#### The HL7 Europe Medication, Prescription and Dispense FHIR IG and its alignment with Xt-EHR

Webinar, 17 July 2025 16.00-17.00 CEST

**Online on Teams** 











## **The EHDS FHIR IG ecosystem**



#### An HL7 Europe webinar series 2025

The HL7 Europe Medication, Prescription and Dispense FHIR IG and its alignment with Xt-EHR Introductions

- Presenters:
  - Giorgio Cangioli, HL7 Europe
  - Daniel Karlsson, Swedish eHealth agency
  - Rutt Lindström, TEHIK, Estonia and HL7 Europe

• Facilitator: Michael Strübin, HL7 Europe



## Housekeeping

- To help ensure a successful webinar please:
  - Use the chat (for comments, questions...)
  - Use reactions/emojis during the presentations
  - Raise your hand if you'd like to speak
  - If you are invited to speak, please turn on your video and say who you are
- The webinar will be recorded.
- Link to recording and slides (in pdf) on <u>www.hl7.tv</u> will be emailed to all registered participants.
- Links on the slides can be clicked and opened on your device: try it.
- Your feedback is welcome: we will invite you to complete an online survey.



### The HL7 Europe Medication, Prescription and Dispense FHIR IG and its alignment with Xt-EHR Agenda

- Welcome, introductions, housekeeping
- Introduction of the FHIR IG ecosystem for the EDHS Giorgio Cangioli, HL7 Europe
- The Xt-EHR logical model and the EEHRxF IG for ePrescription and eDispensation Daniel Karlsson, Swedish eHealth agency
- The FHIR Medication Prescription and Dispense (MPD) IG Rutt Lindström, TEHIK, Estonia
- Discussion and Q&A
- Next steps





## Who am I

## Giorgio Cangioli Technical Lead – HL7 Europe

- Senior Consultant
- Technical Lead and Board member, HL7 Europe
- TSC and Board member, HL7 International
- Chair of the eHMSEG STF Architecture WG
- Author of several UV and EU HL7 CDA and FHIR Igs (including IPS)

## The context: EHDS Primary use



## The context: not only cross-border !







### The context: priority categories for primary use



Member States may provide by virtue of national law that additional categories of personal

The Commission is empowered to adopt delegated acts <...> by adding, modifying or removing the main characteristics of the priority categories



Medical test results, including laboratory and other diagnostic results and related reports



Discharge report



**Patient summary** 



Medical imaging studies and related imaging reports;



ePrescription/ eDispensation

## The context: several actors engaged





## The supported solution



Europe

## The HL7 FHIR IG ecosystem for EHDS

Europe



## **Collaborative Development in Motion**

- The result of a highly participatory, multistakeholder process spanning the European health ecosystem.
- Laboratory Report: 113 distinct participants from 22 countries (including USA) and EC Solution Providers [average ~30 attendees]
- MPD: 114 distinct participants from 26 countries (including USA) and EC Solution Providers [average ~30 attendees]
- HDR/EPS/Core: 160 distinct participants from 24 countries (including Sri Lanka, United Arab Emirates, Saudi Arabia and USA) and EC Solution Providers [average ~35 attendees]





My health @ EU eHealth Digital Service Infrastructure A service provided by the European Unior





# HL7 FHIR IGs overview

¢Н	IL7 <sup>°</sup> FHIR <sup>°</sup>	Patient Summary	Laboratory Results	Hospital Discharge Report	ePrescription eDispensation	Medical Imaging and reports	BASE
	Global Standard						Ø
	European Standard	WORK	٢			( )	
	European <i>"Official"</i>	(IF	IF	IF	IF	IF	IF
	European X-border	<u>_</u>	0	8			
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# Legenda - HL7 FHIR IGs overview\*





\* Extra slide added after popular demand





HL7 Europe

# HL7 FHIR IGs overview





BASE	Base and Core	Ballot Recon.	<ul> <li><u>https://hl7.eu/fhir/base/</u></li> <li>https://hl7.eu/fhir/base-r5/</li> </ul>	June 1st – June 30th 2025
×1	Laboratory Results	STU	<ul> <li>https://hl7.eu/fhir/laboratory/</li> </ul>	
	Medical Imaging and reports	Ballot Recon.	<ul> <li>https://hl7.eu/fhir/imaging-r5/</li> </ul>	June 1st – June 30th 2025
	Hospital Discharge Report	Ballot	<ul> <li>https://hl7.eu/fhir/hdr/</li> </ul>	June 15th – August 31st 2025
	ePrescription eDispensation	Ballot	<ul> <li><u>https://hl7.eu/fhir/mpd</u></li> <li>https://hl7.eu/fhir/mpd-r5/</li> </ul>	June 15th – August 31st 2025
BASE	Extensions	Ballot Recon.	https://hl7.eu/fhir/extensions/	June 1st – June 30th 2025



