for multiple prescriptions in one session. This process applies for physical as well as online pharmacies.
Cross-border considerations	Relate to parts/steps of dispensing procedure deviating from national dispensing procedure. Due to the current lack of an EU-wide system for identification of medicinal products and variations in the national pharmaceuticals markets, additional information may need to be provided to support identification and/or disambiguation of the products when sharing electronic dispensations cross border. For example, this may include dose form and lists of ingredients with strength.
Variations	Dispense decline Dispense medication before receiving a prescription Substitution or override of prescription by the dispenser

7.3.1.1. Functional requirements

The main functional requirements for dispensing are what is provided in the dataset (see 8.4). In addition, the following requirements are stated:

- The patient SHALL be identified using methods of identification according to D5.1, section 5.1.2.
- The dispenser SHALL be identified, authenticated, and authorised to use the EHR system to produce the dispense record(s) related to a prescription (see D5.1, section 5.1.2).
- The EHR system used for dispensation SHALL have the ability to retrieve prescriptions from a prescription repository where the patient's prescriptions are stored. This repository will be responsible for keeping track of amount of remaining dispensable product after dispense, if any.

7.3.2. Variations of dispensing use case

7.3.2.1. Substitution or override of prescription by the dispenser

A health professional (e.g. a pharmacist) using an EHR system with medication dispensation system functions to substitute a medication or override an existing prescription. Changes to a prescription can be made by changing the value of any data element in an existing prescription or by invalidating (e.g. by changing the status of) an existing prescription and creating a new prescription.

Substitution is when a prescribed medicinal product is changed to another medicinal product. There are different kinds of substitution, e.g. generic substitution and therapeutic substitution. Generic substitution involves replacing a brand-name drug with a pharmaceutically equivalent drug. Therapeutic Substitution involves replacing a prescribed drug with a different drug that has a similar therapeutic effect but a different chemical structure.

Selection of an actual brand for dispense based on a prescription of active substance/virtual product is not considered substitution.

Override of a prescription occurs when the prescribed medication/dosage information is changed by the dispenser, e.g change of dosage, dose form or route of administration.

Depending on national legislation, substitution, generic substitution and/or selection may be considered an override, or not.

- When a health professional performs override or substitute of a prescription, the dispense records SHALL provide data on what medicinal product was provided to the receiver.
- The EHR system used for dispensation SHALL have access to a prescription repository where the patient's prescriptions are stored and share a dispense record including the override and/or substitution.

7.3.2.2. Dispense decline

A health professional (e.g. a pharmacist) using an EHR system with medication dispensation system functions may, given appropriate reasons, deny a dispense of a prescription. This denial SHALL also be recorded in a (non-)dispense record.

7.3.2.3. Dispense medication before receiving a prescription

A patient visits a pharmacy and requests a medication without having a required prescription: e.g.

- no active prescription for a chronic condition (insulin in case of diabetes),
- no new prescription issued for the prescribed recalled medication,
- emergency medication.

The pharmacist, using their best professional judgement, understands that the patient does need the medication even if it is a prescription drug (or the prescription would be reimbursed if it had a prescription).

The regulation of such situations vary between member states and the patient could also be advised to seek emergency care to get the required medication.

7.4. Adjacent topics

There are situations which relate to prescription and dispensation but are not use cases that are in scope of this deliverable.

7.4.1. Dispensation discard

There can be situations where a dispense was made erroneously and there is a need to send a notice to discard the already communicated dispense record.

This is currently supported by the MyHealth@EU cross-border services, where it is possible to discard the latest dispense made when the medication was not given out. Member states needed this functionality in cases where the dispense was recorded but then cancelled, for example due to the bank transfer failing and customer not being able to pay for the product. However, this functionality does not include clinical information, and despite being a legitimate workflow step, it might not have any impact on the exchange format.

7.4.2. Reviewing a set of current or past prescriptions

In health care settings, the health professional may need information about current treatments or active prescriptions to assess the current clinical status of the patient, plan further prescriptions (prescriber), or safely dispense medications (dispenser). This information may be presented through medication summary (similar to the section in Patient Summary, for which specification is provided in Xt-EHR deliverable D6.1) and/or by a list of active prescriptions.

While the structure and content of a single prescription and dispense is in scope for this deliverable, reconciling and displaying a summary view of prescriptions or treatments, is not constrained from a technical point of view, expecting user interfaces to be designed in a way that best supports the exact use case in focus.

7.4.3. Recall of medication

Recall of a medicinal product is not clinical information but supply related information for a wider audience. However, recall of a medication may have consequences that include triggering different workflows in the clinical care of a single patient.

For example, patients who are currently receiving the recalled medication may be informed that their treatment needs to be changed. In case they are not informed, the pharmacist might refuse to dispense the product, sending the notification back to the prescriber. The workflow, resulting from a recall, depends on the urgency of the situation and the national rules. Technically, the triggered workflow may include any of the following electronic prescription/electronic dispensation use cases:

- Declining the dispense,
- Cancelling an active prescription,
- Changing an active prescription,
- Issuing a new prescription for a substitute product,
- Substituting the product at dispense,
- Dispensing the substitute product before the new prescription is issued.

Recalls include a lot of communication and regulatory work to make sure patients can continue with their treatments in the best possible way. In the context of electronic prescription and dispensation, the recall is a trigger for use cases, not a prescription use case itself.

7.4.4. Online pharmacies

In comparison between online pharmacy dispensing and "regular" dispensing, presented as Use case below, the differences for online dispensing do not impact the format as described in this deliverable (indicated in bold text in the table).

The main differences are in the identification of the patient (or their proxy), and the remote delivery of medicinal product, which falls under the procedures stipulated by national legislation.

Title	**Online pharmacy** dispensing
Purpose	To support the processes **of online pharmacy** dispensing and reuse of dispensation records through the electronic exchange of health data.
Relevance	Dispensation records can be retrieved nationally and across the European Union. Sharing dispensations is a pre-requisite of an electronic prescription system. A dispensation is an indication that a patient has access to the medication and increases likelihood that the patient is in fact consuming the medication.
Domain	Medication

Scale	Cross-border, national/regional
System functional profile	Dispensing system
Context	Electronic dispensation: is defined as the act of electronically retrieving a prescription and reporting on giving out the medicine to the patient as indicated in the corresponding electronic prescription. Source: eHealth Network Guideline
Information	Information about the **online pharmacy** dispensation
Participants	Dispenser Prescriber Patient or nominated proxy
Preconditions	A health professional has made the assessment that a patient is to be treated with a medicinal product, thus there is - in the normal case - a prescription to dispense.
Process steps	The patient or a nominated proxy and the health professional are identified according to eID procedure defined by D5.1 of Xt-EHR. A health professional (pharmacy professional or other health professional) uses an EHR system with a medication dispensation function to retrieve a prescription, validate the prescription, possibly in contact with the prescribing health professional, give out the medicinal products **by remote delivery according to national regulation to the patient (or proxy)** in question and create a record of the dispensation in the EHR system. Can be repeated for multiple prescriptions in one session. This process applies for physical as well as online pharmacies.
Cross-border considerations	Relate to parts/steps of dispensing procedure deviating from national dispensing procedure. Due to the current lack of an EU-wide system for identification of medicinal products and variations in the national pharmaceuticals markets, additional information may need to be provided to support identification and/or disambiguation of the products when sharing electronic dispensations cross-border. For example, this may include dose form and lists of ingredients with strength.
Variations	

8. IMPLEMENTATION GUIDES

The specifications of D6.2 will be using the deliverables D5.1 and D5.2 as a starting point, including the common metadata framework.

Xt-EHR Task 6.2 work is observable in two different implementation guides:

Datasets in the form of logical models are provided in Xt-EHR Logical Information Models Implementation Guide (see 8.4).

- Xt-EHR logical models

HL7 FHIR data exchange specifications are provided in **HL7 Europe Medication Prescription and Dispense Implementation Guide**:

- FHIR R4 version
- FHIR R5 version

The implementation guides are interrelated – all FHIR profiles are based on the logical models provided in the Xt-EHR guide, and mapping from logical models to FHIR profiles is provided in the HL7 Europe FHIR implementation guides. FHIR R4 and R5 implementation guides are functionally identical, allowing implementers to choose the specification according to their current ecosystem and even prepare a multiversion environment if needed.

Xt-EHR logical information models implementation guide content is covered below in the "Data Sets" chapter (see 8.4).

HL7 Europe FHIR implementation guide is covered below in the "HL7 FHIR Implementation Guide" chapter (see 8.6).

8.1. Business and functional specifications

The specifications in this deliverable support use cases related to sharing electronic prescriptions from EHR systems with a prescription function as well as sharing dispense records from EHR systems with a dispense function (see chapter 7).

The functional requirements related to the EEHRxF for prescription and dispensation are expressed in the datasets of section 8.4.

8.1.1. Multi-item prescriptions

HL7 Europe / IHE working group conducted a survey on business requirements and implementation patterns (see e.g. Figure 3). It was concluded that despite MyHealth@EU specification limiting the allowed number of medication items per prescription to only one, and FHIR core specification also allowing only one Medication reference per MedicationRequest, the actual national implementations still have the requirement of allowing and communicating multiple item prescriptions[16].

From a technical point of view, it is worth mentioning that national implementations in focus had chosen at least three different workarounds for grouping multiple MedicationRequests under one prescription or handled the grouping outside FHIR infrastructure.

[16] https://confluence.hl7.org/display/HEU/2024-05-02+MPD

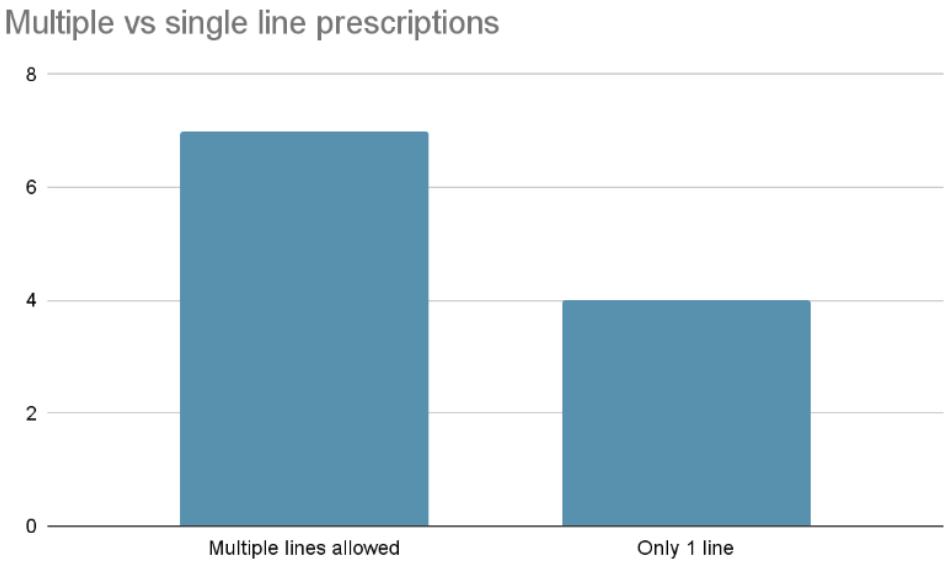


Figure 3. Single- and multiline prescriptions in some Member States.

Xt-EHR is recommended to take this requirement into account when processing future business requirements. HL7 Pharmacy and HL7 Orders and Observations working groups have been asked to provide guidance on this requirement to facilitate harmonisation of implementations.

8.1.2. Prescription workflow and statuses

HL7 Europe / IHE working group gathered information about how well FHIR MedicationRequest statuses match the actual prescription statuses used in national workflows. The 13.06.2024 meeting concluded that national workflows often use prescription system statuses which are wider than statuses allowed for MedicationRequest resource[17]. In FHIR, MedicationRequest status should express the status of the authorisation as a document, and workflow statuses should be expressed in a Task resource. However, this approach is not widely adopted by implementers and[18] clarifications are needed.

8.1.3. Dosaging

A simplified dataset for dosaging information is provided in eHealth Network guidelines. It leaves a lot open to interpretation and does not claim to be exhaustive or sufficient for actual use.

MyHealth@EU specification for dosaging is slightly more structured providing extra granularity but still remains very brief compared to the complexity provided by e.g. the HL7 FHIR Dosage datatype[19].

IHE Medication Prescription and Dispense working group initially decided to refrain from lengthy discussions on this topic and decided to use HL7 FHIR Dosage + Timing data types as IHE data model for

[17] https://confluence.hl7.org/display/HEU/2024-05-30+MPD
[18] https://confluence.hl7.org/display/HEU/2024-06-13+MPD
[19] https://www.hl7.org/fhir/dosage.html

dosaging instructions[20]. HL7 Europe defaults to using IHE dosaging unless a new model is proposed by Xt-EHR.

