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25-26 MARCH 



## Keynote: Belgian eHealth roadmap towards the EHDS & Belgian Integrated Health Record (BIHR) towards integrated care

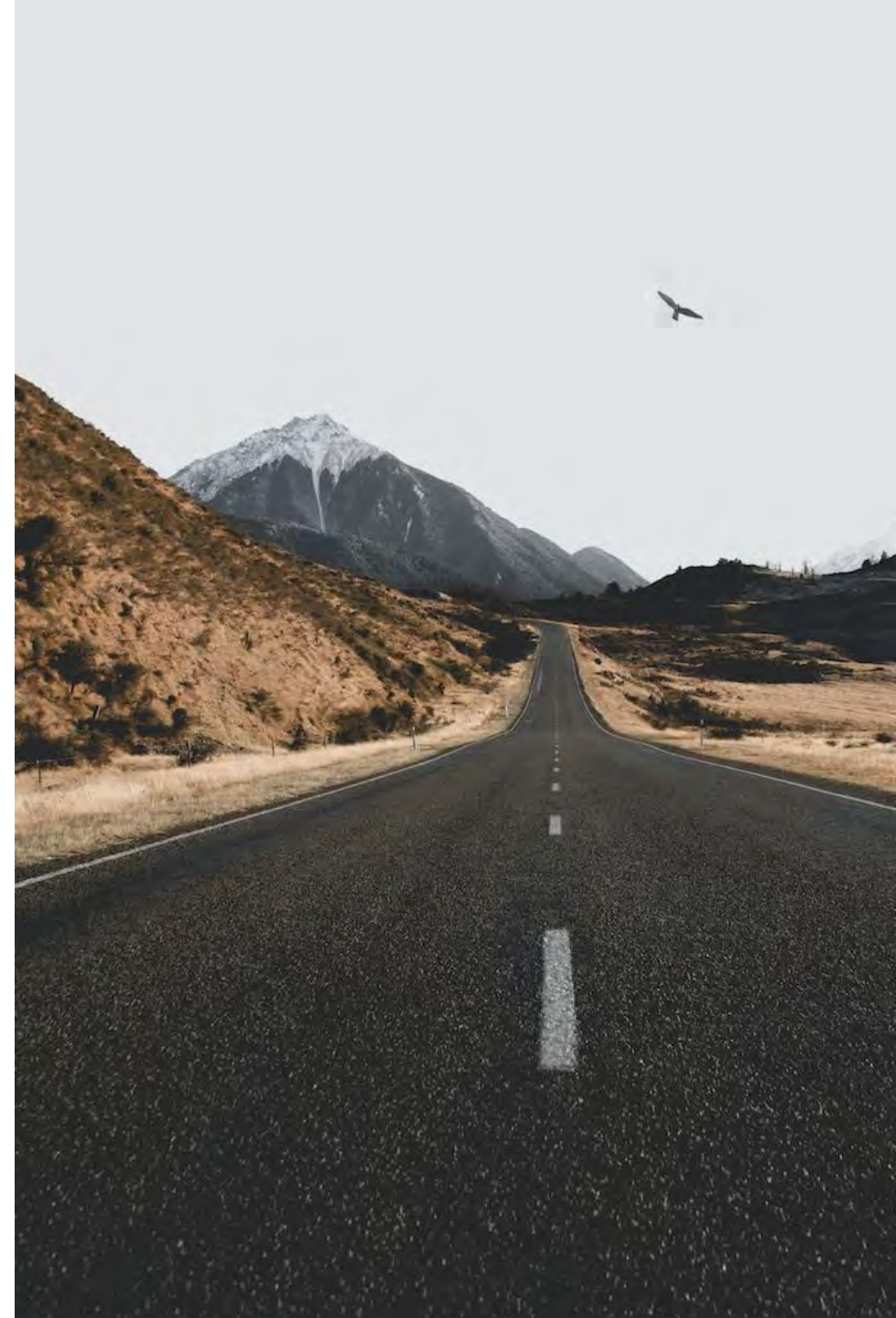


Frank Robben  