# HL7 FHIR IGs overview





BASE	Base and Core	Ballot Recon.	R5: 9-0-4 // R4: 11-2-0	58
\$	Laboratory Results	STU		25
	Medical Imaging and reports	Ballot Recon.	5-3-3	116
	Hospital Discharge Report	Ballot		1
	ePrescription eDispensation	Ballot		0
BASE	Extensions	Ballot Recon.	11-1-0	20

## How to provide your feedback

#### **Balloting**

the formal process that HL7 uses to review and **vote** on specifications prior to publication





#### **Specification Feedback**

the official mechanism for providing feedback about any HL7 specification



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#### **Specification Feedback**

Providing feedback during the ballot the official mechanism for providing feedback about any HL7 specification



Your review and feedback during the ballot period is essential to improve the specification quality before first publication.

Help your affiliate to determine their vote !



# **Specification Feedback**

#### https://jira.hl7.org/





# **Specification Feedback**

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				Required fields are marked	with an asterisk *
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fields marked with an aste				Issue Type*	E Change Request v 📀
	FHIR Specification Feedback (				• Technical Correction
				Default <sup>*</sup> Advanced	
Default <sup>®</sup> Advanced				<ol> <li>Submitting a C</li> </ol>	Comment
	a Change Request a change that is more than a simple Technical Correction to one of HL7's specifications.			Submitting a C	
Specification*	EU Laboratory Report (FHIR) X 🗸				
	List of all specifications that might be reviewed during ballot or otherwise have feedback provided on them. (Filters to those relevant for the issue project)				
Raised in Version	Type to search	Specification*	EU		~
	The specification release that wasofficial at the time the specification comment was raised		US Pharmaceutical Quality/Chemi	stry, Manufacturing and Contro	ols (PQ-CMC) (FHIR)
Summary*			EU Laboratory Report (FHIR)		
Related URL	The URL of the page (or better yet the specific anchor of the section) the comment relates to	Raised in Version	EU Extensions (FHIR)		
			EU Base and Core (R4) (FHIR)		
	Create another Create Cancel	Summary*	EU Base and Core (R5) (FHIR)		
			EU Extensions (R5) [deprecated] (F	HIR)	
		Related URL	EU Imaging Study Report (FHIR)		
			EU Hospital Discharge Report (FH	R)	
		Related Artifact(s)	EU Medication Prescription and D		
			EU Medication Prescription and D	spense (KS) (FHIK)	-

#### 

## **Brief pause for questions**





### The HL7 Europe Medication, Prescription and Dispense FHIR IG and its alignment with Xt-EHR Agenda

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- Discussion and Q&A
- Next steps



End

# **Rutt Lindström**

- Rutt Lindström
- Data standardisation analyst
- TEHIK Estonian eHealth agency
- HL7 Europe









## **Daniel Karlsson**

- The Swedish eHealth Agency (Ehälsomyndigheten)
- Chair of eHN Subgroup of Semantics



• HL7 Sweden



## **EU prescription timeline**



## **EEHRxF: European EHR eXchange Format**



## **The Format in EHDS**



## The Format as information assets



## Where the preparation work is done

Europe



## **Different profiles comply with The Format**

### The Format

	HL7 Europe Medication Prescription and D           Dense         Introduction - Readowit - Improved that - balactices           More Introduction - Readowit - Improved that - balactices         Readowit - Readowit - Readowit - Readowit - Antacas - Readowit - Antacas - Readowit - R	Uri 1 Ballot 1) based on PHIR (HL78: PHIRe Standard) Refr. This is the		
	Officie/URL: http://hlr.eu/fhir/mpd/ImplementationGuide/hlr.fhir.eu.mpd	Version: 0.1.0-ballot		
	Draft as of 2025-06-04 Copyright/Legal: Used by permission of HL7 Europe, all rights reserved Creative Commons I	Computable Name: H17EuMedPrescriptionDispenseIg		
	The scope of the implementation guide is <b>Hedicistic Prescription and Dispense</b> In the <b>E</b> coherent with the <b>European</b> efficientistic and preparative IDES work. This implementation guide is designed to be a field/be basis for national operflocations as well any state of the the state of the Additional information can be found in the Scope and Content section.	Background		
Crossborder				;S
eHealth Digital Service Infrastructure A service provided by the European Union			Table of C         Visition Constraints         Fragment         Search to proper Versificity           Table of C         Search to proper Versificity         Search to proper Versificity           1 Home         Table of C         Search to proper Versificity	nt Q
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## Scope according to the EHDS regulation