Xt-EHR WP 6.2 calls have revealed that agreeing on a more limited scope for Dosaging seems like a reasonable idea but is extremely difficult to achieve. In addition to community pharmacy prescriptions, hospital use cases are also in focus in several countries and complex dosaging issue is increasingly difficult to avoid. Also, as dosaging criteria are compositional, i.e. criteria such as time of day, or day of week are added to form the full criteria, selecting a subset can create uncertainty about whether the full meaning has been captured structurally. Therefore, Task 6.2 participants have decided to initially describe dosaging instructions with full FHIR complexity and add textual guidance on how to reduce the complexity when needed and how to render these complex structures in a user-friendly way. However, IHE Pharmacy Technical Framework proposes some dosaging scenarios that go even further in structural complexity, and depend on the CDA standard for implementation. For some of these scenarios (subordinate acts, conditional dosaging) there is no equivalent solution in FHIR core specification.

MyHealth@EU is free to simplify dosaging for their specific use case if member states agree to do so. Cross-border prescription has a limited scope compared to national implementations, and simplifications may be justified by the nature of the service and its users.

8.1.4. Medicinal product information

Medication information has many forms: for example, regulatory medicines agencies have a very detailed view on a product's data and for this purpose the ISO IDMP data model has been adopted by EMA. Data exchange between marketing authorisation holders/applicants and regulatory authorities uses HL7 FHIR MedicationDefinition resources, which are too complex for clinical medication use cases. In order to make medication data usable in eHealth services, it needs to be transformed in a consistent way, making sure that the harmonisation achieved on a regulatory level persists on patient care level.

On a national level, many approaches to medication data exist in eHealth services. Quite often, medication data is published in a form of a code system where each real product or virtual product has been allocated a code. Within that country, systems are free to exchange just product codes as long as all parties have access to the code system as the source of information.

In cross-border services, the country of treatment typically does not have access to the country of affiliation (Country A) registries and terminology resources, or they are not translatable for the data users in Country B. For making sure that the receiving side in another country understands the request, medication data needs to be described in a structured format within the prescription/dispense message.

UNICOM project included change requests in MyHealth@EU to change the data model and CDA specification for medication information on prescriptions. With these change requests a nested structure was introduced for expressing the contents of packages, including complex packages.

Prescriptions from FHIR perspective were out of scope for UNICOM. This work was continued by IHE Medication Prescription and Dispense working group, and a new profile for Medication resource was proposed. HL7 Europe / IHE joint working group has created a set of change requests to HL7 Pharmacy to

[20] https://profiles.ihe.net/PHARM/MPD/

allow changes and additional information in the core specification. As a result, medication information should be expressed in a similar structure as proposed in eHN Guidelines and MyHealth@EU CDA specification.

Certain data elements have been added by IHE / HL7 Europe (e.g. administration device included in the package), and the business requirement for these elements will be analysed by Xt-EHR.

Additional work should be carried out on related terminologies. SNOMED CT is used by multiple countries as a virtual product layer or a mapping target. Medicines agencies are likely to switch to EMA SPOR terminology[21], while MyHealth@EU has a list of preferred and mandatory value sets already defined.

8.1.5. Device as dispenser

In the dataset and in the technical interoperability specification, a device can be listed as the dispenser. An example of such a device would be automated medication dispensers increasingly being put into practice in Member States. The use of device as dispenser will likely vary between Member States, and the interpretation of which actors play which role in the dispense of medication using automated dispenser will likely also vary. The specifications proposed support this practice and Member States may need to be prepared to see dispense data where the dispense has been made by a device.

8.1.6. Reimbursement

This topic covers the data requirements for reimbursement information, not the processes of national and/or cross-border reimbursement which are clearly out of scope of this deliverable.

Reimbursement of prescriptions has been declared out of scope for eHN guidelines, MyHealth@EU and IHE. However, this has been one of the issues repeatedly raised by Member States and Xt-EHR is in a good position to analyse the possibility of harmonisation. Further, the ISO/DIS 17523:2024 draft international standard lists “Reimbursement information” as one of the requirements.

The complexity of reimbursement comes from the fact, that reimbursement rules differ significantly across Member States. The rules are typically a combination of data that is kept on patient level, medicinal product level, and practitioner level. The resulting reimbursement information with additional terms or limitations is communicated on a prescription and it may be different on a dispense.

Xt-EHR Task 6.2 investigated different approaches to prescription reimbursement and to see if there are ways to provide guidelines on how to deal with this on a national level. Xt-EHR does not have a mandate to propose including reimbursement data in cross-border services.

Assessing the prescription reimbursement information as described in four of the Xt-EHR participant countries, the differences between countries included differences in the national legislation around reimbursement, differences in the kind of data represented and differences in the way the data requirements were implemented.

To conclude, the assessment showed that there is currently no basis for adding reimbursement information to the Xt-EHR data sets.

[21] https://spor.ema.europa.eu/sporwi/

8.1.7. Structure and free text

The balance between the level of structure and the possibility to add free-text information to the datasets has been a constant concern in the discussions leading up to the logical models. Where a larger extent of free text data elements in addition to structured and/or coded data elements would facilitate implementation, it also poses challenges for checking conformity, doing translation and/or transcoding (within or across Member State borders), and for overall reuse of data.

In the development of the logical models, the need for a pattern with free text as a fallback mechanism—used when structured and coded data cannot or should not be provided—was addressed. There are several variations of this pattern.

When coded data elements are expected, generally CodeableConcept as a data type from HL7 FHIR is used, and the free-text alternative is available as an in-built mechanism of that data type.

To allow specification of further details using free text, additional string-typed element is added.

For highly structured datasets, it is possible to also provide a summary text element to be used as an alternative or complement to the structured and/or coded data elements. Examples are "comment" data elements throughout the models or Medication dosaging.text which can be a summary of dosaging information when structured data cannot be provided.

8.1.8. Conformity

To assess conformity to the models presented here, each data element needs to be assigned a conformity level for each context in which data is produced or consumed. In this document only the conformity level that applies to all contexts is presented.

Obligations may, and often do, differ depending on the context in which the specifications are used. For example, in Member States which have a system for identifying prescribable products there is no need to provide the ingredients of the product, as that information can be looked up when needed. In a cross-border context, where there today is no pan-European system of product identifiers, the identification of the prescribed drug depends on there being information on at least the active ingredients. This can be seen in the differences between the obligations stated in the MyHealth@EU Requirements Catalogue and the obligations seen as a result of this work. The difference in these obligations may be managed at the national level through the National Concept Point for eHealth.

8.2. Data quality requirements

Data quality requirements include several aspects such as semantics, uniformity, consistency, accuracy and completeness. These data quality requirements are to a large extent described in the datasets (see 8.4) and the technical interoperability specifications (see 8.6).

8.2.1. Quality of master data

Each EHR system that has a function to produce medication prescriptions shall make use of an up-to-date master data catalogue, including:

- patient registry,
- list of available medications

- list of authorised health professionals

8.3. Semantic specifications

Exchanging prescription and dispensation data across European countries requires the use of standardised code systems to ensure interoperability. eHealth Network guidelines outline the preferred code systems for cross-border services within the MyHealth@EU, such as EDQM, UCUM, WHO ATC, and EMA SPOR SMS.

While international standards support consistent data exchange, most countries use national code systems in their clinical workflows. In most countries, a locally coded set of medication concepts are made available as a code system or a registry. Code systems for medication concepts as such, have never been in scope for cross-border electronic prescription and electronic dispensation, where the emphasis is put on the attributes of the medication product, especially due to the fact that one country's medication concepts are hardly ever available for another country's pharmacist.

These local variations may be deeply rooted in clinical systems (including decision support or substitution or reimbursement mechanisms) and discontinuing them may be a slow or unnecessary process. Therefore, this deliverable and related implementation guides give recommendations and examples rather than forcing the same solution for everyone. However, the ability to map local representations to cross-border services' requirements should always be considered, even when the systems do not communicate with other countries directly.

8.3.1. Medication concepts

Medication as a concept (CodeableConcept from a terminology or FHIR resource) on a prescription can be anything from just substance to a certain pack size of a branded product. Similarly, the level of package details varies greatly. On a dispense, physical package identifier can be captured. Closely linked is the concept of dosage and how it is represented on a prescription - some details about a prescribed product may be captured in dosaging information or in the details of the prescribed product.

8.3.1.1. *Medication and dosage*

When only a substance is prescribed, the dosaging information also contains the dosage (strength) and route of administration. In the following example, the prescriptions are built differently, but the order is likely the same. The reason for preferring elements in dosaging instead of elements in medication is to allow flexibility in choosing the exact product (the dispenser or nurse has the freedom to decide between different oral dose forms according to the patient's needs or preferences).

Table 2. Medication and dosage.

Medication	Dosage
paracetamol	125 mg, oral route, when needed
paracetamol 125 mg / 5 mL oral suspension	5 mL when needed

Route/method of administration is one of the data elements that describes the medication as well as dosaging (administration instructions). When a medicinal product is authorised, it is authorised for certain routes of administration. However, one product may have multiple authorised routes, or a product can be used with an off-label route. A product with a dose form "drops for eye, nose or ear" can be used for all these body sites,

but on a prescription, we typically want to express the administration route for this particular case. Therefore, route on a prescription is typically conveyed in dosaging information, even though product catalogues list routes in medication details.

8.3.1.2. *Virtual vs real product*

When a medication is prescribed it may be prescribed as a virtual product (for generic prescriptions) or as a real product. In some countries, prescribing a real product implies that the product cannot be substituted as the prescriber has chosen a real product over a virtual product for a reason. In other countries, substitution is allowed or even expected as the real product represents just one possible alternative and any other similar product can be chosen unless specifically stated otherwise on the prescription.

Virtual products, just like real products, may be represented as a concept from a code system or a FHIR resource with filled-in attributes. In many countries real products and virtual products are interlinked, allowing a simpler selection and substitution. Internationally known code systems like RxNorm and SNOMED CT contain medication concepts on different levels, allowing moving up and down on granularity levels of the product.

ISO IDMP also represents medicinal product information on different levels: Medicinal Product, Packaged Product, Pharmaceutical Product, and Manufactured Item. Note, that ISO IDMP Pharmaceutical Product represents the administrable form of a specific real product (containing information about excipients), while PhPID (Pharmaceutical Product Identifier) is designed to represent a more abstract classification for products. HL7 FHIR resources for implementing ISO IDMP are provided in MedicationDefinition module of the HL7 FHIR standard[22].

8.3.1.3. *Medicinal product dictionaries*

Various code systems exist for medication concepts. SNOMED CT contains concepts for describing a medication (dose forms, substances, units) as well as precoordinated medication concepts with different granularity. SNOMED CT international release contains only virtual products - the most granular of them is clinical drug, which maps to manufactured item in ISO IDMP.

SNOMED CT national extensions may include data of real medicinal products - branded medicinal products as well as packages. While codes for these national products would be different in each country, they all leverage the international content of SNOMED CT and follow the agreed concept model.

The granularity of prescribed medication depends on the type of concept chosen for a particular implementation. For example, the following table illustrates how concepts on different levels or following different standards compare to each other (* marks information that might be implied by relationships with related concepts).

[22] https://www.hl7.org/fhir/R5/medication-definition-module.html

Table 3. Comparison of standards for medication identification.

Concept type	Active substance	Strength	Manufactured dose form	Administrable dose form	Authorised name	Pack size
ISO IDMP Medicinal Product	+	+	+	*	+	*
PhPID Level 4	+	+	-	+	-	-
SNOMED Clinical Drug	+	+	+	-	-	-
SNOMED Real Drug Package	+	+	+	-	+	+

Most countries operate their own national terminology or register for medicinal product - often both, as the medicines agency publishes the data as a register and another organisation remodels it as a code system. These sources allow the actual prescription and dispensation to include only product code/identifier and have each system look up the details of the products from the source system. However, there can be no expectation that a pharmacy system from another country should be able to do lookups into any other country's product dictionary. Therefore, cross-border service includes the product code as well as an essential set of details about the product.

8.3.2. Substances (active ingredients)

EMA SPOR Substance Management Services (SMS) provides a list of coded substances - active ingredients (salts as well as moieties) and excipients. It is used in EMA SPOR services, recommended in eHealth Network guidelines, and implemented in MyHealth@EU cross-border services.

On a national level, local code systems or SNOMED CT are also often used. There is no official mapping between SNOMED CT and EMA SMS, but as they both use official INN names assigned by WHO, mapping by name may be helpful.

