SNOMED CT in Europe

22-23 MAY 2024 | BRUSSELS | ONLINE

snomed.org/snomed-ct-in-europe

CONFERENCE

European Health Data Space (EHDS)

23 MAY 2024 | 10:00 - 10:30

Marcello Melgara

eHealth International Projects Programme Manager, Università Cattolica del Sacro Cuore, Rome, Italy

HOST: SNOMED International

SUPPORTED BY: European Commission | beEU belgium24.eu

European Commission

- eHN SG on Semantic & Tech IOP
- eHMSEG Semantic Task Force
- Xt-EHR Joint Action in preparation of Implementing Acts for EHDS Regulation

EUROPEAN HEALTH DATA SPACE (EHDS)

- Define / Harmonise / Impose common rules, all over Europe to:
  - Create
  - Get
  - Share
  - Use
  - Reuse
- Health Data and Documents

➢ *The New EHDS Regulation*

- *Electronic Health Records (EHR)*
- *Electronic Health Record Services for EEHRxF*

European EHR Exchange Format (EEHRxF)

- EEHRxF:
  - Patient Summary
  - ePrescriptions / eDispensations
  - (Hospital) Discharge Reports
  - Laboratory Results and Reports
  - Medical Images/Image Studies and Image Reports
- Implementing Acts to adopt, at National and Cross-Border level
  - Implementation Guidelines
  - Common Specifications
- To allow the implementation by Stakeholders / Vendors

European EHR Exchange Format (EEHRxF), according to the Regulation

Article 6

European electronic health record exchange format

1. The Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 5, setting out the European electronic health record exchange format. The format shall include the following elements:

   (a) datasets containing electronic health data and defining structures, such as data fields and data groups for the content representation of clinical content and other parts of the electronic health data;

   (b) coding systems and values to be used in datasets containing electronic health data;

   (c) technical specifications for the exchange of electronic health data, including its content representation, standards and profiles.

European EHR Exchange Format (EEHRxF), according to the Regulation

3. The common specifications may include elements related to the following:

(a) datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;

(b) coding systems and values to be used in datasets containing electronic health data;

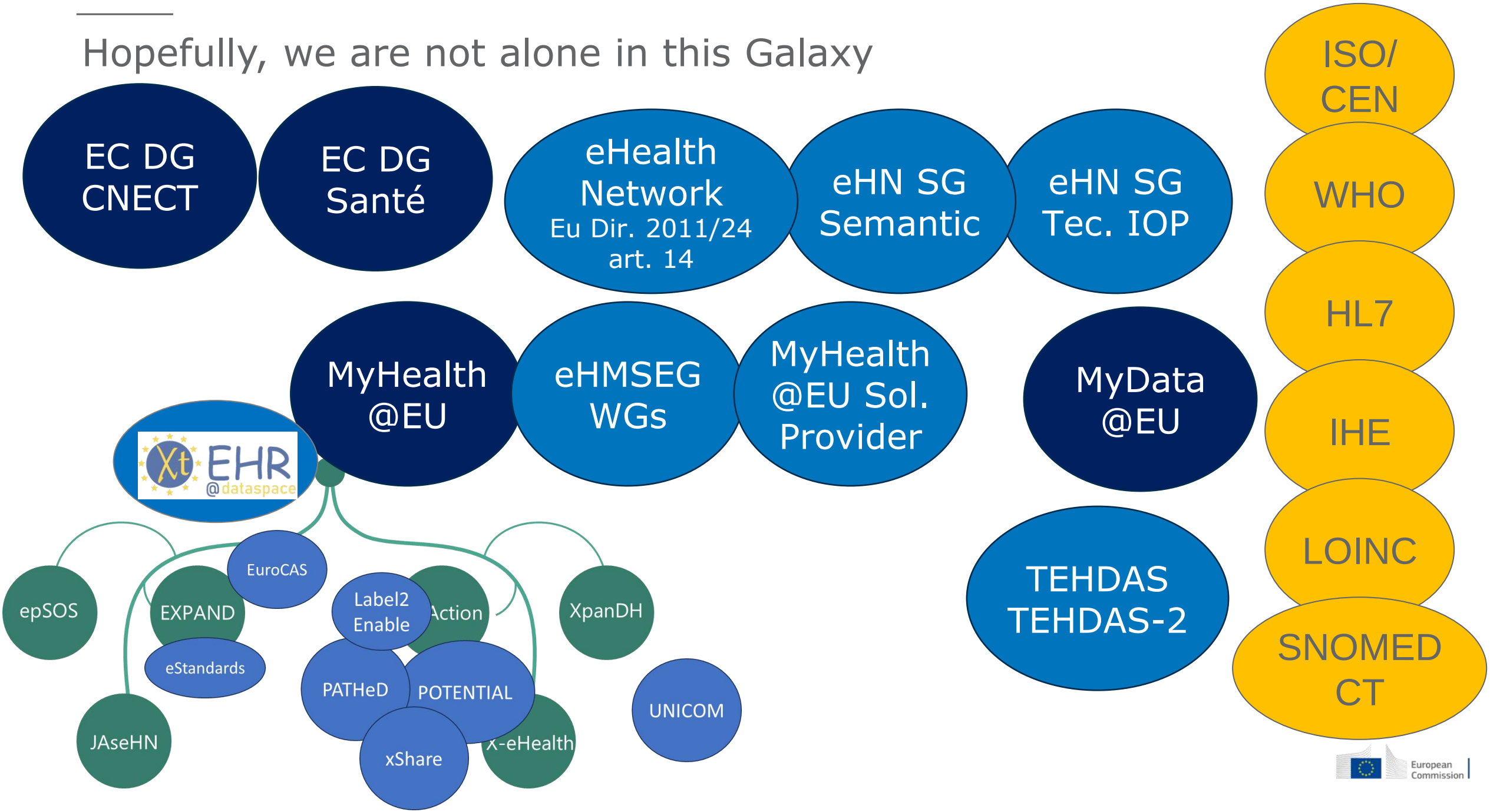
(c) other requirements related to data quality, such as the completeness and accuracy of electronic health data;

(d) technical specifications, standards and profiles for the exchange of electronic health data;

(e) requirements and principles related to security, confidentiality, integrity, patient safety and protection of electronic health data;

(f) specifications and requirements related to identification management and the use of electronic identification.