#### https://hl7.eu/fhir/mpd/scope.html

Electronic health data category		Main characteristics of electronic health data included under the category	
2.	Electronic prescriptions	Electronic health data constituting a prescription for a medicinal product as defined in Article 3, point (k), of Directive 2011/24/EU.	
3.	3.Electronic dispensationsInformation on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription.		
		<ul> <li>(k) 'prescription' means a prescription for a medicinal product or for a issued by a member of a regulated health profession within the med 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the in which the prescription is issued;</li> </ul>	eaning of Article

Member States shall ensure that pharmacies operating on their territories, <u>including online</u> pharmacies, are able to dispense electronic prescriptions issued in other Member States,

under the conditions laid down in Article 11 of Directive 2011/24/EU.

## **Scope according to the EHDS regulation**

The scope of EHDS requirements does not include:

- Internal healthcare prescription workflows, e.g. draft prescriptions
- Prescription repositories, i.e. how prescriptions and dispenses are managed in MSs



## **National tendencies**

- FHIR facades for existing prescription systems
- 15 A lot of work on medication overviews 10 Mostly FHIR R4, also R5 5 Answered survey Work on eP/eD FHIR Work on Medication solution List

# **Prescription List vs Medication Overview**

### **Prescription List**

Prescribed	Dosage	Dispensed product	Issue date	Prescriber
Nitrofurantoin 50mg tablet	1 tablet a day, continuously	NITROFURANTOIN ORIFARM	16.10.2023	E. Mass
Nitrofurantoin 50mg tablet	1 tablet a day, continuously	NIFURANTIN 50MG	22.06.2023	E. Mass
Nitrofurantoin 50mg tablet	1 tablet a day, continuously	NITROFURANTOIN ORIFARM	21.03.2023	E. Mass
Amoxicillin 875mg + clavulanic acid 125mg	1 tablet twice a day, 7 days	AUGMENTIN	22.12.2023	L. Gustav
Nitrofurantoin 50mg tablet	1 tablet a day, continuously	NITROFURANTOIN ORIFARM	18.01.2023	E. Mass
Nitrofurantoin 50mg tablet	1 tablet a day, continuously	NITROFURANTOIN ORIFARM	12.09.2022	E. Mass
Nitrofurantoin 50mg tablet	1 tablet a day, continuously	NITROFURANTOIN ORIFARM	08.06.2022	A. Tenn

### **Medication Overview**

Treatment	Dosage	Indication	Start date	Stock	Author
	1 tablet a day,	Cystitis		10	
Nitrofurantoin 50mg	continuously	prevention	20.10.2014	days	M. Sarkov
Amoxicillin 875mg +	1 tablet twice				
clavulanic acid 125mg	a day, 7 days	Cystitis	22.12.2023	0	L. Gustav



Treatment	Dosage	Issue date	Prescriber	
	1 tablet a day,			
Nitrofurantoin 50mg	continuously	16.10.2023	E. Mass	


# HL7 Europe / IHE Joint Working Group

- 23 calls between April 2024 and March 2025
- Over 100 participants
- Over 20 countries involved
- SDOs and projects:
  - IHE International
  - HL7 Pharmacy
  - Xt-EHR
  - xShare
  - XPanDH
  - MyHealth@EU





# Parallel work items of the joint group

## https://hl7.eu/fhir/mpd/



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This page is part of the HL7 Europe Medication Prescription and Dispense (v0.1.0-ballot: TU 
e 1 Ballot 1) based on FHIR (HL7 $\otimes$  FHIR $\otimes$  Standard) R4e 1. This is the current published version. For a full list of available versions, see the Directory of published versions?

#### 1 Home

	īcial URL: :p://hl7.eu/fhir/mpd/ImplementationGuide/hl7.fhir.eu.mpd	Version: 0.1.0-ballot
Dra	aft as of 2025-06-04	Computable Name: Hl7EuMedPrescriptionDispenseIg
Co	Converse by Logal - Used by permission of HL7 Europe, all rights recorded Creative Commons License	

#### 1.1 Scope

Europe

The scope of this implementation guide is **Medication Prescription and Dispense** in the **European** Context. It is coherent with the European eHN Guidelinest<sup>®</sup> and preparatory EHDS work.