In MyHealth@EU services, substances are allowed to be coded with ATC. However, ATC is a classification of products, not a code system for ingredients. Also, ATC does not include excipients or modifications like salts. Therefore, ATC is not recommended for coding active or inactive ingredients.

8.3.3. Dose form, unit of presentation, package type, route of administration

Dose form, unit of presentation, package type and route of administration are all semantically different concepts, that have overlapping elements or defining relationships with each other. A unit of presentation may be "tablet" and overlap with the dose form "tablet", or it may be "vial" possibly overlapping with package type "vial". Many dose forms include route of administration or package type information in the name. Depending on the code systems used, the need for the following concepts may vary.

Table 4. Comparison of terminology standards.

Coded attribute	EDQM	EMA RMS	SNOMED CT
Dose form	10221000 Film-coated tablet	100000073665 Film-coated tablet	1163573008 Film-coated oral tablet

Coded attribute	EDQM	EMA RMS	SNOMED CT
Route of administration	20053000 Oral use	100000073619 Oral use	26643006 Oral route
Packaging	30009000 Box	100000073498 Box	(no equivalent)
Unit of presentation	15054000 Tablet	200000002152 Tablet	732936001 Tablet (unit of presentation)

Dose forms have been harmonised between EDQM Standard Terms and SNOMED CT, and the mappings exist. EDQM Standard Terms, EMA RMS and SNOMED CT all provide a useful addition to lists of terms by adding attributes to dose forms. Each dose form is equipped with the following attributes:

- basic dose form (e.g., cream, tablet),
- state of matter (e.g., solid, gas),
- transformation (e.g., dissolve, disperse),
- release characteristics (e.g., conventional release, prolonged release),
- intended site (e.g., oral, dental),
- administration method (e.g., swallow, inject).

Dose form attributes can be used for creating decision logic in electronic prescription systems and other clinical processes. They can also be helpful for mapping dose forms between different code systems.

The preferred code system for all these elements is currently EDQM Standards Terms, and so it is used in MyHealth@EU services. However, other code systems are not discouraged, as long as they are mappable to cross-border value sets.

8.3.4. Units

There are several types of units used on prescriptions and dispenses:

- units of measurement for independent physical units (e.g., milligram, gram, millilitre, hour, etc);
- units of presentation for smallest countable items in a medicinal product package (e.g., tablet, vial, bottle);
- units of product usage (dosaging) for marking the dosage (possibly a subset of the two above with vague additions, such as "application", "table spoon", etc).

Unified Code for Units of Measure (UCUM) is widely used for units in eHealth and beyond - not only for medicinal product information, but also in laboratory results and other measurements. In eHealth services UCUM notations are generally used as codes for units of measurement, which is the preferred code system for units in HL7 FHIR. When UCUM is used for units of presentation/usage, code "1" may be used to indicate any countable item. Brackets notation like "{tablet}" is allowed but not encouraged in HL7 FHIR.

In EMA RMS list, the same concepts are coded with RMS codes, and mapping from RMS units to UCUM is provided if it exists. RMS does not declare UCUM to be the source code system for units of measure, leaving a possibility of deviating from it.

SNOMED CT also includes units of measurement with SNOMED CT codes.

Table 5. Comparison of unit of presentation terminology standards.

Coded attribute	EDQM	EMA RMS	SNOMED CT
Unit of presentation	15054000 Tablet	200000002152 Tablet	732936001 Tablet (unit of presentation) or 428673006 Tablet - unit of product usage
Unit of measurement	µg microgram(s)	100000110656 microgram(s)	258685003 mcg

Units of presentation and units of usage are overlapping, but unit of presentation is more common for packaging information, while units of usage may be more focused on dosaging information. Unit of presentation as an independent data element is a characteristic of a product, and an extension for this data is available in the Medication profile in the FHIR IG. Units of usage are not provided as an element or a value set in this IG, and unit of presentation is used instead.

The preferred code system for units of measurement is UCUM.

The preferred code system for units of presentation is EDQM Standard Terms, but using other code systems is not discouraged as long as the ability to map to cross-border services' code systems is ensured.

8.3.5. Classifications

Anatomical Therapeutic Chemical Classification System (ATC) has been known and used since 1976. ATC is widely used in prescription systems, clinical decision support systems, and even on physical pharmacy shelves.

In EMA RMS, WHO ATC has been recoded with RMS codes. The list owner is considered WHO, and EMA is allowed to add concepts that are pre-accepted for use in the source system but will come into effect in the future. It is important to be aware of the versions and their effective dates when using ATC. It has been noticed in cross-border electronic prescription service, that countries adopt the new version of ATC at different times. Many countries publish ATC with a national code system identifier (canonical URL in FHIR), even when the content is unaltered. In some countries, additional codes have been added to ATC for various reasons, and automatic 1:1 mapping with other countries' ATC concepts may not be achievable.

This specification encourages using ATC as a classification in the data element 'classification'.

ATC is not recommended for medication or substance codes, as it is limited in scope and granularity.

PhPID (Pharmaceutical Product Identifier) as defined in ISO IDMP can also serve as a classification, or even as medication code, as the level 4 PhPID provides significantly more granularity than ATC.

Multiple more classifications exist, but in most cases, they are relevant only in their local setting, and the code systems can be locally defined.

8.4. Datasets

The datasets below were developed based on requirements identified in the sources listed above (see chapter 5). The definitions of the datasets are provided in the Xt-EHR Logical Information Models Implementation Guide in the form of logical models. For each model a mindmap figure and two tables are presented in this document. The two tables describe the source of requirements and relationship to the eHealth Network guidelines, MyHealth@EU Requirements Catalogue, and detailed description for each data element respectively.

The columns of the detailed descriptions table are as follows:

1. Number – a number indicating the hierarchical position within the model. This number is not necessarily unique or stable over time.
2. Data element – the name of the data element and its path in the logical model
3. Description – a description of the data element
4. Data type – the data type of the value(s) of the data element
5. Cardinality – the minimum and maximum number of occurrences of a value of a data element
6. Preferred code system – the recommended code system for data elements with a coded datatype

In the UML-like diagrams, the choice datatypes are represented using a diamond form with the alternative types referenced by dashed relation.

8.4.1. Medication prescription

The medication prescription model (see EHDSMedicationPrescription) represents electronic prescriptions as referred to in EHDS Article 14 and Annex II 2. The medication prescription model shares part of its header with the common header facilitating common metadata between priority categories. In addition to the common header elements, the medication prescription model shares common models for patient, health professional, organization (e.g. for health care providers or pharmacies) and devices (e.g. administration device included with the medicinal products). The medication and dosaging models are described here and are reused in other priority category models.

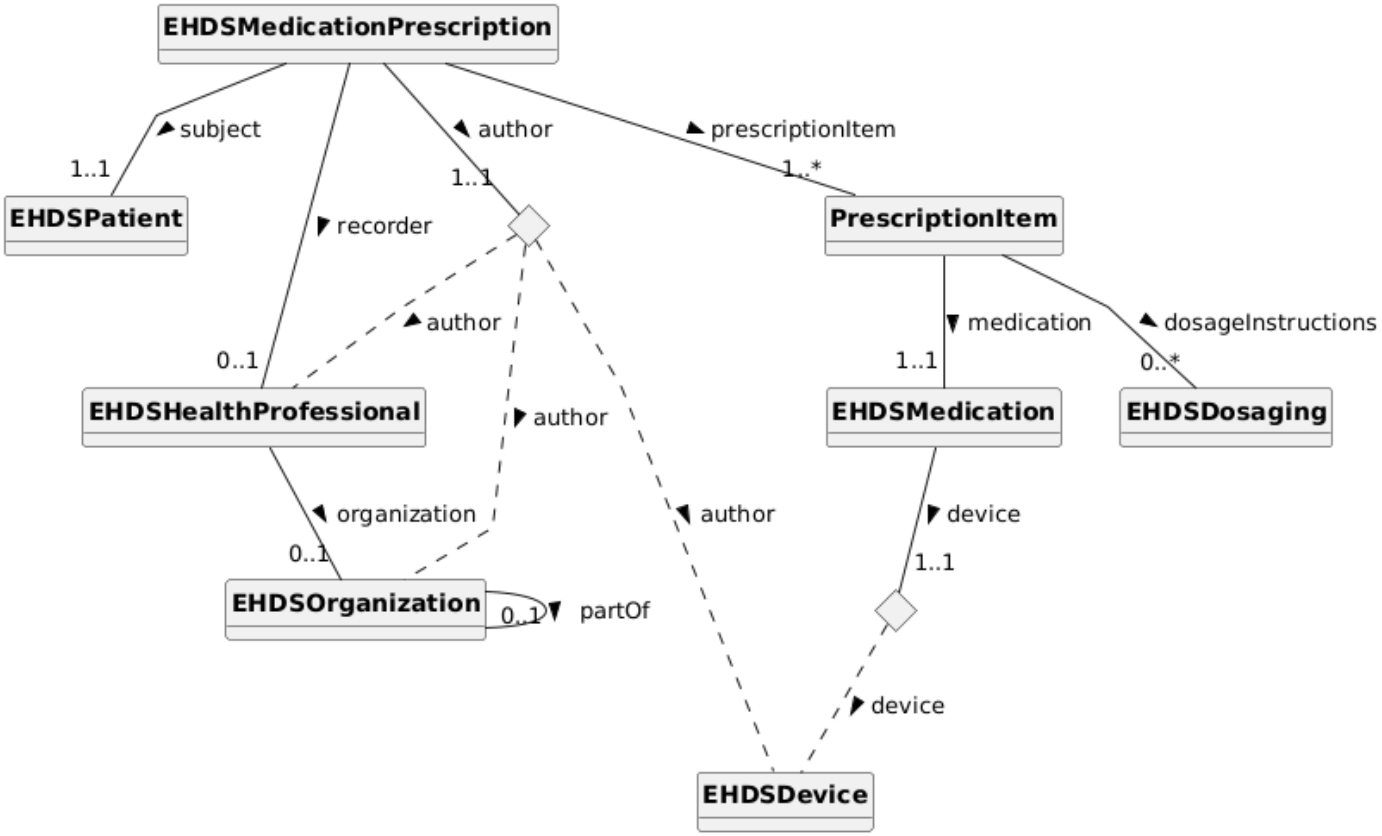


Figure 4. Medication prescription overview.

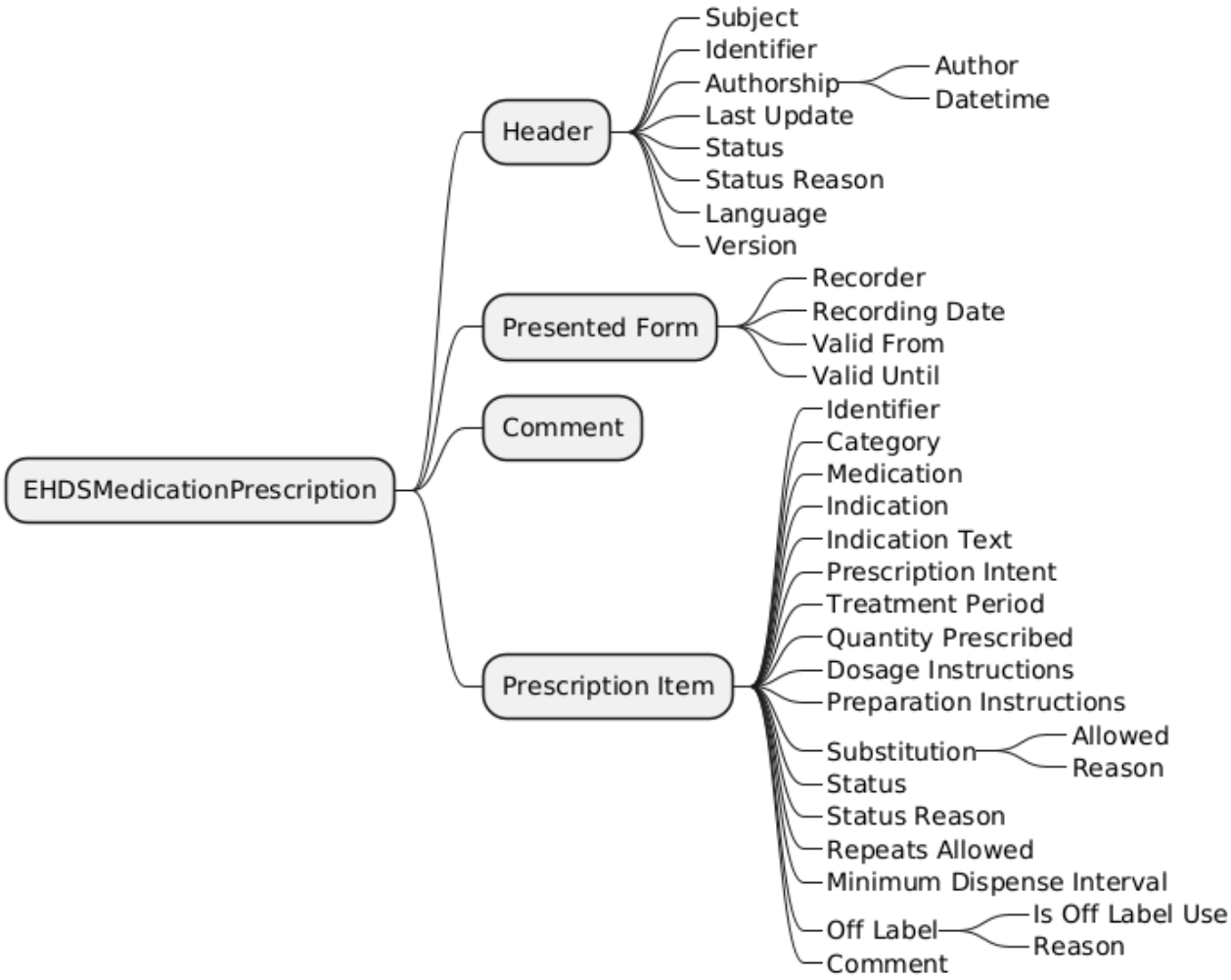


Figure 5. Medication prescription logical model.