Hopefully, we are not alone in this Galaxy



eHealth Network Guidelines

- Developed by the eHN SGs, in strict co-operation between EC and Member States nominated experts
- Consolidated with the support of National Stakeholders and SDOs
- Adopted by the eHN, as:
  - Voluntary guidelines for national implementation
  - Normative high-level specifications for cross-border services in MyHealth@EU
- For EEHRxF services:
  - Patient Summary
  - ePrescriptions / eDispensations
  - Hospital Discharge Reports
  - Laboratory Results and Reports
  - Medical Images/Image Studies and Image Reports
  - ✓ Plus, the General Guidelines, for all the above services

eHealth Network Guidelines

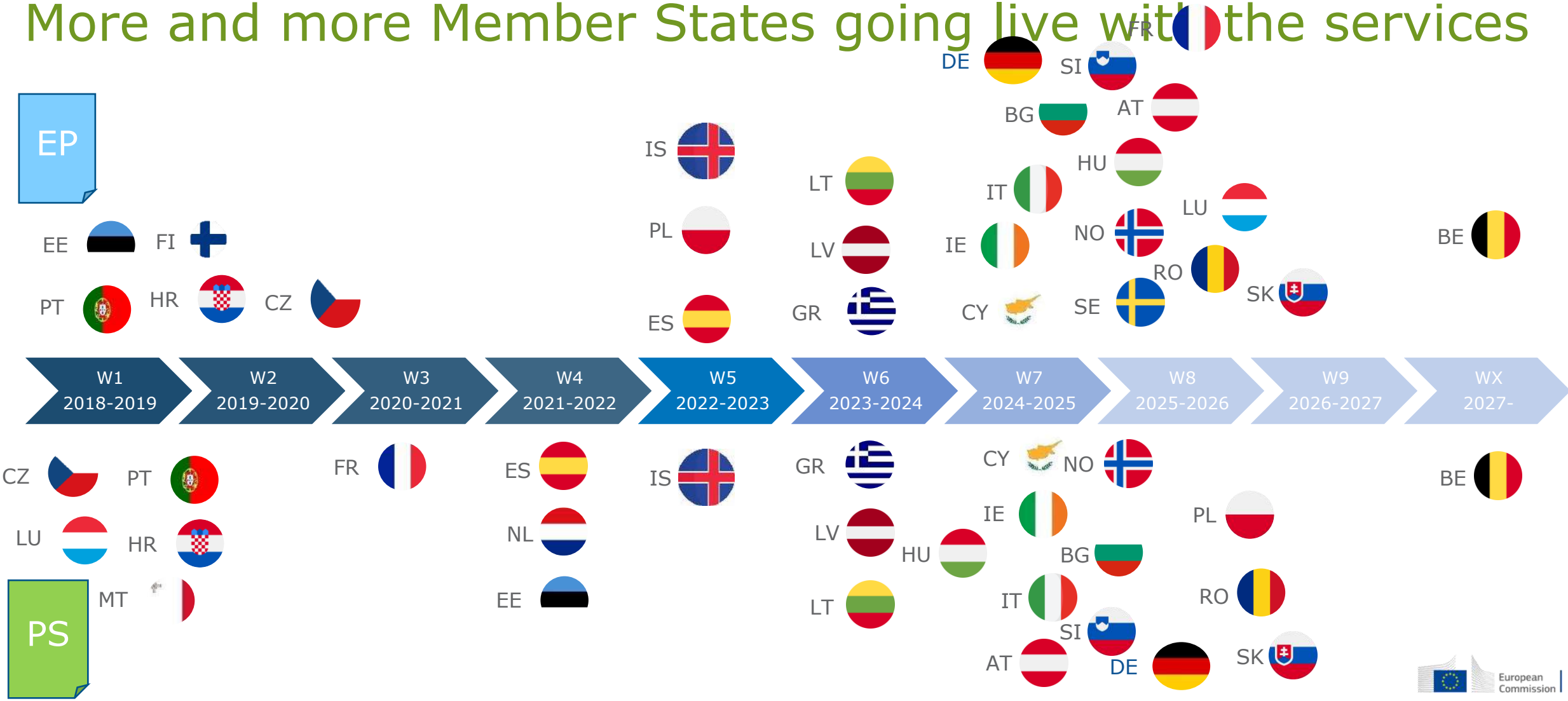
- eHN Guidelines are:
  - Technology & Project independent
- eHN Guidelines contain:
  - General requirements, on Legal and Organisational aspects, Security, Privacy, Patient and Health Professional Identification, Technical and Semantic Interoperability, Terminologies, Testing, …
  - The Data sets / main data elements (without cardinalities)
  - Preferred International Code Systems, per data element.
  - Additional requirements for cross-border services

