



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

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

Stakeholder Consultation Briefing Supporting Document

2025, 12 June

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1 Stakeholder Consultation Target Groups

As part of Xt-EHR strategy, selected deliverables will undergo stakeholder consultation. This document intends to engage stakeholders with knowledge on the following topics:

- National and local implementation of electronic prescription and dispensation services
- Support of national or local electronic prescription and dispensation services
- Prescription and dispensation master data, including medicinal products and substances
- MyHealth@EU services, including cross-border electronic prescription and dispensation services
- Development or specification of Electronic Health Record (EHR) systems with prescription and dispensation functions, including vendor and health professional perspectives
- Use of EHR systems with prescription and/or dispensation functions in healthcare settings
- Health professionals' perspectives on specification and/or procurement of EHR systems

2 Overview of Work Package 6

The work in WP6 – *Electronic* prescriptions and patient summary towards EHDS – builds on previous work done by the eHealth Network, including the MyHealth@EU services. WP6 provides proposals for harmonized datasets, coding systems and values, and technical interoperability specifications for the European Electronic Health Record Exchange Format (EEHRxF) according to Article 15 of the EHDS Regulation. The proposals aim to support both national and cross-border exchange of health data.

To achieve this, two reports are developed:

- D6.1 – *Patient Summary: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems*
- D6.2 – *Electronic prescription and electronic dispensation: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems*

This document focuses on the stakeholder consultation for D6.2.

3 Overview of Deliverable 6.2 – Electronic prescription and electronic dispensation: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

D6.2 – “Electronic prescription and electronic dispensation: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems” establishes the requirements and specifications for EHR systems to support the exchange and interoperability of electronic prescriptions and electronic dispensations across the European Union.

The deliverable contains a review of relevant guidelines, specifications, and standards including eHealth Network guidelines, MyHealth@EU requirements, previous EU projects, and ISO standards.

The two major use cases the deliverable aims to support (see Chapter 7 of the deliverable) is that of (1) sharing an electronic prescription that will allow (2) the dispensation of that prescription and information about the dispensation to be shared back to relevant parties.

The deliverable includes and references to the Xt-EHR logical models and to HL7 FHIR implementation guides (IG) developed in collaboration with HL7 Europe and IHE.

4 Stakeholder feedback requested for D6.2

Here we present a set of questions deemed relevant for the consultation of this deliverable. The questions are meant to trigger comments, not all questions need to be answered, and comments not related to these specific questions are of course welcome. To ensure that the description of the EEHRxF, the functional and technical requirements and specifications are understandable to stakeholders, including healthcare providers and EHR system vendors, WP6 seeks specific feedback from consultation participants in the following areas:

01 General definitions

The document presents different definitions that were summarised for the use of this document. The main sources used for the definitions were the proposed EHDS regulation and MyHealth@EU. Other sources were used when available to complement missing definitions.

1 Feedback Requested

- Are the definitions clearly and appropriately described for the context of the deliverable document?
- What improvements would you like to propose?

02 Use Case description (chapter 7)

A number of use cases are presented divided into the main categories (1) Electronic prescription and (2) Electronic dispensation, with subsequent variations of the respective. In addition to this a third category called Adjacent topics (not use cases *per se*) is presented. As the concern of EHDS is sharing of health data, and not the healthcare processes leading up to or managing electronic prescriptions and/or dispensations, the use cases are described from a data sharing perspective.

2 Feedback Requested

- Are the use cases clearly described and relevant in their entirety?
- Are there additional use cases that should be included?
- Are the actors described relevant? Are there actors missing?
- Are there any comments on the Adjacent topics section?

03 Dataset

The datasets of the deliverable consist of data elements with a name and a description as well as additional information related to the specification of the data elements (see example below).

No.	Data Element	Description	Datatype	Cardinality	Preferred Code System
C.1.2	Classification	Classification (e.g. ATC; narcotic/psychotropic; orphan drug; etc.)	CodeableConcept	0..*	WHO ATC
C.1.3	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.	string	0..1	

In chapter 8.4, a number of tables describe the datasets of the deliverable. Dataset overviews are also provided as UML diagrams and mindmap-style diagrams to aid readers. Each table gives per data element the name, description, datatype, cardinality, and any preferred code system in case the datatype allows coded data. The tables also include numbers (No.) to present the hierarchical structure of the data elements and allow referencing to the individual data elements.

The tables presented in the deliverable are views of the logical models developed by Xt-EHR. These logical models are included in this consultation and are presented in full here <https://build.fhir.org/ig/Xt-EHR/xt-ehr-common/branches/stakeholder-consultation-D6-2/>

Following the tables with datasets are search parameters and obligations. The obligation framework is a way to express which data elements are required given a certain EHR system function, in this case a prescriber function and a dispensation function. The data elements to be used for searching personal health data is listed in chapter 8.5.

3 Feedback Requested

- Does the respective dataset include all relevant data elements?
- Are the datasets and data elements described to a sufficient level of detail?
 - Is there any ambiguous or unclear content in the descriptions for the datasets elements, please elaborate?
- Are the preferred code systems in the datasets adequate? Are there code systems missing?
- Are there any risks regarding structuring data in the proposed way?
- Are there any foreseen administrative burdens for health professionals?
- Are the search parameters (See 8.5) for the dataset adequate?

04 Implementation guide

The technical interoperability specifications were developed in collaboration between Xt-EHR and HL7 Europe based on requirements from Xt-EHR supporting EHDS implementation. These specifications are not presented in whole in the deliverable but published elsewhere. As decided by the Xt-EHR participants, the technical specifications are represented using the HL7 FHIR standard. The HL7 Europe FHIR IG for Medication Prescription and Dispense, including in this consultation, can be found here:

- <https://hl7.eu/fhir/mpd/> (R4)
- <https://hl7.eu/fhir/mpd-r5/> (R5)

3 Feedback Requested

- For which data elements would you like to see more restricted terminology bindings (what would they be)?
- Should Dosage.text be mandatory, considering the complexity and potential variations in the whole Dosage structure?
- Are the defined extensions adequate?
- Are the examples adequate and helpful? Are there specific scenarios that are not covered by examples?
- What kind of additional narrative guidance would you expect to see in the implementation guide?
- Is the mapping from logical models to FHIR profiles helpful?

5 Contacts for questions

- **For questions related to the organisation of the consultation:** please ask the representative from your country who shared the information and documents on the stakeholder consultation.
- **For questions related to D6.2 content:** please reach out to the following Xt-EHR WP6 representatives:
Task 6.2 Leaders (Swedish eHealth Agency): daniel.karlsson@ehalsomyndigheten.se,
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