8.4.2. Medication dispense and Dispense decline

Medication dispense and Dispense decline models are two models, both representing a variation of a dispense record.

The medication dispense model (see EHDSMedicationDispense) represents electronic dispensations as referred to in EHDS Article 14 and Annex II 3. The medication dispense model shares part of its header with the common header facilitating common metadata between priority categories. In addition to the common header elements, the medication dispense model shares common models for patient, health professional, organization (for e.g. pharmacies) and devices (e.g. dispensing devices). The medication and dosaging models are described here and are reused in other priority category models.

7.3.2.2

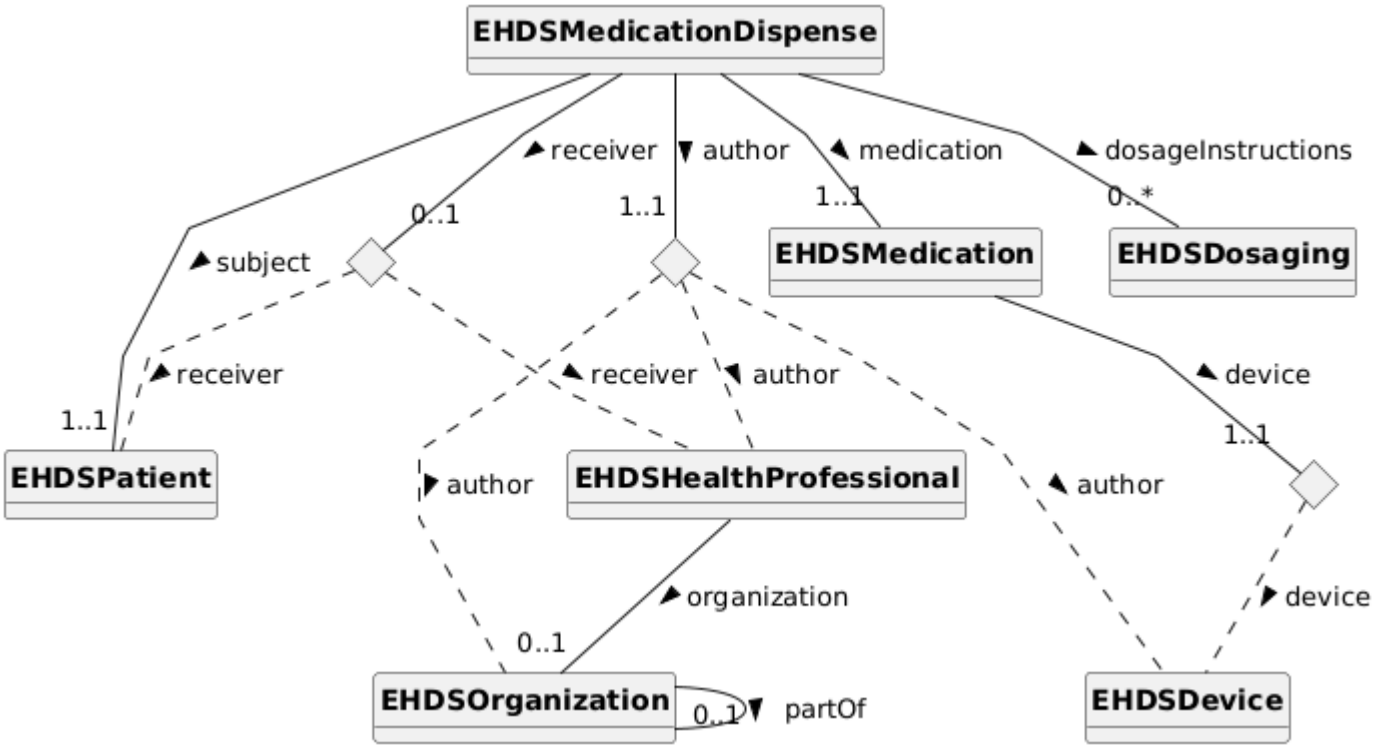


Figure 6. Medication dispense overview.

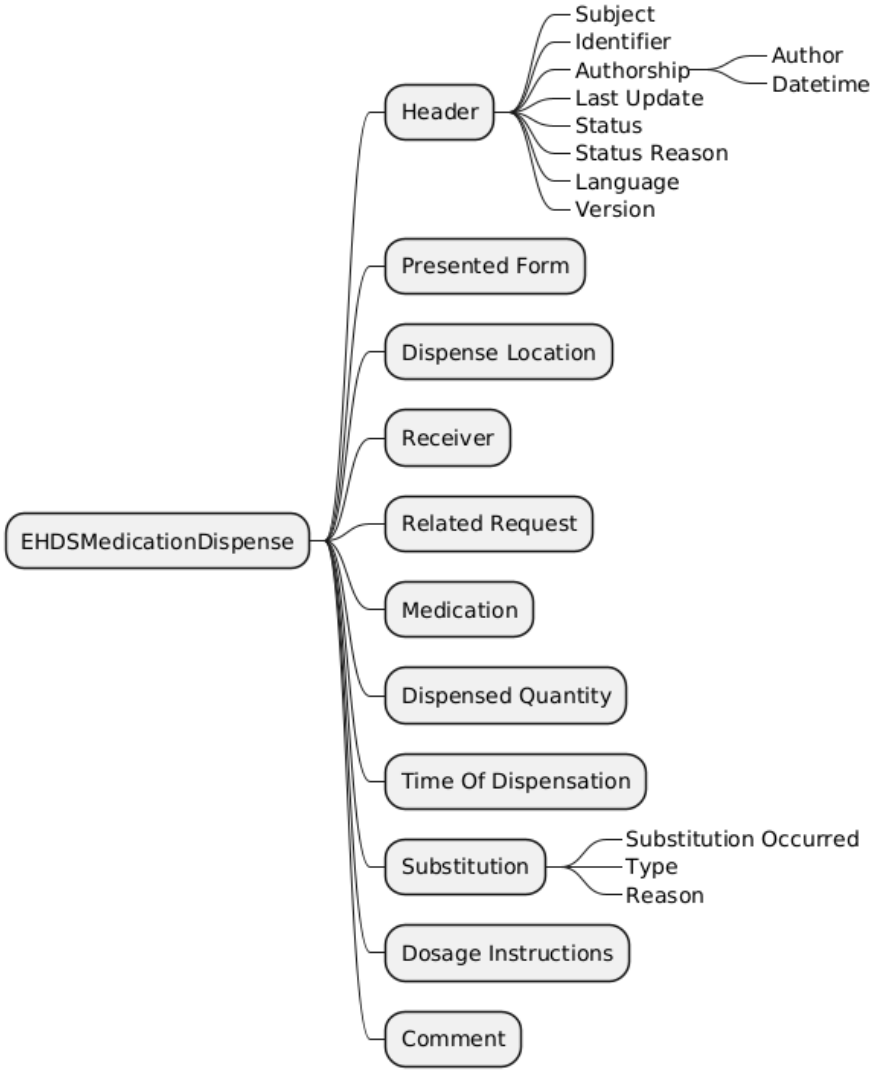
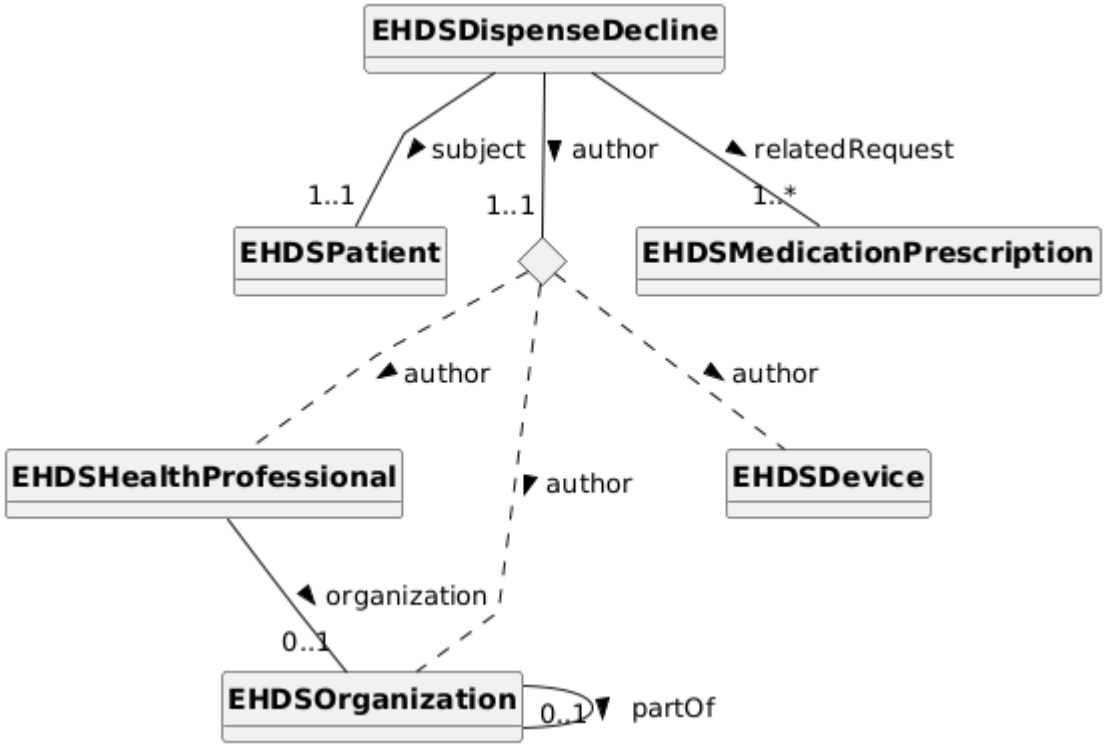


Figure 7. Medication dispense logical model.

A dispense can also be declined by the dispenser (see 7.3.2.2). In this case, no medication is handed over to the receiver. EHDSDispenseDecline model represents the data set communicated back to the health professional about the fact of not being able to dispense the product.