## ScopePurposeBackground

→ European scope
→ Focuses on EHDS
→ Content profiles

## https://profiles.ihe.net/PHARM/MPD/



#### IHE MPD (Medication Prescription and Dispense)

Official URL: https://profiles.ihe.net/PHARM/MPD/ImplementationGuide/ihe.pharm.mpd	Version: 1.0.0-comment-2	
Active as of 2025-05-08	Computable Name: IHE_PHARM_MPD	
ppyright/Legal: IHE http://www.ihe.net/Governance/#Intellectual_Property		

The IHE MPD profile defines global data exchange specifications for medication prescription and dispense, in different settings and compatible with different workflows and jurisdictions.

OverviewOrganization of This Guide

## → Global scope

- → Wider focus (incl hospitals)
- → Transactions + content \_

## **MPD IG lives in an ecosystem**



## **EHDS Scope**



## **Xt-EHR Scope**



## **HL7 Europe Scope**



## HL7 Europe + IHE Joint Group Scope



## What's in the MPD IG?



This page is part of the HL7 Europe Medication Prescription and Dispense (v0.1.0-ballot: STU 2 1 Ballot 1) based on FHIR (HL7® FHIR® Standard) R4 2. This is the current published version. For a full list of available versions, see the Directory of published versions 2

### 1 Home

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Draft as of 2025-06-04	<i>Computable Name:</i> Hl7EuMedPrescriptionDispenseIg
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### 1.1 Scope

The scope of this implementation guide is **Medication Prescription and Dispense** in the **European** Context. It is coherent with the European eHN Guidelines and preparatory EHDS work.

- Scope
- Purpose
- Background

## **Data requirements from Xt-EHR**



## → Models in Xt-EHR

→ FHIR profiles for R4 & R5

→ Mappings from models to FHIR R4 and R5

> https://hl7.eu/fhir/mpd/profiles.ht ml



## **Terminology requirements still setting**



Draft as of 2025-06-04

eHN guideline & Xt-EHR preferred codesystems: EDQM, UCUM, ATC, EMA

https://hl7.eu/fhir/mpd/terminology.html

FHIR IG mostly example ValueSets

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This profile defines how to represent Medication data on ePrescription and eDispensation

Computable Name: NedicationEuMod

# **Multi-item prescription**

- 11 countries (out of 18) allow multiple items
- 4 different approaches found in national IGs
- MyHealth@EU specification allows 1 item
- Help from IHE and HL7 to provide guidance
- Multi-item dispense is rare

HI 7

Europe



https://hl7.eu/fhir/mpd/implementationnotes.html#multi-item-prescriptions

# **ISO IDMP requirement challenge**

#### 1. Example 1: Losec Control 20mg gastro-resistant tablets 1



- Any identifier works
- Data model very big
- No global terminology
- EMA SPOR for eHealth?



## **Any IDMP concept fits into Medication**

HI 7

Europe



## Support simple & complex medications

## Medication (Canifug Cremolum)

doseForm: Creme + Pessary

code: ... Ingredient item1:

Medication (creme) doseForm: vaginal creme ingredient: clotrimazole 10mg/g totalAmount: 1 tube / 20g

Ingredient item 2:

Medication (pessary) doseForm: pessary ingredient: clotrimazole 100mg totalAmount: 6 pessaries



SizeOfItem (and other extension) in <u>Medication profile</u> from IHE MPD

Medication concepts explanation in IG



# **Open topics - ideas and feedback welcome**

- Terminology expectations?
- Workflow expectations?
- API expectations (search parameters to support)?
- Minimal requirements for dosage interoperability?
- Additional guidance on any existing parts?

R4: <u>https://hl7.eu/fhir/mpd/</u>

R5: https://hl7.eu/fhir/mpd-r5/



# **Consultation and balloting**

- HL7 Europe MPD (R4 & R5): June 15 August 31 https://hl7.eu/fhir/mpd/
- Xt-EHR Stakeholders consultation: June 15 Sept 15
  - Deliverable D6.2 (Document)
  - EHDS logical models
  - HL7 Europe FHIR IG
- Agreement between Xt-EHR and HL7 Europe to reconcile results of consultation





# Xt-EHR makes the<br/>proposal to ECImplementing acts<br/>come into force

EHRs must conform to eP/eD specifications



Formalising, MS negotiations



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End

## **Next steps**

- Feedback survey: <u>https://forms.office.com/e/cmR5arVaSr</u>
- Webinar recording and slides to be posted on <u>www.hl7.tv</u>
- Get involved:
  - Open HL7 Europe consultations: Go to <u>https://hl7europe.eu/hl7-europe-opens-second-ballot-review-round-for-this-summer/</u>
  - Open Xt-EHR consultations: Go to <u>https://www.xt-ehr.eu/stakeholders-engagement/</u>
  - General for HL7 Europe: Go to https://hl7europe.eu/get-engaged/
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