MyHealth@EU specifications and Assets

- MyHealth@EU specifications are:
  - Normative for cross-border services
  - Technology & project specific
  - Incrementally aligned with International standards for the specific services
- MyHealth@EU Specifications consist of:
  - Functional normative and non-normative requirements, including legal & organisational
  - Monitoring framework
  - Data Sets, with cardinalities per data element (mandatory, required, optional
  - Semantic specifications with the ValueSet per data element, indicating the selected values from the adopted international code systems
    - » For SNOMED CT based ValueSets, only concepts from SNOMED CT GPS and HL7 Free sets are used, until now
  - Technology specific Implementation Guide (HL7 CDA-V2 Level 3 & Level 1, HL7 FHIR)
  - Technical Specifications and OpenNCP Reference Implementation, Central Terminology Server
  - Testing strategy and tools
  - Compliance check / audit procedures

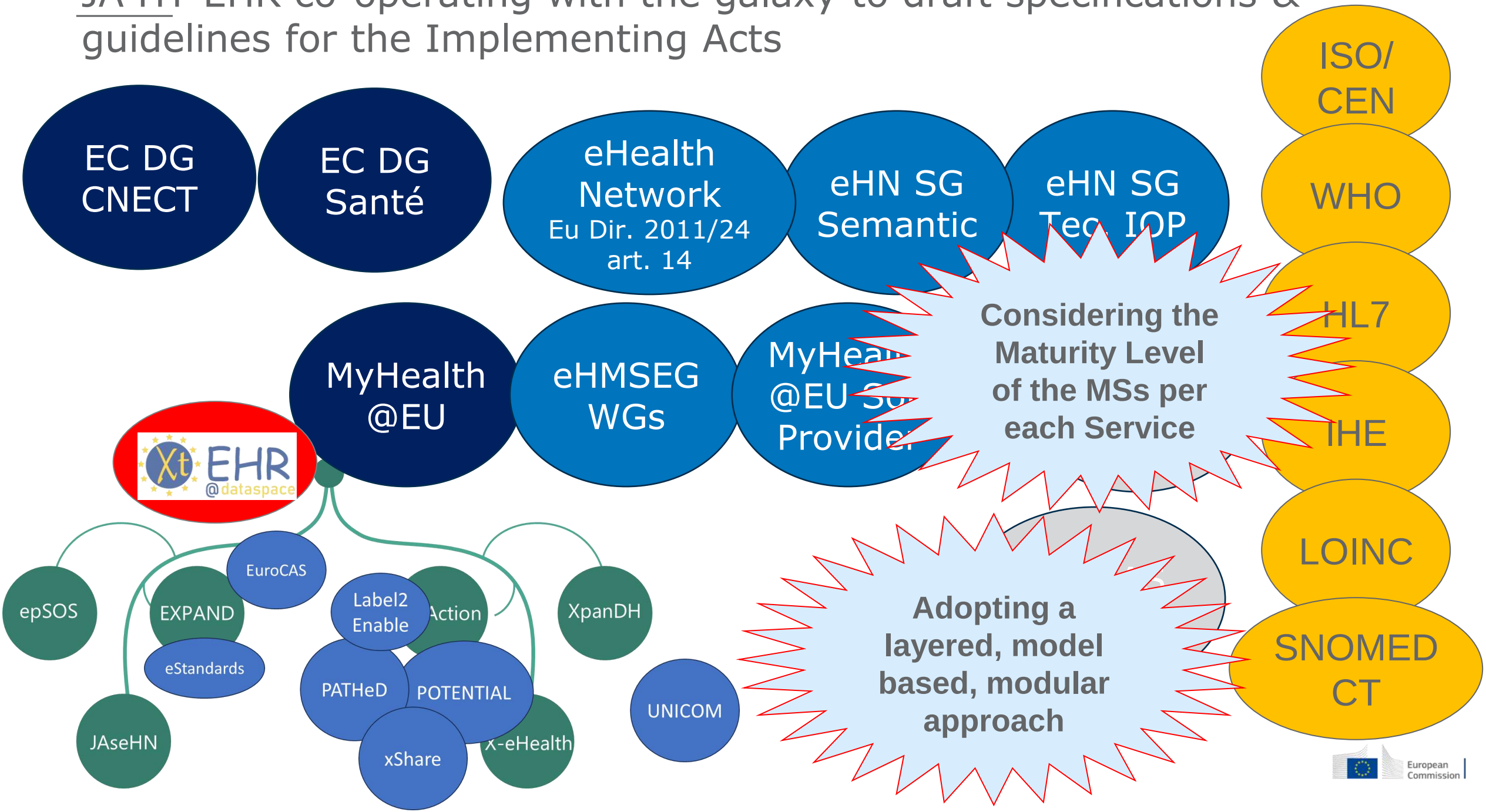
MyHealth@EU Roadmap

More and more Member States going live with the services



European Commission

JA HT-EHR co-operating with the galaxy to draft specifications & guidelines for the Implementing Acts



Zooming in on Medicinal Products

- Medicinal / Pharmaceutical Products Data Set is included in all the services
  - In eP/eD as main data set
  - In PS as Medication Summary, Allergies, Vaccinations
  - In Hospital Discharge Reports, like in PS, and as prescribed therapy
  - In Lab Reports and Image Reports as test methods / treatments
- Highly specified both in the Registration Process, by EMA / National Competent Authorities and as ePharmacy, and as pharmacovigilance
- Commonalities and specificities along the full Medicinal Product Life Cycle
- UNICOM Project saw the co-operation among 11 NCAs and most of the MSs participating in MyHealth@EU

Thank you!

Anne Moen
Faculty of Medicine, University of Oslo &
Coordinator, Gravitate-Health Public-Private Partnership
//www.gravitatehealth.eu

Christian Hay,
Sr Consultant Healthcare

…and many other colleagues ☺

- Dr Robert A. Stegwee
- *Chair, CEN Technical Committee 251 Health Informatics*

UNICOM

European Commission

Defining Semantic Interoperability for Health

UNICOM

- What is your role in the life-cycle of a medicinal product?