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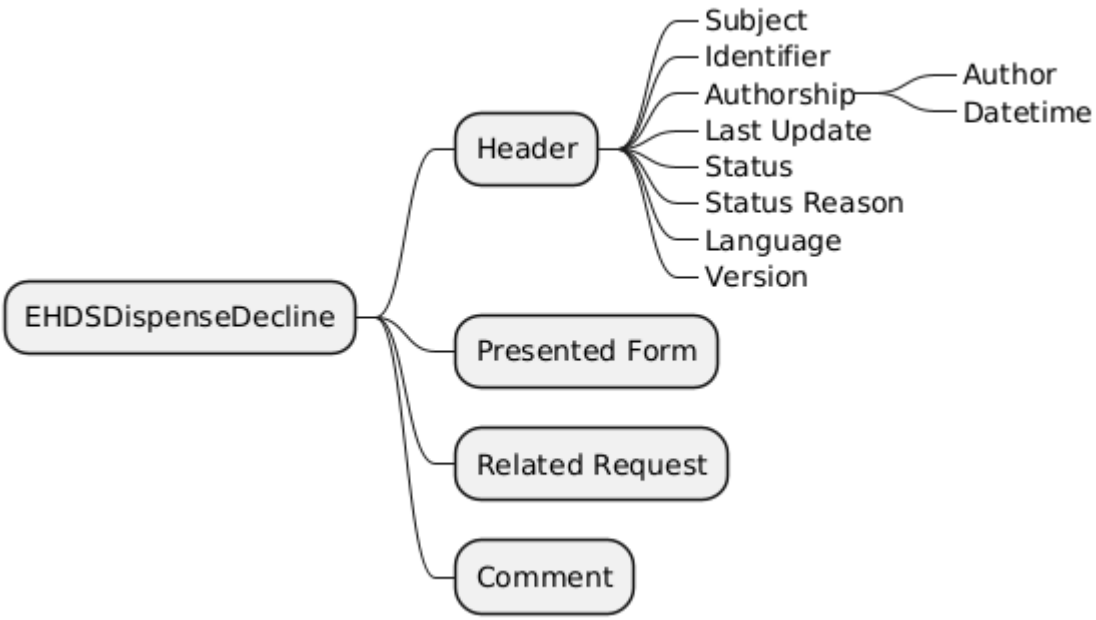
1086 **Figure 8 Medication dispense decline overview**



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1088 **Figure 9 Dispense decline logical model**

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1091 ## 8.4.3. Medication

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Medication model (see EHDSMedication) provides a flexible data set structure for representing medication data in different ways and on a different granularity level (see more in 8.3.1 Medication concepts).

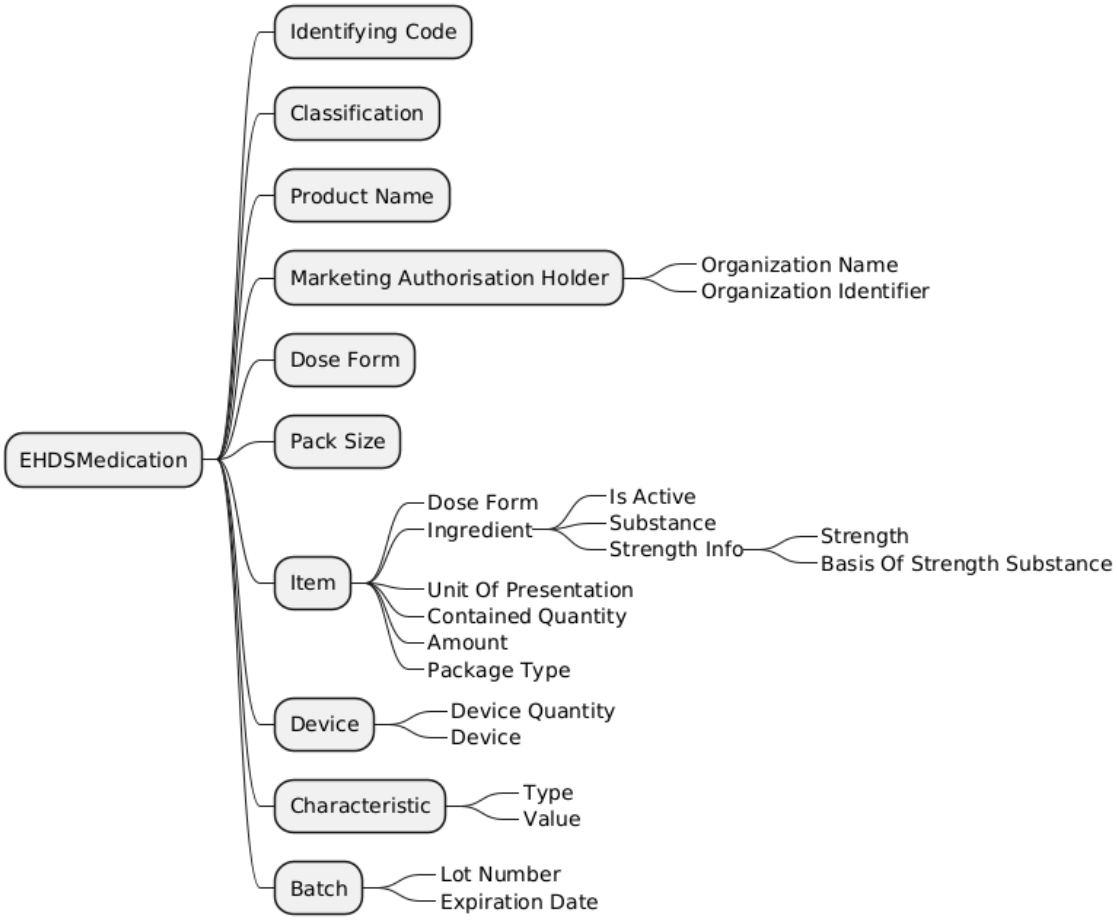

Figure 10. Medication logical model.

8.4.4. Dosaging

Dosaging model (see EHDSDosaging) represents a combination of dosage and timing of the expected administration events.

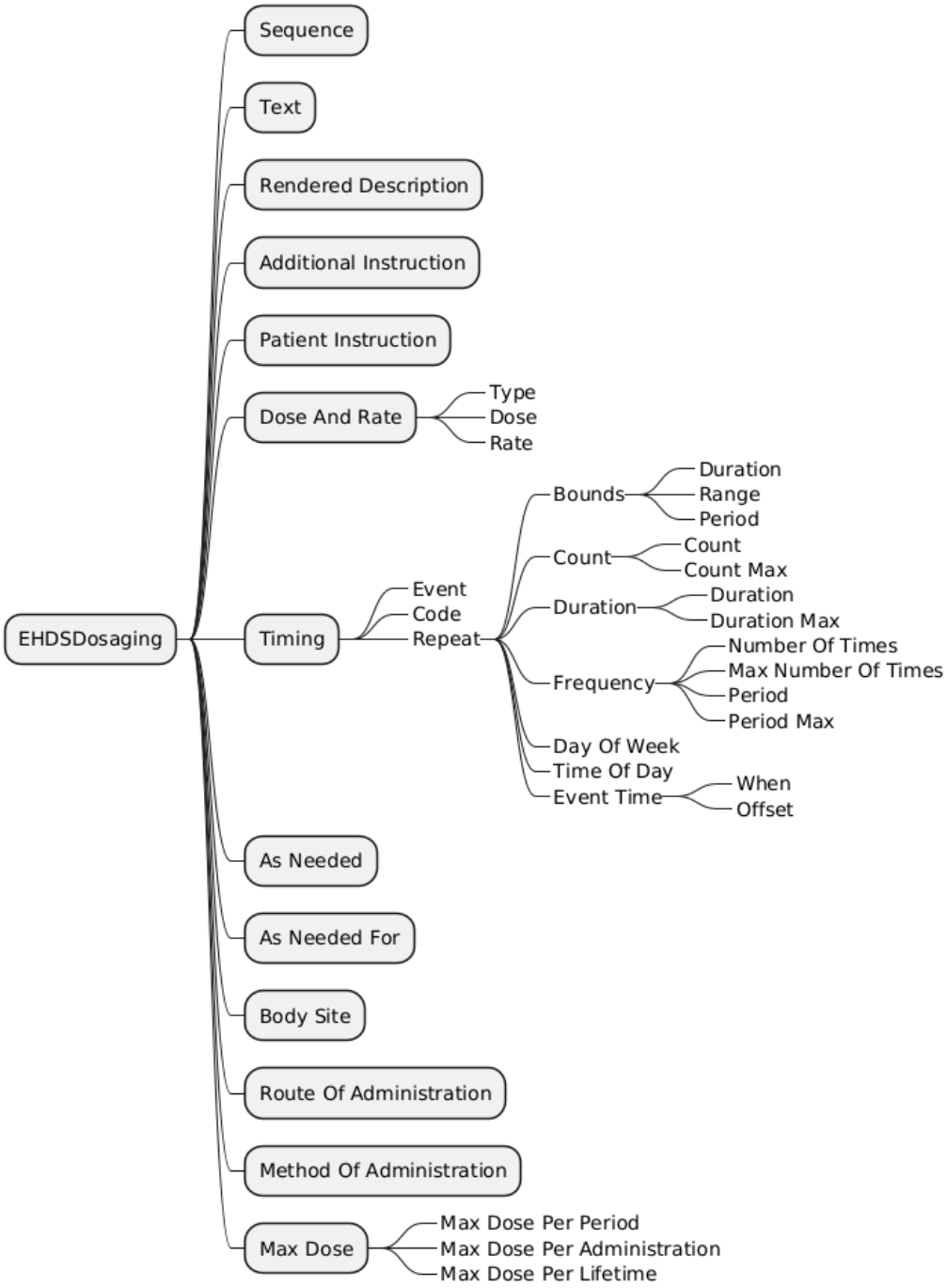

Figure 11. Dosaging logical model.

8.4.5. Dataset descriptions

Note that the numbers presented in the first column are not to be seen as unique references to the data elements and are not valid outside the scope of this deliverable. For example, they do **not** correspond to the data element codes used in the eHealth Network guidelines.

The following tables are automatically derived from the Xt-EHR Logical Information Models.

Mapping from the logical model data elements to FHIR profiles is provided in the HL7 Europe FHIR implementation guides (see 8.6).

8.4.5.1. Medication prescription table

Table 6. Medication prescription (EHDSMedicationPrescription)

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
A.1	.header	Header	Prescription header	Prescription header data elements	Base	1..*	
A.1.1	..subject	Subject	The person for whom the medication is prescribed/ordered. [Used for searching]	Patient/subject information	EHDSPatient	1..1	
A.1.2	..identifier	Identifier	Business identifier(s) for the prescription. [Used for searching]	Business identifier for the object	Identifier	0..*	
A.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*	
A.1.3.1	…author	Author	The prescriber, the person who made the prescription, and who takes the responsibility of the treatment. [Used for searching]	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganization, EHDSDevice	1..1	
A.1.3.2	…datetime	Datetime	Time of issuing (signing) the prescription by health care professional. [Used for searching]	Date and time of the issuing the document/resource by its author.	dateTime	1..1	
A.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1	
A.1.5	..status	Status	Status of the prescription, this should not be status of treatment.	Status of the resource	CodeableConcept	1..1	

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
			For multi-item prescription, the status of prescription is often related to statuses of single lines. In case of single-item prescriptions, the status for line is usually the status of prescription. [Used for searching]				
A.1.6	..statusReason	Status Reason	Reason for the current status of prescription, for example the reason why the prescription was made invalid or why the prescription was changed from previous	Reason for the current status of the resource.	CodeableConcept, string	0..1	
A.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
A.1.8	..version	Version	Version	Business version of the resource.	string	0..1	
A.2	.presentedForm	Presented Form	Entire prescription as issued. Various formats could be provided, PDF format is recommended.	A narrative easy-to-read representation of the full dataset, e.g. PDF-version of a document	EHDSAttachment	0..*	
A.2.1	..recorder	Recorder	The recorder of the prescription/draft in the information system	The recorder of the prescription/draft in the information system	EHDSHealthProfessional	0..1	
A.2.2	..recordingDate	Recording Date	Time of authoring the prescription/draft in the information system	Time of authoring the prescription/draft in the information system	dateTime	0..1	
A.2.3	..validFrom	Valid From	Effective date of the prescription. The prescription is not dispensable before this date. In most cases this information repeats issueDate. [Used for searching]	Effective date of the prescription. The prescription is not dispensable before this date. In most cases this information repeats issueDate. [Used for searching]	dateTime	0..1	

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
A.2.4	..validUntil	Valid Until	The validity period end date. The prescription is not dispensable after this date. [Used for searching]	The validity period end date. The prescription is not dispensable after this date. [Used for searching]	dateTime	0..1	
A.3	.comment	Comment	Additional information or comments	Additional information or comments	string	0..*	
A.4	.prescriptionItem	Prescription Item	Prescription line for one medication. In many countries, only one item is allowed. In case multiple medications are allowed, all lines need to be authored together.	Prescription line for one medication. In many countries, only one item is allowed. In case multiple medications are allowed, all lines need to be authored together.	Base	1..*	
A.4.1	..identifier	Identifier	Identifier for a single item on prescription, if exists. In case of single-item prescription, this identifier is typically the same as prescription identifier.	Identifier for a single item on prescription, if exists. In case of single-item prescription, this identifier is typically the same as prescription identifier.	Identifier	0..1	
A.4.2	..category	Category	Category or categories of prescription. For example type of reimbursement, or type of prescription (e.g. hospital, private, etc).	Category or categories of prescription. For example type of reimbursement, or type of prescription (e.g. hospital, private, etc).	CodeableConcept	0..*	
A.4.3	..medication	Medication	Prescribed product, branded, generic, virtual, extemporal, etc	Prescribed product, branded, generic, virtual, extemporal, etc	EHDSMedication	1..1	
A.4.4	..indication	Indication	Reason for the prescription (typically diagnosis, or a procedure)	Reason for the prescription (typically diagnosis, or a procedure)	CodeableConcept, EHDSCondition	0..*	
A.4.5	..indicationText	Indication Text	Reason for the prescription in textual form. This might not be allowed by some implementations.	Reason for the prescription in textual form. This might not be allowed by some implementations.	string	0..1	
A.4.6	..prescriptionIntent	Prescription Intent	Intent of the prescription - prophylaxis, treatment, anesthesia, etc	Intent of the prescription - prophylaxis, treatment, anesthesia, etc	CodeableConcept	0..1	