ICT reuse and Smals CEO, founder eHealth  
platform

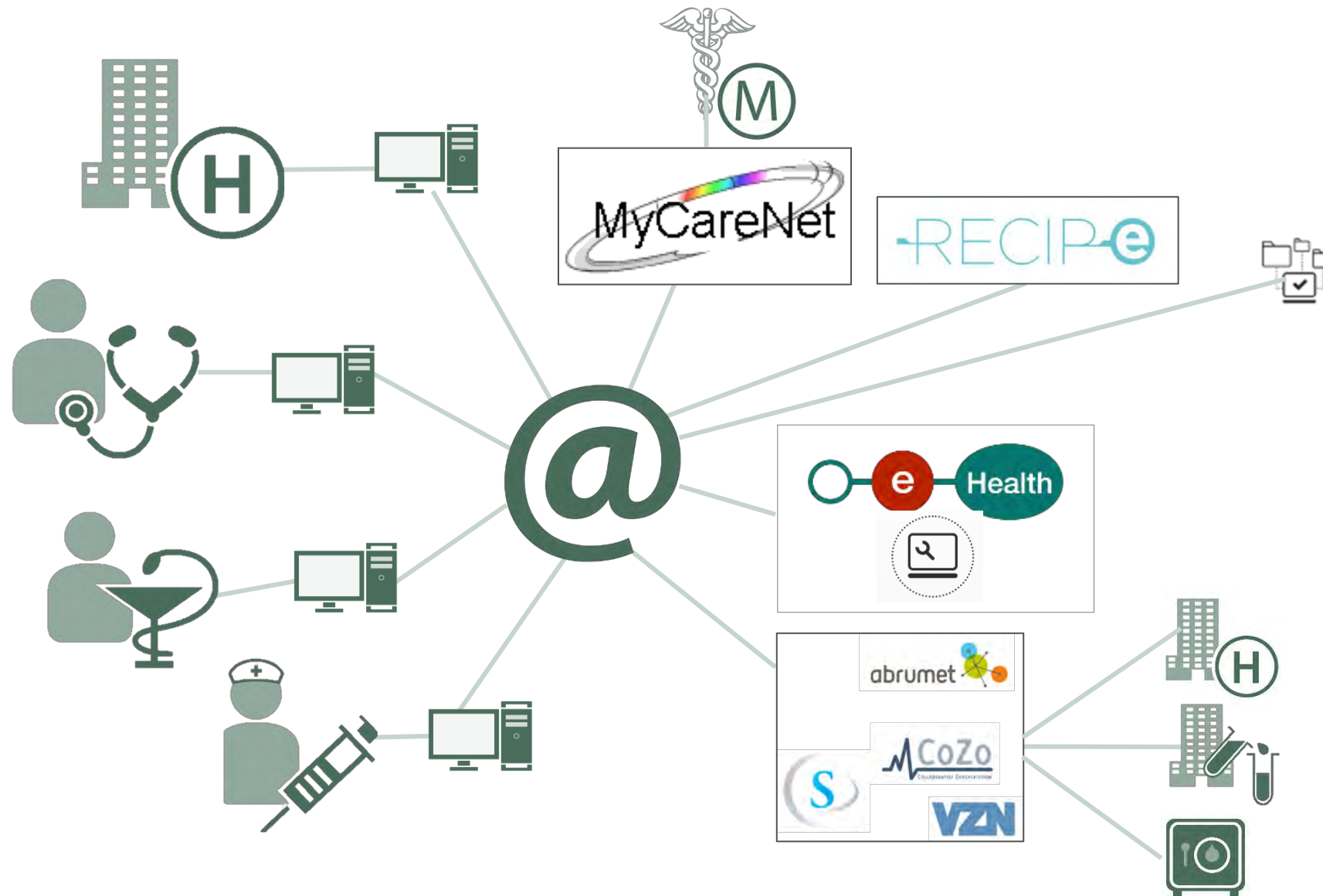


# eHealth (primary use) in Belgium

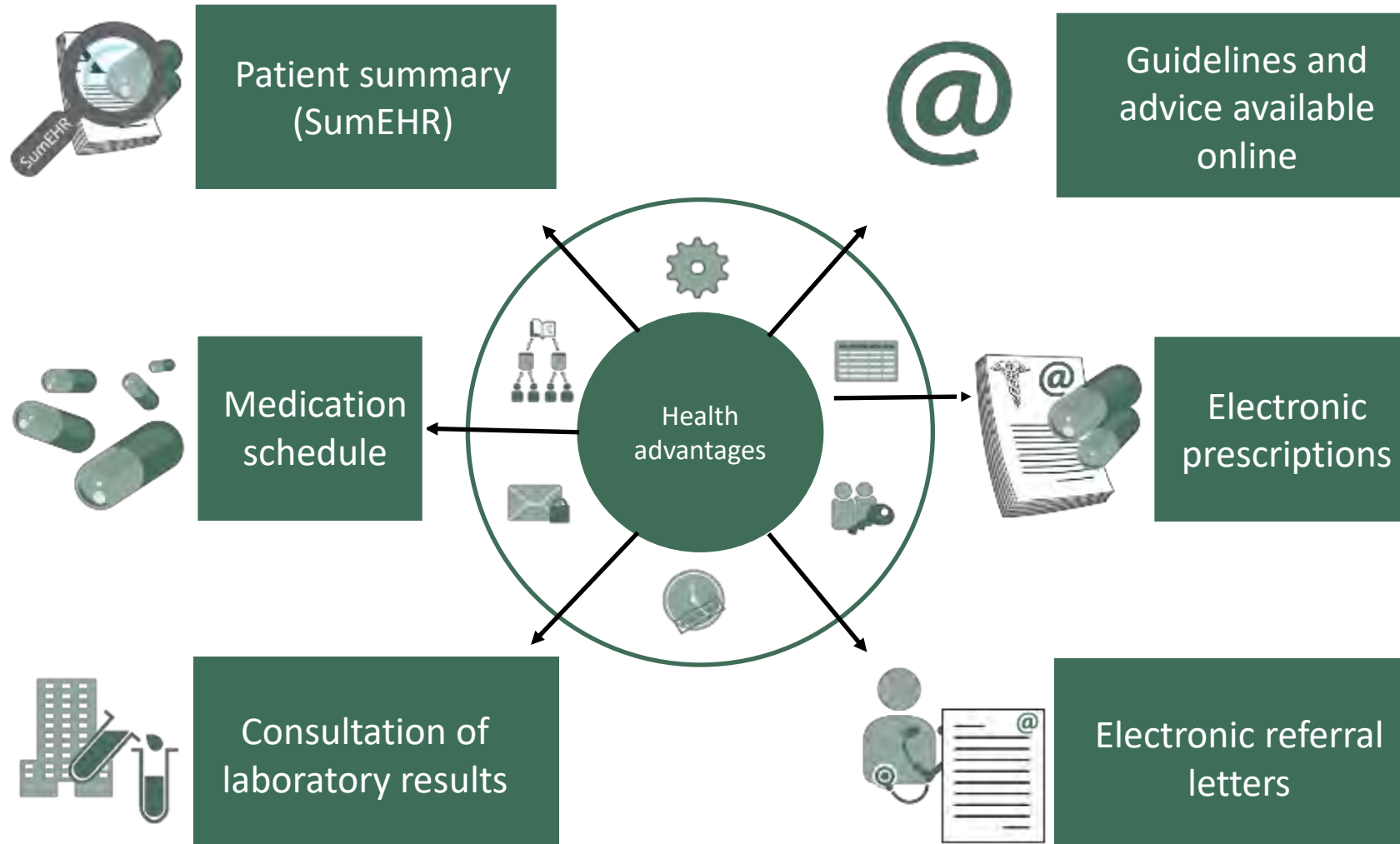
- brief overview
- Belgian Integrated Health Record (B-IHR) for integrated care
- Belgian roadmap towards EHDS