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

European Commission

Towards a seamless MP Data Value Chain

Semantic interoperability will **facilitate data sharing across the full life cycle and all actors involved in handling MP information**

- **Pharmaceutical companies**
- **National Medicinal Products Regulatory Authorities (NMAs)**
- **Pharmacovigilance Systems (patient safety)**
- **Providers of medicinal product dictionaries**
- **Clinical software producers (EHR, Hospital Information, CDS, CPOE, PS, ePrescribing systems**
- **Healthcare professionals using these systems**
- **Pharmacy Systems (Order Systems, Supply Chain/Logistics/Stock Management Systems)**
- **eProduct Information/Patients/Intelligent apps for patient empowerment**
- **National ePrecription Systems**
- **xBorder digital health services**
- **Clinical trials/medical research**
- **Health systems & Public Health**

and across **different languages, alphabets, health cultures**

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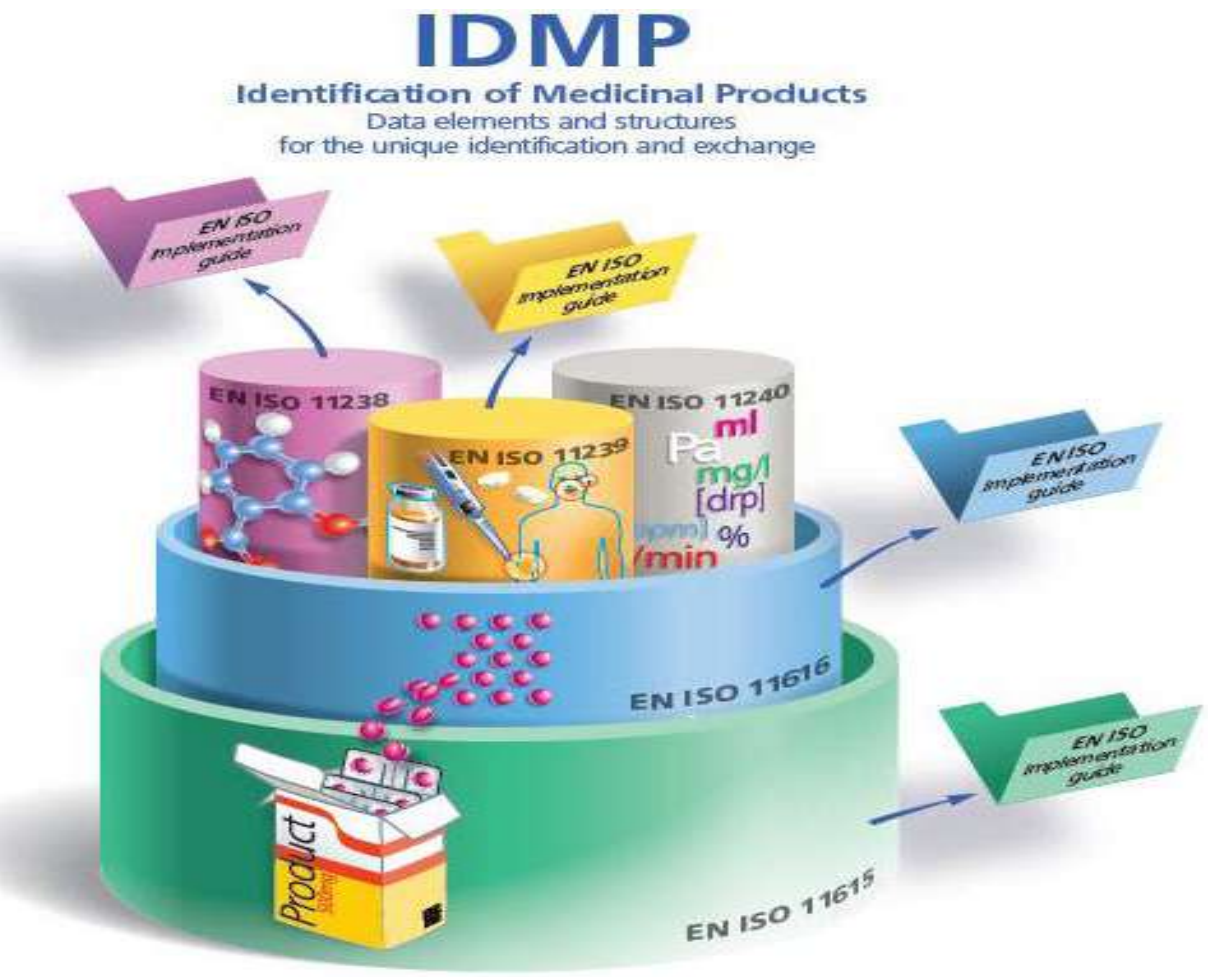
Concrete Solution:

International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP) Suite of Standards, and their harmonised adoption among NCAs



The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:

- ***Medicinal* Products** (MPID) and **Packages** (PCID) - ISO 11615
- ***Pharmaceutical* Products** (PhPID) - ISO 11616
- ***Substances*** (Substance ID) - ISO 11238
- ***Pharmaceutical Dose Forms***, units of presentation, routes of administration and packaging - ISO 11239
- ***Units of Measurement*** (UCUM) - ISO 11240

ISO IDMP standards apply to both authorised and developmental medicinal products for *human* use