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
A.4.7	..treatmentPeriod	Treatment Period	Period over which the medication is to be taken (in case of multiple dosaging schemes, this would be the overall period of all dosages.)	Period over which the medication is to be taken (in case of multiple dosaging schemes, this would be the overall period of all dosages.)	Period	0..1	
A.4.8	..quantityPrescribed	Quantity Prescribed	Overall quantity of prescribed product (e.g number of packages or number of tablets).	Overall quantity of prescribed product (e.g number of packages or number of tablets).	Quantity	0..1	UCUM, EDQM Standard Terms
A.4.9	..dosageInstructions	Dosage Instructions	Dosaging and administration instructions	Dosaging and administration instructions	EHDSDosaging	0..*	
A.4.10	..preparationInstructions	Preparation Instructions	Additional instructions about preparation or dispense	Additional instructions about preparation or dispense	string	0..1	
A.4.11	..substitution	Substitution	Whether and which type of substitution is allowed for this medication treatment item	Whether and which type of substitution is allowed for this medication treatment item	Base	0..1	
A.4.11.1	…allowed	Allowed	Whether and to what extent substitution is allowed.	Whether and to what extent substitution is allowed.	boolean, CodeableConcept	0..1	
A.4.11.2	…reason	Reason	Reason for the substitution requirement (e.g. Biological product, Patient allergic to an excipient in alternative products, etc)	Reason for the substitution requirement (e.g. Biological product, Patient allergic to an excipient in alternative products, etc)	CodeableConcept, string	0..1	
A.4.12	..status	Status	Status of a single item of a multi-item prescription. In case of single-item prescriptions, the status of prescription has the same meaning as the status of the item.	Status of a single item of a multi-item prescription. In case of single-item prescriptions, the status of prescription has the same meaning as the status of the item.	CodeableConcept	1..1	
A.4.13	..statusReason	Status Reason	Reason for the current status of prescription, for example the reason why the prescription was made invalid or why the	Reason for the current status of prescription, for example the reason why the prescription was made invalid or why the prescription was changed from previous	CodeableConcept, string	0..1	

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
			prescription was changed from previous				
A.4.14	..repeatsAllowed	Repeats Allowed	Number of refills authorized	How many times the prescription item can be dispensed in addition to the original dispense.	integer	0..1	
A.4.15	..minimumDispenseInterval	Minimum Dispense Interval	Minimum Dispense Interval	If a prescription allows for repeated dispensations, the interval between dispensations shall be stated here.	Quantity	0..1	
A.4.16	..offLabel	Off Label	Indicates that the prescriber has knowingly prescribed the medication for an indication, age group, dosage, or route of administration that is not approved by the regulatory agencies and is not mentioned in the prescribing information for the drug	Indicates that the prescriber has knowingly prescribed the medication for an indication, age group, dosage, or route of administration that is not approved by the regulatory agencies and is not mentioned in the prescribing information for the drug	Base	0..1	
A.4.16.1	…isOffLabelUse	Is Off Label Use	Indicates off-label use. Must be 'true' when .reason is provided.	Indicates off-label use. Must be 'true' when .reason is provided.	boolean	1..1	
A.4.16.2	…reason	Reason	Reason or related clarification for off-label use	Reason or related clarification for off-label use	CodeableConcept, string	0..*	
A.4.17	..comment	Comment	Additional information or comments	Additional information or comments	string	0..*	

8.4.5.2. Medication dispense table

Table 7. Medication dispense (EHDSMedicationDispense)

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
B.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..*	
B.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1	
B.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*	
B.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*	
B.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganization, EHDSDevice	1..1	
B.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1	
B.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1	
B.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1	
B.1.6	..statusReason	Status Reason	Reason for the current status of the resource.	Reason for the current status of the resource.	CodeableConcept, string	0..1	
B.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
B.1.8	..version	Version	Version	Business version of the resource.	string	0..1	
B.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full dataset, e.g. PDF-version of a document	A narrative easy-to-read representation of the full dataset, e.g. PDF-version of a document	EHDSAttachment	0..*	
B.3	.dispenseLocation	Dispense Location	Location of dispense	Location of dispense	EHDSLocation	0..1	
B.4	.receiver	Receiver	Identification of the person who received the dispensed medication, especially when it was not the patient	Identification of the person who received the dispensed medication, especially when it was not the patient	EHDSPatient, EHDSHealthProfessional, EHDSRelatedPerson	0..1	

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
B.5	.relatedRequest	Related Request	Identifier of the prescription or prescription item the dispense is related to	Identifier of the prescription or prescription item the dispense is related to	Identifier	0..*	
B.6	.medication	Medication	Exact dispensed product	Exact dispensed product	EHDSMedication	1..1	
B.7	.dispensedQuantity	Dispensed Quantity	Number of dispensed packages if the pack size is known, or number of smaller items/units	Number of dispensed packages if the pack size is known, or number of smaller items/units	Quantity	1..1	UCUM, EDQM Standard Terms
B.8	.timeOfDispensation	Time Of Dispensation	Date and time of dispensation	Date and time of dispensation	dateTime	1..1	
B.9	.substitution	Substitution	Indicated whether substitution was made by the dispenser	Indicated whether substitution was made by the dispenser	Base	0..1	
B.9.1	..substitutionOccurred	Substitution Occurred	Indicated whether substitution was made by the dispenser	Indicated whether substitution was made by the dispenser	boolean	1..1	
B.9.2	..type	Type	What kind of substitution was made by the dispenser	What kind of substitution was made by the dispenser	CodeableConcept	0..1	
B.9.3	..reason	Reason	Reason why the substitution was made or why the expected substitution was not made.	Reason why the substitution was made or why the expected substitution was not made.	CodeableConcept	0..*	
B.10	.dosageInstructions	Dosage Instructions	Dosaging and administration instructions	Dosaging and administration instructions	EHDSDosaging	0..*	
B.11	.comment	Comment	Additional information or comments	Additional information or comments	string	0..*	

8.4.5.3. Dispense decline table

Table 8 Dispense decline (EHDSDispenseDecline)

Code	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
C.1	.header	Header	Common header for all patient-related data	Common header for all patient-related data	Base	1..*	
C.1.1	..subject	Subject	Subject	Patient/subject information	EHDSPatient	1..1	
C.1.2	..identifier	Identifier	Business identifier for the object	Business identifier for the object	Identifier	0..*	
C.1.3	..authorship	Authorship	Authorship	Resource authoring details	Base	1..*	
C.1.3.1	…author	Author	Author	Author(s) by whom the resource was/were authored. Multiple authors could be provided.	EHDSHealthProfessional, EHDSOrganization, EHDSDevice	1..1	
C.1.3.2	…datetime	Datetime	Date and time of authoring/issuing	Date and time of the issuing the document/resource by its author.	dateTime	1..1	
C.1.4	..lastUpdate	Last Update	Date and time of the last update to the resource	Date and time of the last update to the document/information	dateTime	0..1	
C.1.5	..status	Status	Status of the resource	Status of the resource	CodeableConcept	1..1	
C.1.6	..statusReason	Status Reason	Reason for not dispensing the medication	Reason for the current status of the resource.	CodeableConcept, string	1..1	
C.1.7	..language	Language	Language	Language in which the resource is written. Language is expressed by the IETF language tag.	CodeableConcept	0..1	BCP 47
C.1.8	..version	Version	Version	Business version of the resource.	string	0..1	
C.2	.presentedForm	Presented Form	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	A narrative easy-to-read representation of the full data set, e.g. PDF-version of a document	EHDSAttachment	0..*	
C.3	.relatedRequest	Related Request	The single-item prescription or prescription line item that was declined by the dispenser. [Used for searching]	The single-item prescription or prescription line item that was declined by the dispenser. [Used for searching]	EHDSMedicationPrescription	1..*	

Code	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
C.4	.comment	Comment	Additional information about why the dispensation was declined.	Additional information about why the dispensation was declined.	string	0..1	

8.4.5.4. Medication table

Table 9 Medication (EHDSMedication)

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
D.1	.identifyingCode	Identifying Code	Identifier or code for the product (virtual product, branded product or package). If several identifiers are specified, they shall not have conflicting meanings or very different granularities.	Identifier or code for the product (virtual product, branded product or package). If several identifiers are specified, they shall not have conflicting meanings or very different granularities.	CodeableConcept, Identifier	0..*	
D.2	.classification	Classification	Classification (e.g. ATC; narcotic/psychotropic; orphan drug; etc.)	Classification (e.g. ATC; narcotic/psychotropic; orphan drug; etc.)	CodeableConcept	0..*	WHO ATC
D.3	.productName	Product Name	Name of the product (full name, invented name, other). When the product has different names, the appropriate one for the context should be used. Translations of names can be provided.	Name of the product (full name, invented name, other). When the product has different names, the appropriate one for the context should be used. Translations of names can be provided.	string	0..1	
D.4	.marketingAuthorisationHolder	Marketing Authorisation Holder	Marketing authorisation holder or manufacturer of the medicinal	Marketing authorisation holder or manufacturer of the medicinal	Base	0..1	

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
			product. Relevant for identifying the exact product.	product. Relevant for identifying the exact product.			
D.4.1	..organizationName	Organization Name	Name of the organisation holding the authorisation for marketing/mahufacturing	Name of the organisation holding the authorisation for marketing/mahufacturing	string	0..1	
D.4.2	..organizationIdentifier	Organization Identifier	Identifier of the organisation and/or its physical location	Identifier of the organisation and/or its physical location	Identifier	0..*	
D.5	.doseForm	Dose Form	Dose form(s) on a product level. Dose form for a single package item is defined below.	Dose form(s) on a product level. Dose form for a single package item is defined below.	CodeableConcept	0..1	EDQM Standard Terms
D.6	.packSize	Pack Size	Overall amount of product in one package (100ml; 20 tablets; 1 creme & 6 pessaries)	Overall amount of product in one package (100ml; 20 tablets; 1 creme & 6 pessaries)	Quantity	0..*	UCUM for units of measure. EDQM Standard Terms for units of presentation.
D.7	.item	Item	A medication item. For combination packs, this can be manufactured items with each item having its own dose form and ingredients+strengths defined	A medication item. For combination packs, this can be manufactured items with each item having its own dose form and ingredients+strengths defined	Base	0..*	
D.7.1	..doseForm	Dose Form	Dose form	Dose form	CodeableConcept	0..1	EDQM Standard Terms
D.7.2	..ingredient	Ingredient	Ingredients	Ingredients	Base	1..*	
D.7.2.1	…isActive	Is Active	Marks if the ingredient is considered an active ingredient. Typically excipients are not needed, so by default active ingredients are expected.	Marks if the ingredient is considered an active ingredient. Typically excipients are not needed, so by default active ingredients are expected.	boolean	0..1	

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
D.7.2.2	…substance	Substance	Substance	Substance	CodeableConcept	1..1	EMA SPOR SMS
D.7.2.3	…strengthInfo	Strength Info	Strength of the product - amount of substance per unit	Strength of the product - amount of substance per unit	Base	0..1	
D.7.2.3.1	….strength	Strength	Concentration or presentation strength, e.g 100mg/1ml or 500mg per 1 tablet	Concentration or presentation strength, e.g 100mg/1ml or 500mg per 1 tablet	Ratio	1..1	
D.7.2.3.2	….basisOfStrengthSubstance	Basis Of Strength Substance	Substance that the strength refers to, in case it's different from the main substance	Substance that the strength refers to, in case it's different from the main substance	CodeableConcept	0..1	EMA SPOR SMS
D.7.2.4	…unitOfPresentation	Unit Of Presentation	Unit of presentation for the manufactured item (tablet, vial, tube). Typically, the smallest countable object in the package.	Unit of presentation for the manufactured item (tablet, vial, tube). Typically, the smallest countable object in the package.	CodeableConcept	0..1	EDQM Standard Terms
D.7.3	..containedQuantity	Contained Quantity	Manufactured item quantity for liquids (3ml / 1 vial)	Manufactured item quantity for liquids (3ml / 1 vial)	Ratio	0..1	
D.7.4	..amount	Amount	Number of such manufactured items in this product (5 vials)	Number of such manufactured items in this product (5 vials)	Quantity	0..1	UCUM for units of measure. EDQM Standard Terms for units of presentation.
D.7.5	..packageType	Package Type	Type of package of the medication item	Type of package of the medication item	CodeableConcept	0..1	EDQM Standard Terms for packaging.
D.8	.device	Device	Administration device included in the product	Administration device included in the product	Base	0..*	
D.8.1	..deviceQuantity	Device Quantity	Number of such devices	Number of such devices	Quantity	1..1	