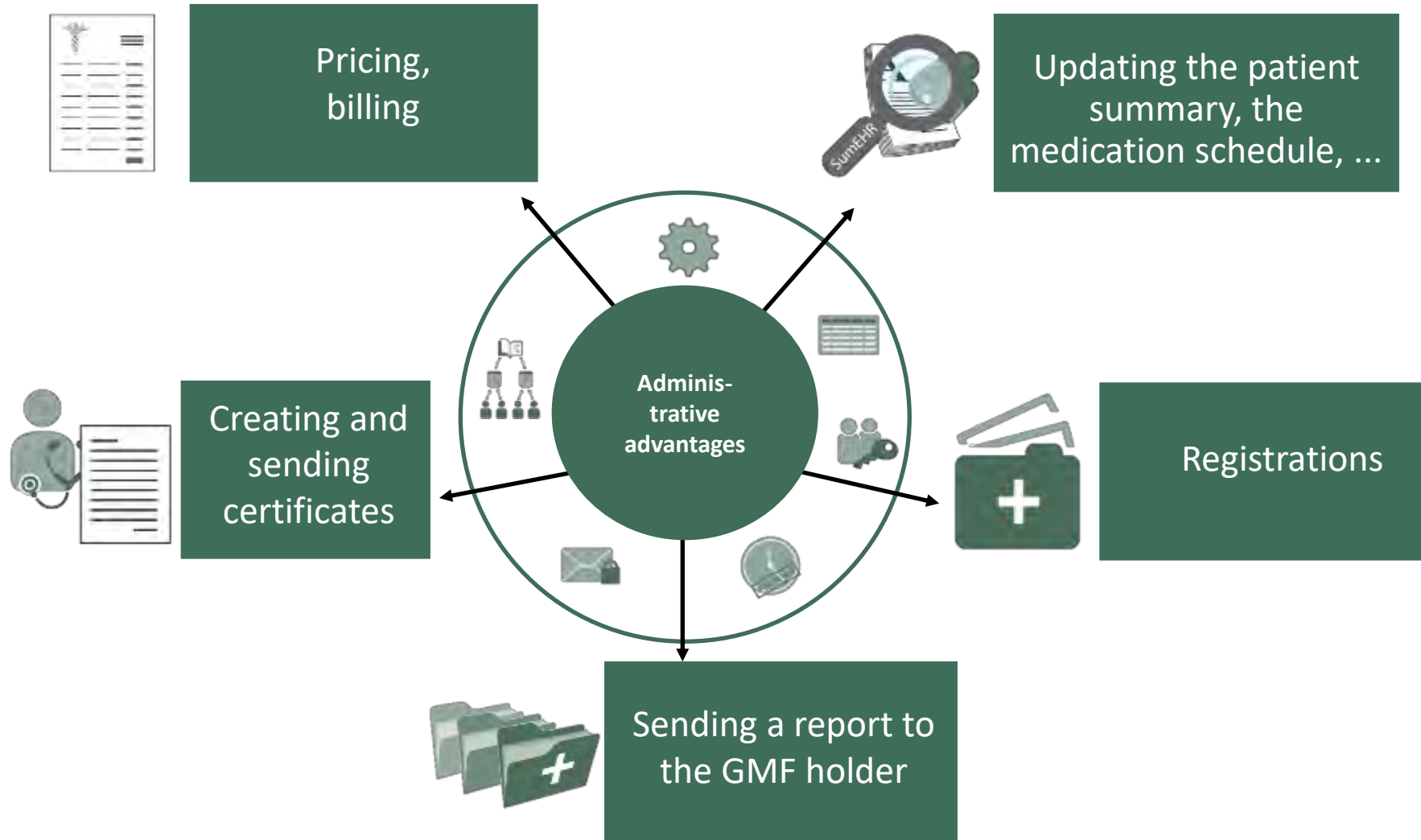
# Overview of the Belgian eHealth landscape