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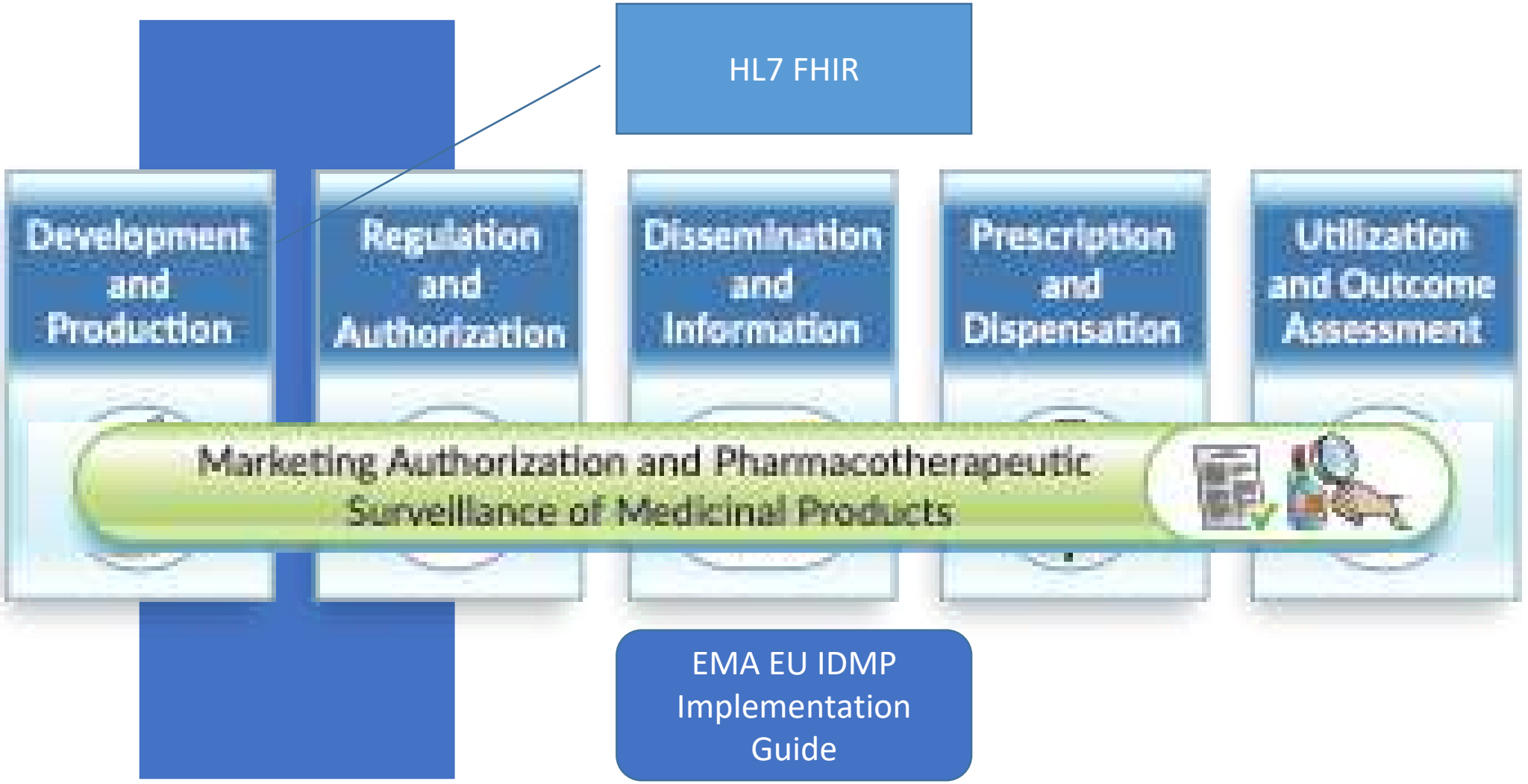
Submission of medicinal product information



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IDMP/FHIR compatible Electronic Application Forms
PLM: Product Life Cycle Management

UNICOM

WP 3

Web Tool supporting IDMP/FHIR compatible application dataset formats

New

DADI --> PLM

Applicants

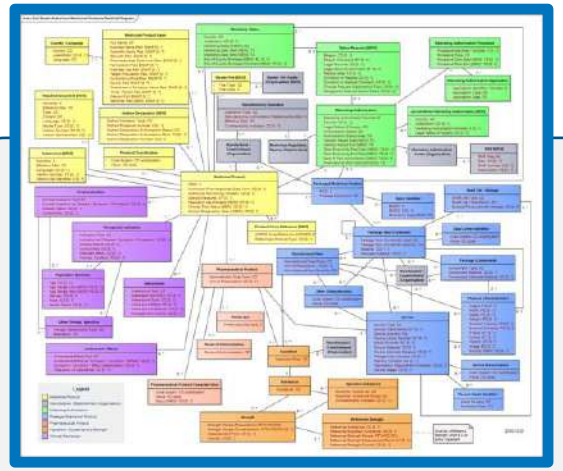
Initial Applications

Lifecycle Management

Regulators

New
Retrieving master data

New
IDMP/FHIR format



ISO IDMP Data Model

Substance Terms, Organisation data, Referentials
(EMA, providing controlled dictionaries)

Medicinal Products
(PMS, providing master data for medicinal products)