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
D.8.2	..device	Device	Device coded	Device coded	CodeableConcept, EHDSDevice	1..1	
D.9	.characteristic	Characteristic	Other features of the product	Other features of the product	Base	0..*	
D.9.1	..type	Type	A code expressing the type of characteristic	A code expressing the type of characteristic	CodeableConcept	1..1	
D.9.2	..value	Value	Description of the characteristic	Description of the characteristic	boolean, CodeableConcept, string, Quantity, dateTime, integer, decimal, Ratio	0..1	
D.10	.batch	Batch	Batch information of a medicinal product. Typically recorded during dispense or administration, rarely known or relevant for a prescription/request.	Batch information of a medicinal product. Typically recorded during dispense or administration, rarely known or relevant for a prescription/request.	Base	0..1	
D.10.1	..lotNumber	Lot Number	Batch identifier of the medicinal product	Batch identifier of the medicinal product	string	0..1	
D.10.2	..expirationDate	Expiration Date	Batch expiration date of the medicinal product.	Batch expiration date of the medicinal product.	dateTime	0..1	

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8.4.5.5. Dosaging table

Table 10 Dosaging (EHDSDosaging)

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
E.1	.sequence	Sequence	Order of the dosage instruction, in case one treatment consists of several dosaging schemes	Order of the dosage instruction, in case one treatment consists of several dosaging schemes	integer	0..1	
E.2	.text	Text	Free text usage/dosage instructions when structured dosage information is not fully provided	Free text usage/dosage instructions when structured dosage information is not fully provided	string	0..1	
E.3	.renderedDescription	Rendered Description	Text representation rendered from all dosaging data elements with a value	Text representation rendered from all dosaging data elements with a value	string	0..1	
E.4	.additionalInstruction	Additional Instruction	Coded instructions, e.g warnings to the patient, like 'may cause drowsiness' etc	Coded instructions, e.g warnings to the patient, like 'may cause drowsiness' etc	CodeableConcept	0..*	
E.5	.patientInstruction	Patient Instruction	Patient oriented instructions as free text	Patient oriented instructions as free text	string	0..1	
E.6	.doseAndRate	Dose And Rate	Amount of medication administered per one dose (= one timing)	Amount of medication administered per one dose (= one timing)	Base	0..*	
E.6.1	..type	Type	The kind of dose or rate specified (e.g calculated, ordered, etc).	The kind of dose or rate specified (e.g calculated, ordered, etc).	CodeableConcept	0..1	
E.6.2	..dose	Dose	Amount of medication per one dose. (1 tablet, 2-3 tablets, 20ml)	Amount of medication per one dose. (1 tablet, 2-3 tablets, 20ml)	Quantity, Range	0..1	
E.6.3	..rate	Rate	Time period during which one defined dose is administered (per 1 hour, per 5-10 minutes)	Time period during which one defined dose is administered (per 1 hour, per 5-10 minutes)	Ratio, Quantity, Range	0..1	

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
E.7	.timing	Timing	When medication should be administered (period, time of day, frequency, etc)	When medication should be administered (period, time of day, frequency, etc)	Base	0..1	
E.7.1	..event	Event	Exact date and/or time of the administration	Exact date and/or time of the administration	dateTime	0..*	
E.7.2	..code	Code	Timing abbreviation (AM - morning, Q4H - once in every 4 hours, BID - twice a day, etc)	Timing abbreviation (AM - morning, Q4H - once in every 4 hours, BID - twice a day, etc)	CodeableConcept	0..1	
E.7.3	..repeat	Repeat	Repetition of the administration.	Repetition of the administration.	Base	0..1	
E.7.3.1	…bounds	Bounds	Time bounds for the treatment (current dosaging scheme). Only one of the following can exist.	Time bounds for the treatment (current dosaging scheme). Only one of the following can exist.	Base	0..1	
E.7.3.1.1	….duration	Duration	Number of time units, e.g 10 days	Number of time units, e.g 10 days	Quantity	0..1	
E.7.3.1.2	….range	Range	A range of numbers of time units, 5-10 days	A range of numbers of time units, 5-10 days	Range	0..1	
E.7.3.1.3	….period	Period	Start and end date, 05.08.2023 - 10.08.2023	Start and end date, 05.08.2023 - 10.08.2023	Period	0..1	
E.7.3.2	…count	Count	Number of times to repeat, exact or range	Number of times to repeat, exact or range	Base	0..1	
E.7.3.2.1	….count	Count	Number of times (e.g ‘once’, ‘10 times’)	Number of times (e.g ‘once’, ‘10 times’)	integer	0..1	
E.7.3.2.2	….countMax	Count Max	Maximum number of times (e.g ‘maximum 10 times’)	Maximum number of times (e.g ‘maximum 10 times’)	integer	0..1	
E.7.3.3	…duration	Duration	Duration of one administration, exact or range	Duration of one administration, exact or range	Base	0..1	
E.7.3.3.1	….duration	Duration	Duration of administration (e.g ‘5 minutes’, ‘1 hour’)	Duration of administration (e.g ‘5 minutes’, ‘1 hour’)	Quantity	0..1	

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
E.7.3.3.2	….durationMax	Duration Max	Maximum duration of administration (e.g 'maximum 1 hour')	Maximum duration of administration (e.g 'maximum 1 hour')	Quantity	0..1	
E.7.3.4	…frequency	Frequency	Frequency of intake/administration (e.g 'three times a day')	Frequency of intake/administration (e.g 'three times a day')	Base	0..1	
E.7.3.4.1	….numberOfTimes	Number Of Times	Number of times per period (e.g '3 times')	Number of times per period (e.g '3 times')	integer	0..1	
E.7.3.4.2	….maxNumberOfTimes	Max Number Of Times	Maximum number of times per period (e.g. 'maximum 3 times')	Maximum number of times per period (e.g. 'maximum 3 times')	integer	0..1	
E.7.3.4.3	….period	Period	Duration to which the frequency applies (e.g '… / 1 day')	Duration to which the frequency applies (e.g '… / 1 day')	Quantity	0..1	
E.7.3.4.4	….periodMax	Period Max	Upper limit of the period (e.g … / 4-6 hours)	Upper limit of the period (e.g … / 4-6 hours)	Quantity	0..1	
E.7.3.5	…dayOfWeek	Day Of Week	The day of the week of administration, e.g Mon, Tue, etc	The day of the week of administration, e.g Mon, Tue, etc	CodeableConcept	0..*	
E.7.3.6	…timeOfDay	Time Of Day	Time of day of administration (e.g '10:00')	Time of day of administration (e.g '10:00')	time	0..*	
E.7.3.7	…eventTime	Event Time	An event the administration is bound to, e.g 'before meal', '30 min before meal'	An event the administration is bound to, e.g 'before meal', '30 min before meal'	Base	0..*	
E.7.3.7.1	….when	When	Time period or event ('before meal', 'immediately', 'morning')	Time period or event ('before meal', 'immediately', 'morning')	CodeableConcept	0..*	
E.7.3.7.2	….offset	Offset	minutes from event, before or after (?not sure how to show before/after with only positive integers)	minutes from event, before or after (?not sure how to show before/after with only positive integers)	integer	0..1	
E.7.3.8	…asNeeded	As Needed	Take as needed	Take as needed	boolean	0..1	
E.7.4	..asNeededFor	As Needed For	Take as needed for the coded reason	Take as needed for the coded reason	CodeableConcept	0..*	

No.	Path	Element	Short	Description	Datatype	Cardinality	Preferred Code System
E.8	.bodySite	Body Site	Body site of administration	Body site of administration	CodeableConcept	0..1	
E.9	.routeOfAdministration	Route Of Administration	Route of administration	Route of administration	CodeableConcept	0..1	
E.10	.methodOfAdministration	Method Of Administration	Method of administration	Method of administration	CodeableConcept	0..1	
E.11	.maxDose	Max Dose	Maximum dose for the patient	Maximum dose for the patient	Base	0..*	
E.11.1	..maxDosePerPeriod	Max Dose Per Period	Upper limit on medication per unit of time	Upper limit on medication per unit of time	Ratio	0..*	
E.11.2	..maxDosePerAdministration	Max Dose Per Administration	Upper limit on medication per one administration	Upper limit on medication per one administration	Quantity	0..1	
E.11.3	..maxDosePerLifetime	Max Dose Per Lifetime	Upper limit on medication per lifetime of the patient	Upper limit on medication per lifetime of the patient	Quantity	0..1	

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8.5. Dataset search parameters

For each dataset, the following data elements have been selected to be required for searching health data in EHR systems, i.e. EHR systems SHALL allow search of medication prescription and dispense using the parameters below and should return matching values.

8.5.1. Medication prescription search parameters

Table 11 Medication prescription search parameters

No.	Data Element
A.1.1	Subject
A.1.2	Identifier (of prescription)
A.4.1	Identifier (of prescription item)
A.1.3.1	Author
A.1.3.2	Datetime
A.1.5	Status (of prescription)
A.2.3	Valid From
A.2.4	Valid Until
A.4.12	Status (of prescription item)

8.5.2. Medication dispense search parameters

Table 12 Medication dispense search parameters

No.	Data Element
B.1.1	Subject
B.1.3.1	Author
B.1.3.2	Datetime
B.1.5	Status
B.1.2	Identifier
B.5	RelatedRequest

8.6. FHIR Implementation Guide

HL7 Europe FHIR Implementation Guide for Medication Prescription and Dispense is a result of several EU projects working together in a joint working group with HL7 Europe, IHE, and volunteering stakeholders. The implementation guide is provided as a set of two functionally identical guides:

- FHIR R4 version
- FHIR R5 version

The implementation guide includes:

- eHealth Network guidelines datasets as logical models;
- reference to Xt-EHR logical information models and mappings from the model elements to FHIR profiles (for R4 and R5 versions both);
- HL7 FHIR data exchange profiles for Medication, MedicationRequest (prescription) and MedicationDispense (dispensation);
- Example instances for different profiles and different use cases;
- Guidance on how to handle multi-item prescriptions in HL7 FHIR standard;
- Example value sets for data elements' terminology bindings, including relevant eHDSI value sets;
- Narrative terminology considerations and overview of medication concepts representation in different terminologies and prescription systems.

HL7 Europe FHIR IG for Medication Prescription and Dispense uses the following dependencies that allow using content or restrictions from upstream implementation guides:

- HL7 Europe Base FHIR IG (common European profiles for Patient, Practitioner, Organization, etc);
- HL7 Europe Extensions (all extensions for EHDS use cases are defined in one implementation guide to allow other use cases as well as national implementations use the centrally defined extensions without complications);
- IHE Medication Prescription and Dispense profile (includes similar global content, and introduces extensions reused by HL7 Europe's guide).

HL7 Europe FHIR implementation guides are considered an integral part of this deliverable. However, in addition to the Xt-EHR stakeholder consultation procedures, they also undergo the regular HL7 Europe balloting process.

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9. ANNEX

9.1. Provenance of datasets' requirements

The requirements for the datasets (see 8.4) have been collected from a number of sources presented above (see chapter 6).

The columns of the requirements table are as follows:

1. Source – the source of the requirement
2. Data element – the name of the data element and its path in the logical model
3. Description
4. eHN Guideline code – the code used in the eHN Guideline for the corresponding element
5. eHN Guideline element – the name of the data element in the eHN Guideline
6. MyHealth@EU Requirements Catalogue element – the name of the data element
7. Basic or Extended in MyHealth@EU Requirements Catalogue
8. Mandatory (M), Required (R), or Optional (O) – in MyHealth@EU Requirements Catalogue

In MyHealth@EU the following definitions apply:

- Basic: the section must be present in the document
- Extended: the section can be completely omitted
- Mandatory: when the section is provided, the data element must be provided
- Required: when the section is provided, the data element must be provided, although exceptional justifications can be provided

The sources of requirements have been prioritized as follows below. The eHN Guidelines have been adopted by the Member States and is thus given the highest priority. The numbers below are also used as references in the tables below.