# Actual status



# Actual status



# Some figures

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## Informed consent

**11.512.704** registered consents (97,3%)

## Number of transactions

**19.018.497.753** in 2025  
(+ 11,42%)

## eHealthBox

**112.876.714** messages sent (SOAP)  
**917.260** messages sent (REST)

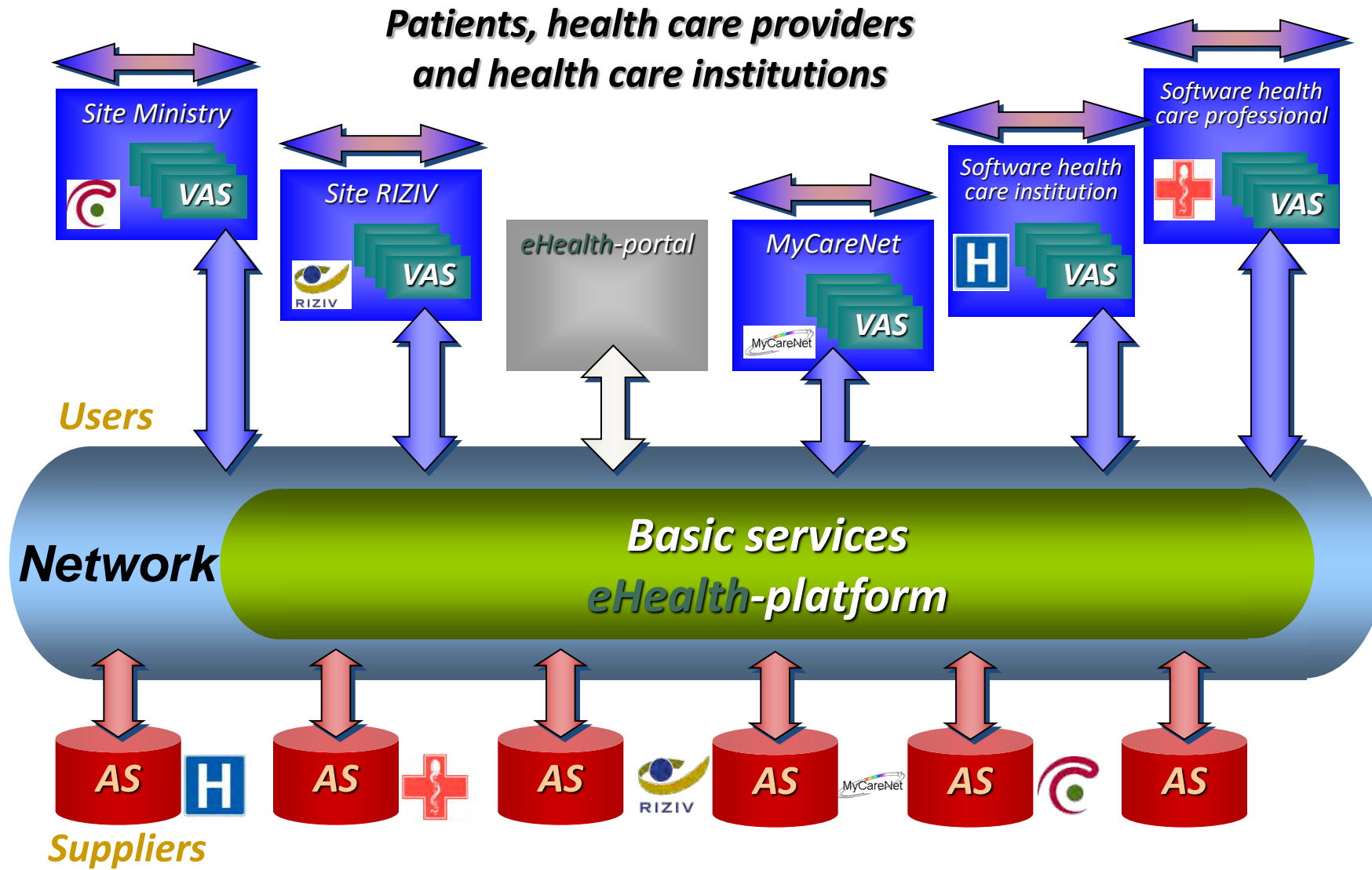
## eHealthBox > eBox

**12.301.272** messages

## Performance & accessibility

**100** % of the KPIs are being met

# Architecture



# Basic services

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eHealth-certificats



Integrated user and access management system



Timestamping



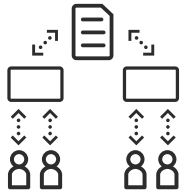
System for end-to-end encryption



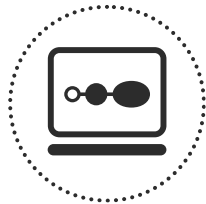
eHealthBox



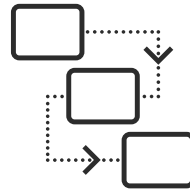
Management of loggings



Reference directories (hub-metahub system)