Regulatory IT-Systems

See also collaboration with UNICOM WP4

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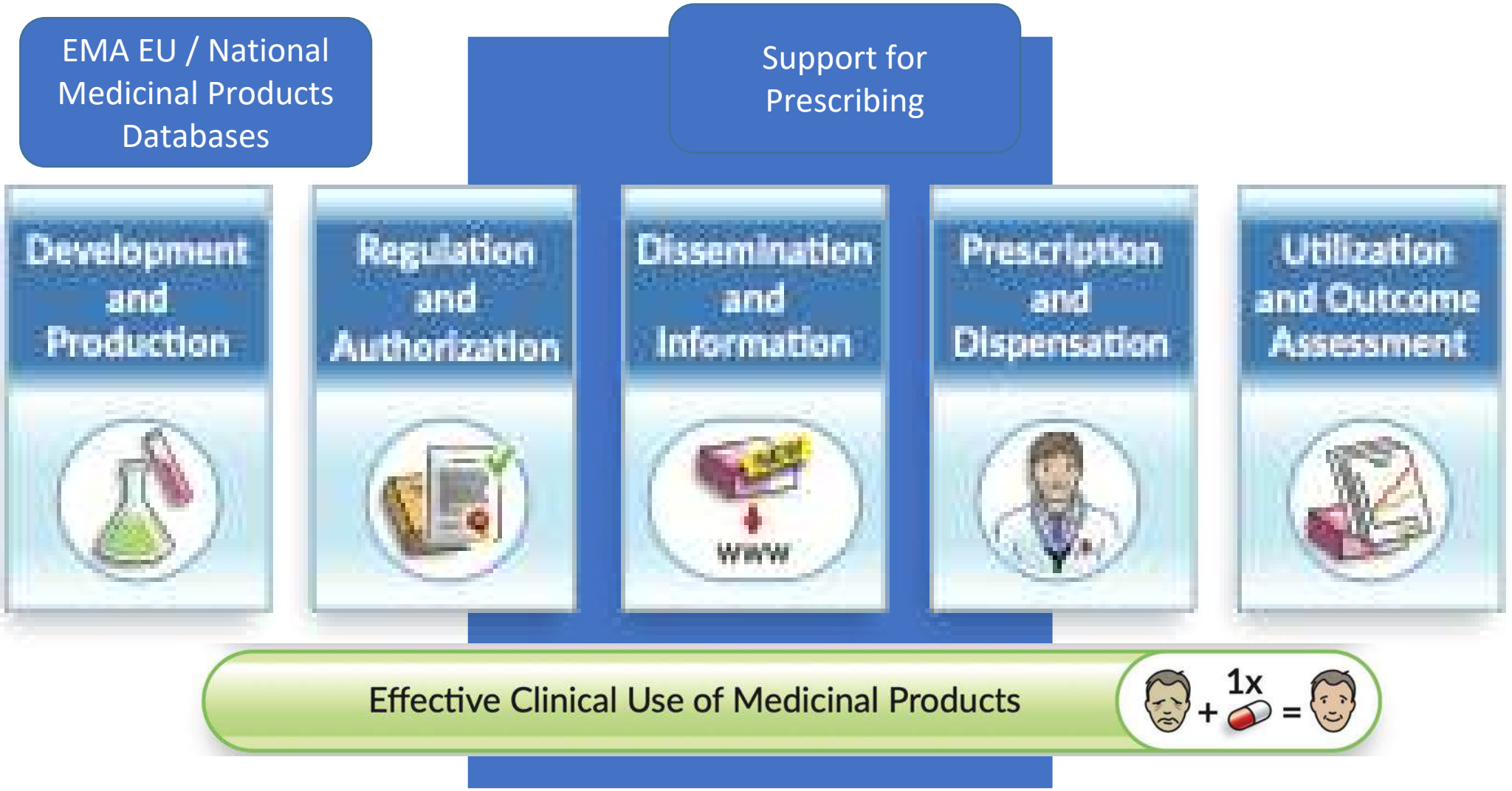
European Commission

Dissemination and Information



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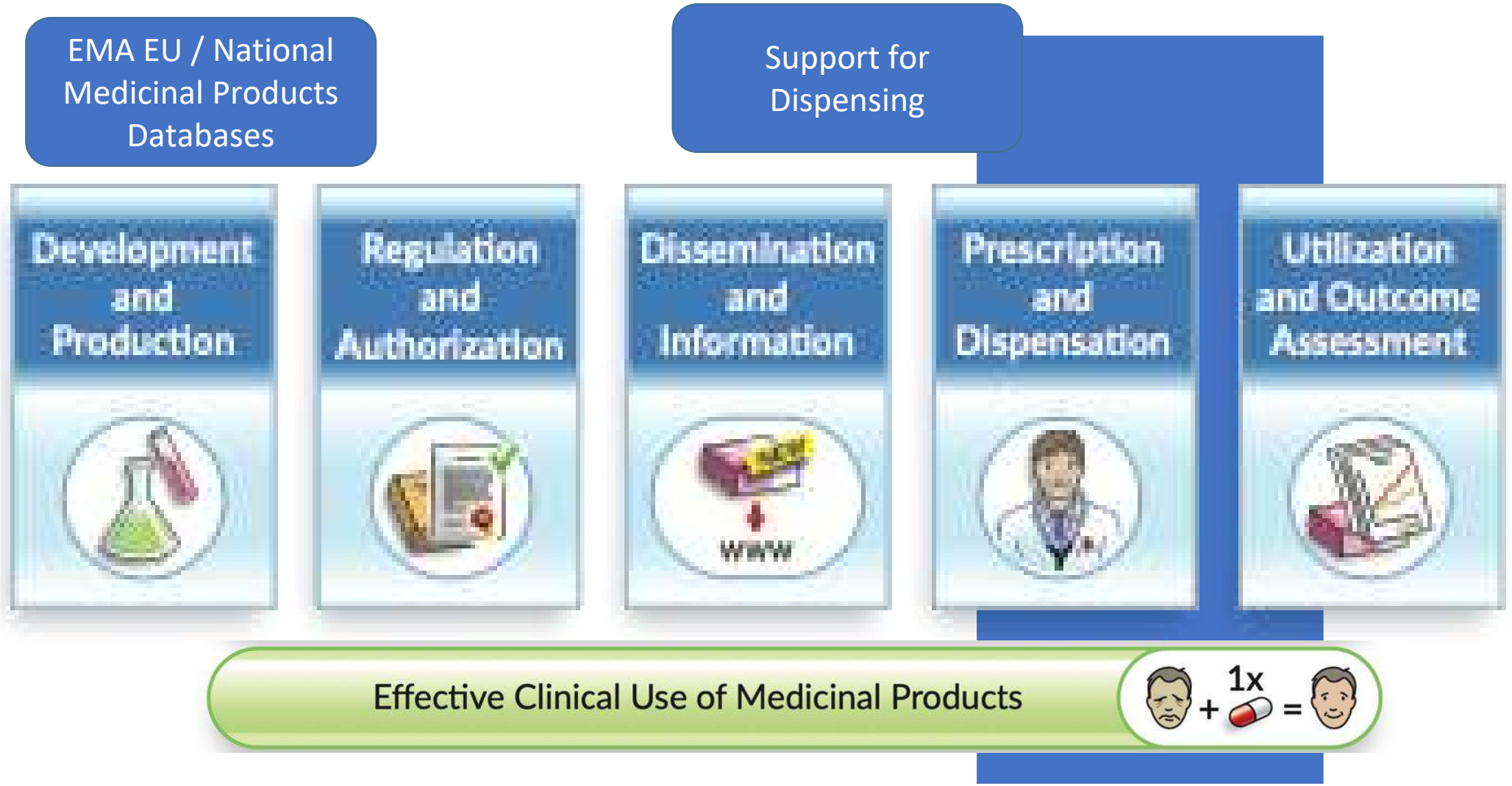
Dispensation at National and Cross-Border level