1. eHN ePrescription and eDispensation Guideline version 3.1
2. eHN Patient Summary Guideline version 3.4
3. eHN Hospital Discharge Report Guideline version 1.1
4. MyHealth@EU Requirements Catalogue version 8.x
5. CEN and ISO Standards
    a. ISO/DIS 17523:2024 *Requirements for electronic prescriptions*
    b. ISO/TS 19293:2018 *Requirements for a record of a dispense of a medicinal product*
    c. ISO 11615:2017 *Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*
    d. ISO/TS 17251:2023 *Business requirements for a syntax to exchange structured dose information for medicinal products*
6. IHE Medication Prescription and Dispense
7. Xt-EHR Deliverable 5.2 Technical requirements for EEHRxF metadata

1210 **Table 13. Medication prescription data elements and sources of requirements (EHDSMedicationPrescription)**

Source	No.	Element	eHN guideline Code	eHN Guideline element	MyHealth@EU Requirements Catalogue	MyHealth@EU Basic / Extended	MyHealth@EU Optionality
7	A.1	Header					
1	A.1.1	Subject	A.1.1	Patient administrative data	Patient Identification, Personal Information	BASIC	R, M
1	A.1.2	Identifier	A.1.2.1	Identifier of the Prescription	Prescription Identifier	BASIC	R
7	A.1.3	Authorship					
1	A.1.3.1	Author	A.1.3	Identification of the prescribing health professional	HP Identifier	BASIC	R
1	A.1.3.2	Datetime	A.1.2.2	Issue date	Date of issue of the prescription	BASIC	R
7	A.1.4	Last Update					
5a	A.1.5	Status					
6	A.1.6	Status Reason					
7	A.1.7	Language					
7	A.1.8	Version					
7	A.2	Presented Form					
6	A.2.1	Recorder					
6	A.2.2	Recording Date					
6	A.2.3	Valid From					
1	A.2.4	Valid Until	A.1.5.8	Prescription expiry date			
6	A.3	Comment					
6	A.4	Prescription Item					
1	A.4.1	Identifier					
6	A.4.2	Category					
1	A.4.3	Medication	A1.4	Identification of the prescribed product	Medicinal Product Description	BASIC	R, M

Source	No.	Element	eHN guideline Code	eHN Guideline element	MyHealth@EU Requirements Catalogue	MyHealth@EU Basic / Extended	MyHealth@EU Optionality
1	A.4.4	Indication	A.1.5.10	Reason for prescription			
1	A.4.5	Indication Text	A.1.5.10	Reason for prescription			
2	A.4.6	Prescription Intent	A.2.4.1.2	Intended use			
1	A.4.7	Treatment Period	A.1.5.5, A.1.5.6	Duration of treatment & Starting date of therapy	Date of onset of treatment, Date of end of treatment	BASIC	R
1	A.4.8	Quantity Prescribed	A.1.5.2	Quantity of prescribed product	Number of packages	BASIC	O
1	A.4.9	Dosage Instructions	A.1.5.3	Dose regimen	Posology Instructions	BASIC	O
5a	A.4.10	Preparation Instructions			Advise to the dispenser	EXTENDED	O
1	A.4.11	Substitution	A.1.5.11	Substitution	Substitution	EXTENDED	O
1	A.4.11.1	Allowed	A.1.5.12	Substitution	Substitution	EXTENDED	O
1	A.4.11.2	Reason	A.1.5.13	Substitution	Substitution	EXTENDED	O
6	A.4.12	Status					
6	A.4.13	Status Reason					
1	A.4.14	Repeats Allowed	A.1.5.9	Repeats			
6	A.4.15	Minimum Dispense Interval					
1	A.4.16	Off Label	A.1.5.10	Reason for prescription			
1	A.4.16.1	Is Off Label Use	A.1.5.10	Reason for prescription			
1	A.4.16.2	Reason					
6	A.4.17	Comment					

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1212 **Table 14. Medication dispense data elements and sources of requirements (EHDSMedicationDispense)**

Source	No.	Element	eHN guideline Code	eHN Guideline element	MyHealth@EU Requirements Catalogue	MyHealth@EU Basic / Extended	MyHealth@EU Optionality
7	B.1	Header					
1	B.1.1	Subject	A.1.1	Patient administrative data	Patient Identification, Patient Personal Information	BASIC	R, M
5b	B.1.2	Identifier			Dispensation Identifier	BASIC	M
7	B.1.3	Authorship					
1	B.1.3.1	Author	B.1.1-3	Identifier and name of the dispenser	HP Identification, HP Personal Information	BASIC	R, M
1	B.1.3.2	Datetime					
7	B.1.4	Last Update					
6	B.1.5	Status					
6	B.1.6	Status Reason					
7	B.1.7	Language					
7	B.1.8	Version					
7	B.2	Presented Form					
6	B.3	Dispense Location	B.1.4-6	Identifier of the pharmacy	Facility (Pharmacy) Identification	BASIC	R
6	B.4	Receiver					
1	B.5	Related Request	B.1.7	Identifier of the prescription	Prescription Identifier	BASIC	R, M
1	B.6	Medication	B.1.8	Medicinal product	Medicinal Product	BASIC	M
1	B.7	Dispensed Quantity	B.1.9	Dispensed quantity	Number of packages	BASIC	M
1	B.8	Time Of Dispensation	B.1.10	Dispensation date	Date of the dispensed medicine event	BASIC	M
1	B.9	Substitution	B.1.11	Substitution	Substitution	BASIC	When a substitution has occurred, the data

Source	No.	Element	eHN guideline Code	eHN Guideline element	MyHealth@EU Requirements Catalogue	MyHealth@EU Basic / Extended	MyHealth@EU Optionality
							element MUST be provided.
1	B.9.1	Substitution Occurred	B.1.11	Substitution	Substitution	BASIC	When a substitution has occurred, the data element MUST be provided.
6	B.9.2	Type					
1	B.9.3	Reason	B.1.13	Substitution			
5b	B.10	Dosage Instructions					
6	B.11	Comment					

The Dispense decline use case is not explicitly mentioned in the eHealth Network guidelines or MyHealth@EU and thus there is no direct correspondence presented here. The Dispense decline use case is a variation of the dispensing use case, and thus, data elements are shared with the logical model for Medication dispense.

Table 15. Medication data elements and sources of requirements (EHDSMedication)

Source	No.	Element	eHN guideline Code	eHN Guideline element	MyHealth@EU Requirements Catalogue	MyHealth@EU Basic / Extended	MyHealth@EU Optionality
1	C.1	Identifying Code	A.1.4.2	Identifier of the medicinal product	Medicinal Product identifier	BASIC	O
1	C.2	Classification	A.1.4.5	Product classification	Medicinal Product Classification	BASIC	O

Source	No.	Element	eHN guideline Code	eHN Guideline element	MyHealth@EU Requirements Catalogue	MyHealth@EU Basic / Extended	MyHealth@EU Optionality
1	C.3	Product Name	A.1.4.1	Name of the medicinal product	Medicinal Product Brand Name	BASIC	O
1	C.4	Marketing Authorisation Holder	A.1.4.3	Marketing authorisation holder	Marketing Authorization Holder of the prescribed medicinal product	BASIC	O
1	C.4.1	Organization Name	A.1.4.3	Marketing authorisation holder			
1	C.4.2	Organization Identifier	A.1.4.3	Marketing authorisation holder			
1	C.5	Dose Form	A.1.4.6	Pharmaceutical dose form(s)	Pharmaceutical Dose Form	BASIC	M
1	C.6	Pack Size	A.1.4.9	Pack size	Package size	BASIC	R
5c	C.7	Item					
1	C.7.1	Dose Form	A.1.4.6	Pharmaceutical dose form(s)	Pharmaceutical Dose Form	BASIC	M
1	C.7.2	Ingredient	A.1.4.4	Active substance(s)			
1	C.7.2.1	Is Active	A.1.4.4	Active substance(s)	Active Ingredient Role(s)	BASIC	M
1	C.7.2.2	Substance	A.1.4.4	Active substance(s)	Active Ingredient(s)	BASIC	M
1	C.7.2.3	Strength Info	A.1.4.4.1	Strength of the active substance(s)	Active Ingredient Strength(s)	BASIC	R
1	C.7.2.3.1	Strength	A.1.4.4.5	Strength of the active substance(s)			
1	C.7.2.3.2	Basis Of Strength Substance	A.1.4.4.6	Strength of the active substance(s)			
1	C.7.2.4	Unit Of Presentation	A.1.4.4.7	Strength of the active substance(s)			

Source	No.	Element	eHN guideline Code	eHN Guideline element	MyHealth@EU Requirements Catalogue	MyHealth@EU Basic / Extended	MyHealth@EU Optionality
1	C.7.3	Contained Quantity	A.1.4.9	Pack size	Package size	BASIC	Required
1	C.7.4	Amount	A.1.4.9	Pack size	Package size	BASIC	Required
1	C.7.5	Package Type	A.1.4.8	Package type			
5c	C.8	Device					
5c	C.8.1	Device Quantity					
5c	C.8.2	Device					
6	C.9	Characteristic					
6	C.9.1	Type					
6	C.9.2	Value					
2	C.10	Batch	A.2.2.1.6	Batch/lot number			
2	C.10.1	Lot Number	A.2.2.1.6	Batch/lot number			
6	C.10.2	Expiration Date					

Table 16. Medication dosaging data elements and sources of requirements (EHDSDosaging)

Source	No.	Element	eHN guideline Code	eHN Guideline element	MyHealth@EU Requirements Catalogue	MyHealth@EU Basic / Extended	MyHealth@EU Optionality
5d	D.1	Sequence					
6	D.2	Text					
7	D.3	Rendered Description					
1	D.4	Additional Instruction	A.1.5.7	Directions for use	Instructions to patient	BASIC	O
1	D.5	Patient Instruction	A.1.5.7	Directions for use	Instructions to patient	BASIC	O

Source	No.	Element	eHN guideline Code	eHN Guideline element	MyHealth@EU Requirements Catalogue	MyHealth@EU Basic / Extended	MyHealth@EU Optionality
1	D.6	Dose And Rate	A.1.5.7	Directions for use	Instructions to patient	BASIC	O
6	D.6.1	Type					
1	D.6.2	Dose	A.1.5.3.1	Number of units per intake	Number of units per intake	BASIC	O
5d	D.6.3	Rate					
4	D.7	Timing			Timing of intakes	BASIC	O
5d	D.7.1	Event					
4	D.7.2	Code			Timing of intakes	BASIC	O
4	D.7.3	Repeat			Timing of intakes	BASIC	O
4	D.7.3.1	Bounds			Timing of intakes	BASIC	O
4	D.7.3.1.1	Duration			Timing of intakes	BASIC	O
4	D.7.3.1.2	Range			Timing of intakes	BASIC	O
5d	D.7.3.1.3	Period					
5d	D.7.3.2	Count					
5d	D.7.3.2.1	Count					
5d	D.7.3.2.2	Count Max					
5d	D.7.3.3	Duration					
5d	D.7.3.3.1	Duration					
5d	D.7.3.3.2	Duration Max					
1	D.7.3.4	Frequency	A.1.5.3.2	Frequency of intakes	Frequency of intakes	BASIC	O
5d	D.7.3.4.1	Number Of Times					
5d	D.7.3.4.2	Max Number Of Times					
4	D.7.3.4.3	Period			Frequency of intakes	BASIC	O
4	D.7.3.4.4	Period Max			Frequency of intakes	BASIC	O

Source	No.	Element	eHN guideline Code	eHN Guideline element	MyHealth@EU Requirements Catalogue	MyHealth@EU Basic / Extended	MyHealth@EU Optionality
5d	D.7.3.5	Day Of Week					
5d	D.7.3.6	Time Of Day					
4	D.7.3.7	Event Time			Frequency of intakes	BASIC	O
4	D.7.3.7.1	When			Frequency of intakes	BASIC	O
4	D.7.3.7.2	Offset			Frequency of intakes	BASIC	O
5d	D.7.3.8	As Needed					
5d	D.7.4	As Needed For					
5d	D.8	Body Site					
1	D.9	Route Of Administration	A.1.5.4	Route of administration	Route of Administration	EXTENDED	O
5d	D.10	Method Of Administration					
6	D.11	Max Dose					
6	D.11.1	Max Dose Per Period					
6	D.11.2	Max Dose Per Administration					
6	D.11.3	Max Dose Per Lifetime					

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