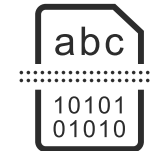
Portal



Coordination of the electronic processes



Consultation of National register and CBSS registers



Coding and anonymising

# B-IHR concept (Belgian Integrated Health Record)

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- | an environment where
  - | every individual has a clear and integrated view of all their own health (care) and welfare data
  - | everyone who takes care of that person has access to all the information that is important for providing high-quality and continuous care
- | everyone involved can actively contribute to keeping the information up to date and accurate
- | services are available to easily record, manage, structure, and share the information
- | services are available to support every person involved in decision-making
- | data can be intensively used, with the necessary data protection guarantees, for
  - | scientific research, development, and innovation
  - | policy support
  - | population management
- | more info at <https://www.frankrobben.be/wp-content/uploads/2023/03/B-IHR.pdf>

# Some key points

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- | 'seamless' entry of high-quality, structured information into electronic health records (EHRs)
  - | supporting components: trilingual SNOMED CT terminology server in EHR systems, with mapping to ICPC-3, ICD-11, ICF, and ICHI, among others
  - | quality control
- | one-time data entry: deriving data for secondary use from EHR systems (new registry policy)
- | operationalization based on care episodes
- | optimization of one-time data storage
  - | medications (prescription, dispensing, medication schedule) (VIDIS (Virtual Drug Information System))
  - | well-coordinated health vaults
- | unlocking information
  - | dashboards for primary use
  - | secondary use
- | care sets in line with European standards (see below, EHDS)

# B-IHR working environment (BWO A)

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- | 15 categories with corresponding care sets in accordance with the FHIR R4 standard and including value sets (SNOMED CT, LOINC, DICOM)
  - | list of problems
  - | clinical data
  - | lab results
  - | imaging
  - | medication overview
  - | vaccinations
  - | allergies
  - | implants
  - | (tele)monitoring data
  - | social factors
  - | family context
  - | life goals
  - | advance directives
  - | care plan & team
  - | BelRAI assessment

# B-IHR working environment (BWO B)

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- | operationalisation based on care episodes
  - | the entirety of records
  - | by the relevant healthcare providers, the healthcare users and, where applicable, informal carers
  - | relating to a specific condition or health issue
  - | from the moment the health care user first seeks professional help
  - | up to and including the last contact regarding this condition or health issue
- | in the initial phase
  - | GPs
  - | pharmacists
  - | nurses
  - | physiotherapists
  - | social workers
- | co-creation

# Other components of the eHealth action plan

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- | concretization of integrated care programs
- | generalization of digital referral and care instructions (UHMEP (Unaddressed Health Message Exchange Platform))
- | generalization of digital discharge letters
- | administrative simplification, including through the reduction and digitization of certificates (e.g. Mult-eMediatt)
- | workload management for healthcare providers
- | training
- | innovation
- | m-health
- | support for implementation in the workplace
- | MyHealth.be as an inter-federal portal
- | literacy and inclusion
- | readjustment of incentives and financing
- | revision of relationship with software suppliers

# EHDS: links to documentation

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| Official Journal of the European Union:

| [https://eur-lex.europa.eu/legal-content/en/TXT/?uri=OJ%3AL\\_202500327](https://eur-lex.europa.eu/legal-content/en/TXT/?uri=OJ%3AL_202500327)

| website of the European Commission regarding EHDS

| [https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds\\_en](https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en)