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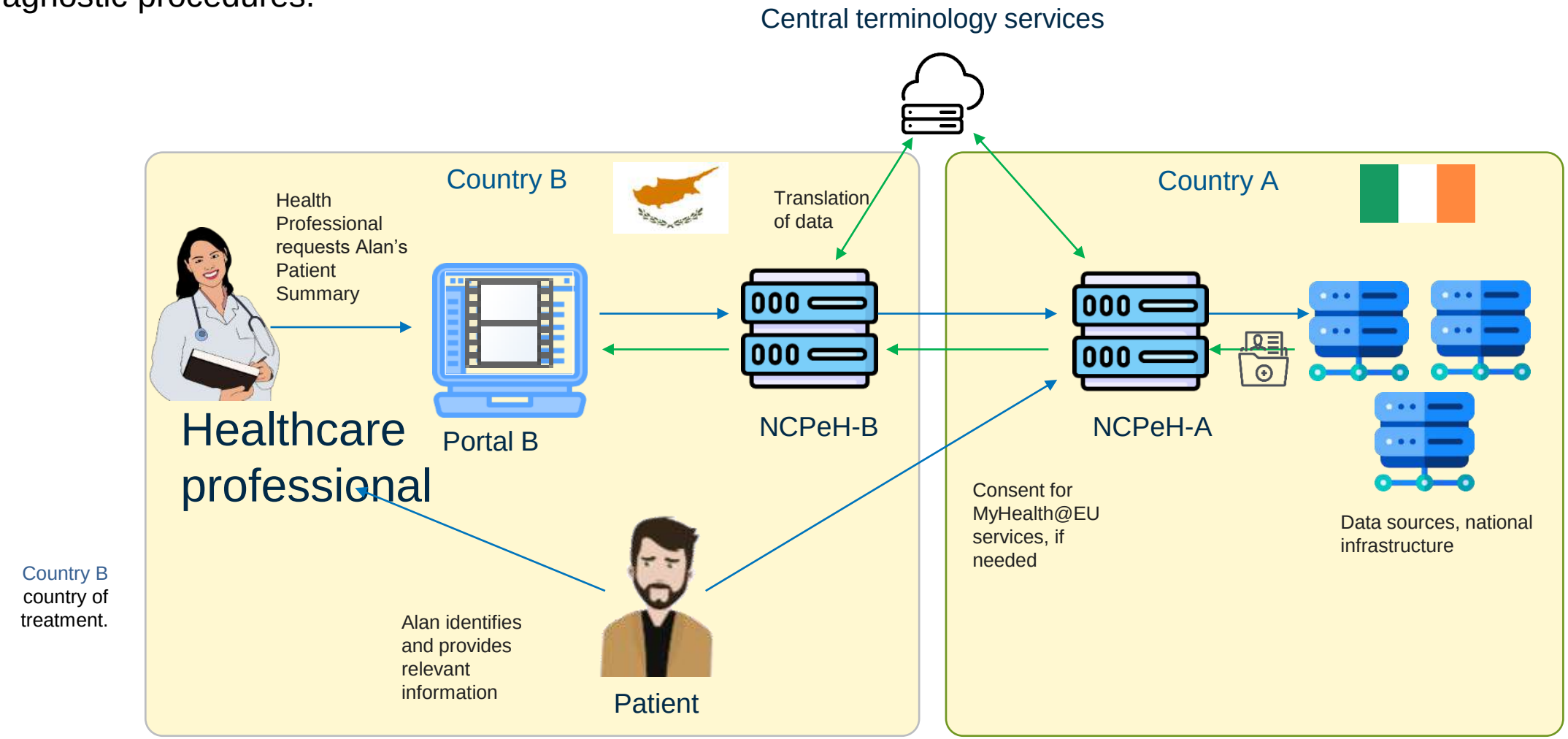
Current supporting MyHealth@EU infrastructure

The current MyHealth@EU infrastructure connects Member States National Contact Points for eHealth (NCPeH) giving **healthcare professionals access to the patient's data.**

In this scenario Patient Summary is returned and displayed in the portal to the healthcare professional in their own language thereby **enhancing the patient's treatment**. **Reducing the potential for clinical errors** and duplicate diagnostic procedures.