| extract of slides of the European Commission showed at webinars

# EHDS in a Nutshell – what is it about?

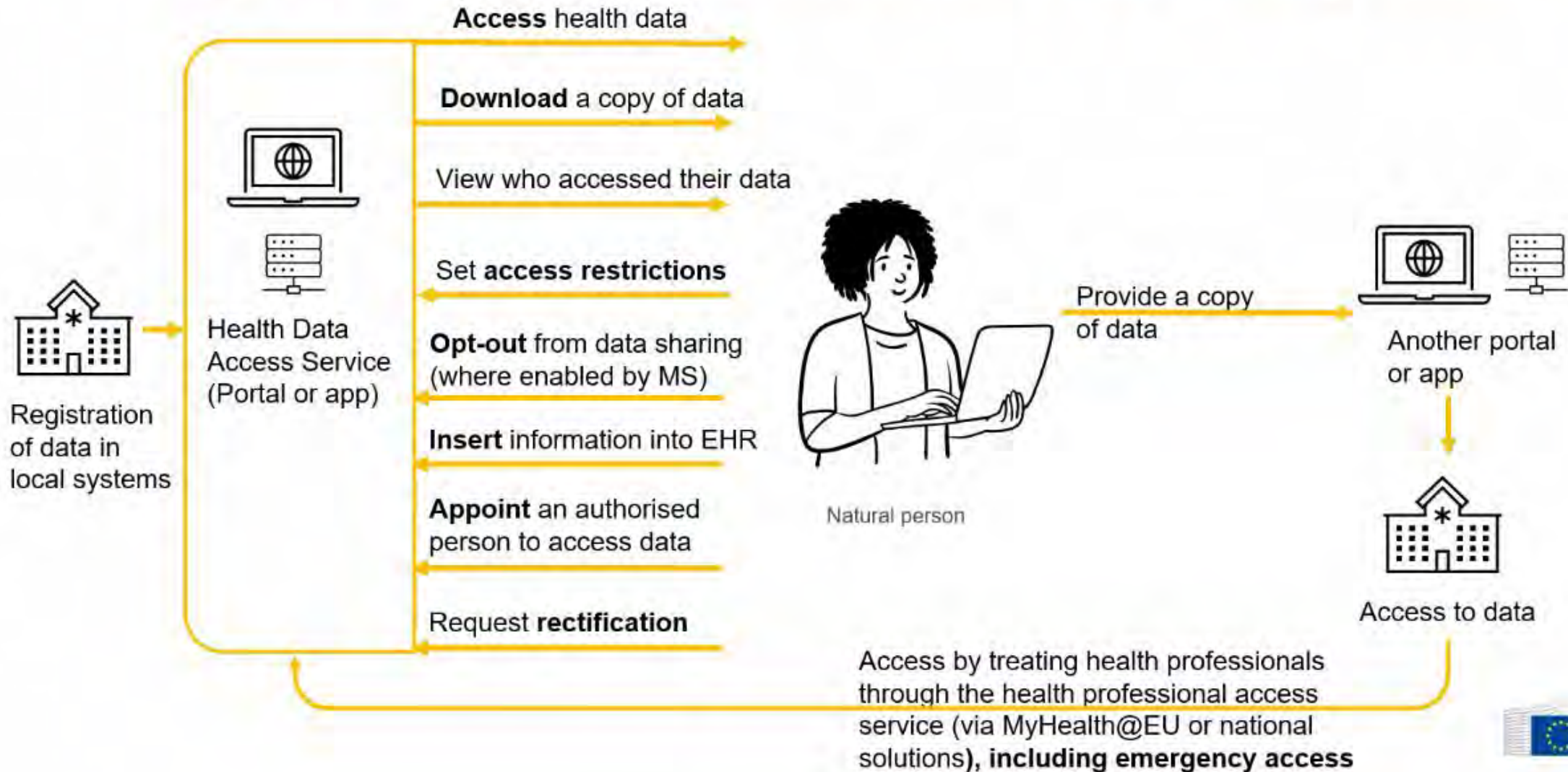
1. Primary use = use of data for the delivery of healthcare
  - Improving patients' access to their health data;
  - Ensuring seamless exchanges for continuity of healthcare.
2. Secondary use = use of data for research and public interest purposes
  - Making data available for research, policy-making etc. in a safe and secure way.
3. Requirements for electronic health record (EHR) systems
  - Creating a single market for electronic health records systems, supporting both primary and secondary use.

# EHDS in a Nutshell – Primary Use

## How?

- Strengthening patients' rights on defined categories of their own data;
- Patient- and health professional-facing services to access data;
- Building on existing voluntary MyHealth@EU infrastructure, not touching upon national rules on provision of care / management of healthcare systems.

# Rights of natural persons in primary use



# Priority categories

## Group 1

- Patient summaries
- Electronic prescriptions
- Electronic dispensations



Detailed specifications for the European Electronic Health Record Exchange Format (EEHRxF) via implementing act, building on work done following 2019 recommendation, several projects etc. => strong Member State involvement

## Group 2

- Medical imaging studies and related imaging reports
- Medical test results, including laboratory test and related reports
- Discharge reports

# EHDS in a Nutshell – Secondary Use

## How?

- Common European rules on who has to make which data available for which purposes and under which conditions
- Common infrastructure
- Health Data Access bodies as orchestrators
- Permits for data use, common safeguards
- Data catalogues of available datasets

# EHDS in a Nutshell – EHR systems

## How?

- Product legislation for two components of EHR systems: interoperability and logging;
- Full harmonisation for those two components;
- Approach based on new legislative framework for product legislation, incorporating recent developments from other product legislation.

# How to demonstrate compliance?

- Self-declaration of conformity by manufacturer – no third-party conformity assessment as in MDR;
- However: EHR systems must pass an automated test in the *digital testing environment* before being placed on the market.;
- Test report becomes part of product documentation;
  - Final 'all fine' report – no obligation to disclose failed reports;
- COM to develop software package for testing environments, MS to deploy;
- What to expect from the testing environment?
  - Details to be developed, but expect simulated actions on the system:
  - Import/export transactions – checking if presentation / translation of test data is correct;
  - Logging of actions – checking if logs are generated in the right format.

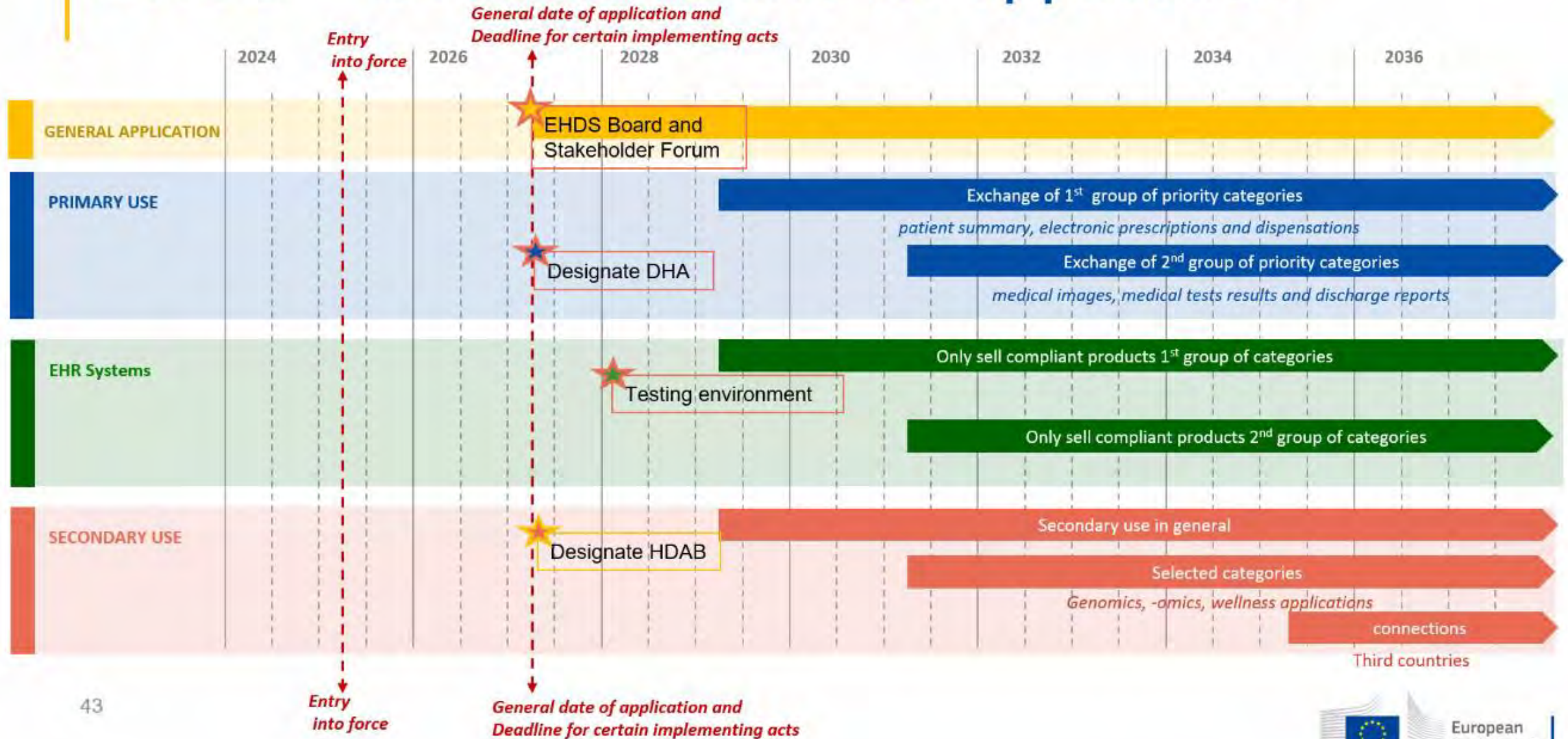
# Registration of EHR systems

- EHR systems will have to be *registered* in a public EU database;
- Aim: provide overview of systems available on the market, transparency for buyers;
- Self-service system for use by manufacturers and other relevant actors;
- Product registration requirements: do it once, information gets forwarded between databases;
- Detailed content of registration to be set out by COM in delegated act.

# Governance – MS and EU level

- MS to set up Digital Health Authorities (primary use) and Health Data Access Bodies (secondary use)
- Coordination on EU level in EHDS Board for exchanging best practices, coming up with guidelines etc.
- COM to provide MyHealth@EU and HealthData@EU infrastructures and certain other services for MS
  - MS Steering groups for guidance

# EHDS – Overall timeline for application



# Some important provisions of EHDS

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- | software packages must meet EU standards to be placed on the EU market
  - | EHR harmonised components (art. 25)
  - | EU declaration of conformity (art. 39)
- | European digital testing environment (art. 40)
  - | European Commission shall develop a European digital testing environment and make the software supporting this environment available as open source
  - | Member States (MS) shall operate a testing environment, preferably by reusing the software developed by the European Commission
- | legal basis for European governance and coordination (art. 96)
  - | the European Commission shall provide the development, maintenance, hosting and operation of the infrastructures and central services required to support the functioning of the EHDS

# Central services mentioned in art. 96 (primary use)

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- | interoperable, cross-border identification and authentication mechanism for natural persons and health professionals
- | a central interoperability platform for digital health ('MyHealth@EU') to provide services to support and facilitate the exchange of personal electronic health data between the national contact points
- | supplementary services that facilitate telemedicine, mobile health, access by natural persons to existing translations of their health data, exchange or verification of health-related certificates
  - | *eg multilingual EU terminology server containing all semantic value sets used in the defined FHIR R4 resources ?*
  - | *eg coordination of end-to-end encryption of health data ?*
  - | *eg pseudonimization service ?*

# General principles for Belgian implementation

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- | need for timely adoption of unambiguous, unique and directly implementable European technical specifications for every message type, concretized in FHIR R4 resources
  - | patient summary
  - | electronic prescription
  - | electronic dispensation
  - | medical imaging studies and related imaging reports
  - | medical test results, including laboratory and other diagnostic result and related reports
  - | discharge report