Common minimum data set for implementation in the national NCA and eHealth solutions

- In case of more than one EMA attribute is available, the red ones should be preferred
  - Presented in a flat list (to facilitate the presentation), but **IT MUST be considered as a structured model**.

eHDSI data elements	Preferred coding system	Attributes from EMA IG version V2.1 (2021-02)	
		#	Attribute
Active Ingredient	SPOR-SMS	5.5.1.	Substance (code)
		5.5.3.1.	**Reference Substance (moiety)**
Ingredient role	SPOR-RMS	5.1.	Ingredient role
ATC code	WHO - ATC	**1.13.3.**	**ATC Code (s)**
Medicinal Product Code		-	Pharmaceutical Product Identifier (PhPID)
		1.2.	Medicinal product identifier (MPID)
		4.1.	Packaged Medicinal Product Identifier (PCID)
		1.1	Product Management Service Identifier (PMS ID)
Marketing Authorisation Holder	SPOR-OMS	2.8.	Marketing Authorisation Holder (Organisation)
Brand Name of the Medicine		1.14.1.	Full name
Medicinal Product Package	EDQM/UCUM	4.3.	Pack size
		4.7.1.	**Package item (container) type**
		4.7.5.	**Package item (container) quantity**
Package size	EDQM/UCUM	4.10.2.	Manufactured Item Quantity
Strength of the Medicinal Product	EDQM/UCUM	5.5.2.2.2.	Strength (Presentation single value or low limit)
		5.5.2.3.2.	Strength (Concentration single value or low limit)
		5.5.3.3.2.	**Reference strength (Presentation single value or low limit)**
		5.5.3.4.2.	**Reference Strength (Concentration single value or low limit)**
Pharmaceutical Dose Form	EDQM	6.2.	Administrable Dose Form
		1.5.	**Authorised Pharmaceutical Form**
		4.10.3.	Manufactured Dose Form
Quantity Unit	EDQM	**6.3**	**Unit of presentation**
		4.10.1.	Unit of presentation
Route of Administration	EDQM	**6.6.**	**Route of Administration**

Obtain the coded data from NCAs/EMA

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Understanding how to use and report on Adverse Events

EMA EU / National Medicinal Products Databases

Support for cross-border understanding of local / substituted medicinal products

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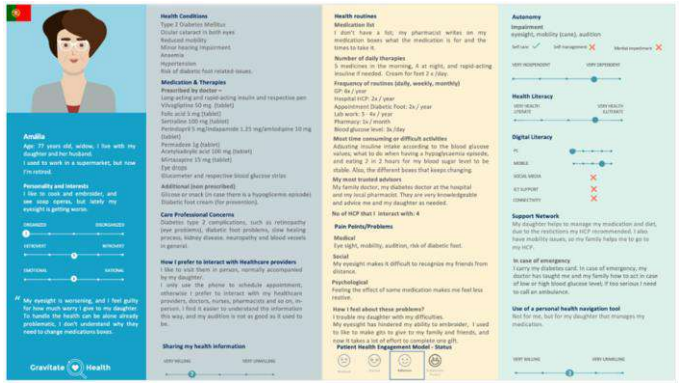
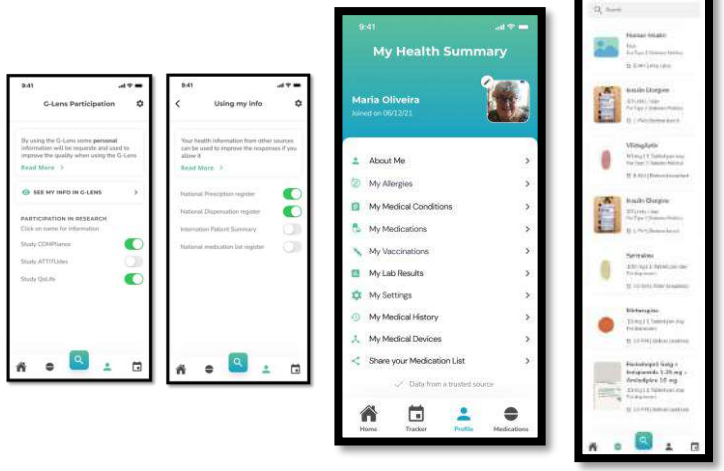
Illustrating work in GRAVITATE HEALTH

Defining the G-lens design methodology - personas



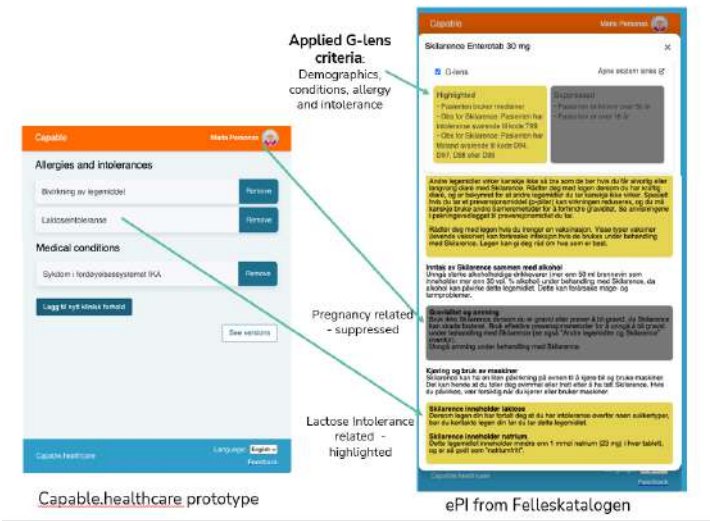


User experience – information services - mock–up -

User advisory group and healthcare ecosystems – 'patient voice' and capacity building. Active external engagement, connections and presence.

Accessing cross-border product information (preferred EU language)*

Example of basic G-lens taking Patient Summary info for focusing of product information*



* *A global HL7 FHIR standard for ePI is in development based on this work. See here.*

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THANK YOU!

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