# General principles for Belgian implementation

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- | need for one unambiguous and unique European structured semantic value set (no mere free text !) for every data element where this is relevant, preferably
  - | SNOMED CT
  - | LOINC
  - | DICOM
  - | ISO
- | software packages must meet EU standards to be placed on the EU market
  - | EHR harmonised components (art. 25)
  - | EU declaration of conformity (art. 39)

# General principles for Belgian implementation

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- | concepts used
  - | MS A: MS from which information must be provided
  - | MS B: MS from where a health professional or a healthcare requests information
- | Belgium is MS A: conversion to the European standard is done as close as possible to the source of information
  - | if information is available in one or a limited number of central databases, by the controller of the database, e.g.
    - patient summary in health vaults
    - electronic prescriptions in Recip-e
  - | if available in PHR, by the software of the controller of the PHR
- | Belgium is MS B: conversion to the national standard is done by the software package of the user

# General principles for Belgian implementation

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- | the interoperable, cross-border identification and authentication mechanism for healthcare users, health professionals and health institutions mentioned in article 96 1 (a) shall ensure that
  - | the healthcare user is correctly identified with person identification data determined by MS A,
  - | the identity of the entity that wants to access personal data (health professional, health institution or healthcare user) is correctly authenticated by an electronic identification means with the level of assurance high within the meaning of the eIDAS regulation, including the European digital identity wallets (EUDI wallets)
  - | the qualification as a health professional or health institution is correctly determined by MS B and communicated to MS A in accordance with a uniform European classification
  - | the healthcare relationship between the healthcare user and the health professional or health institution is correctly determined by MS B and its existence is confirmed to MS A

# General principles for Belgium implementation

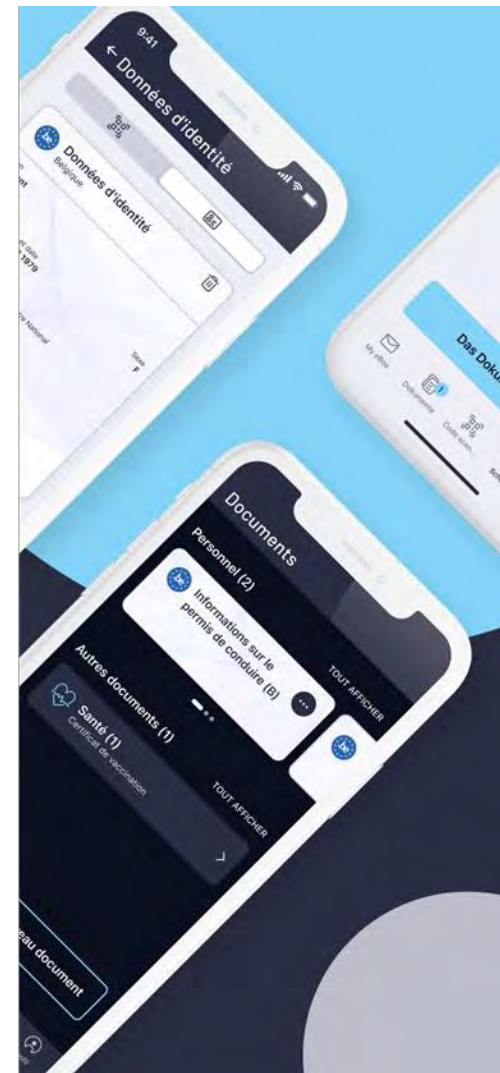
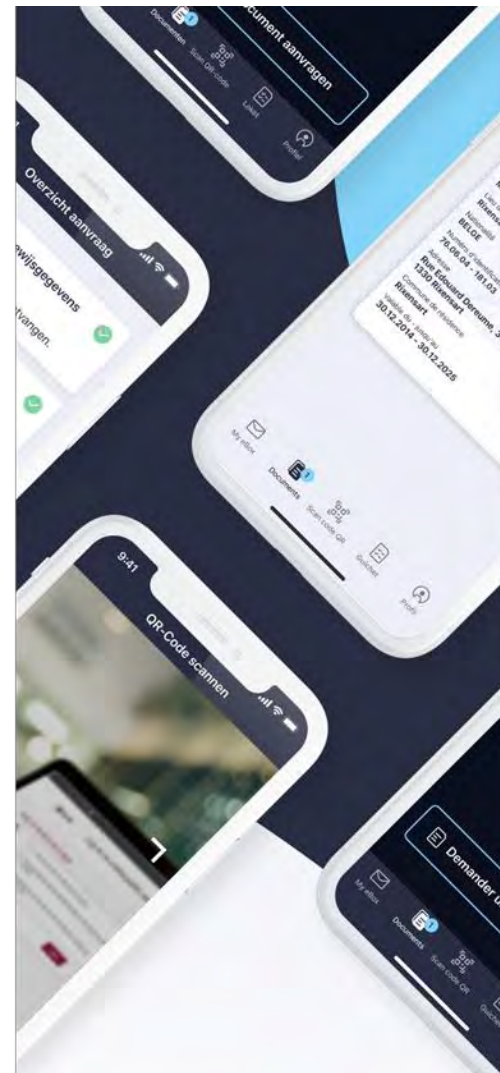
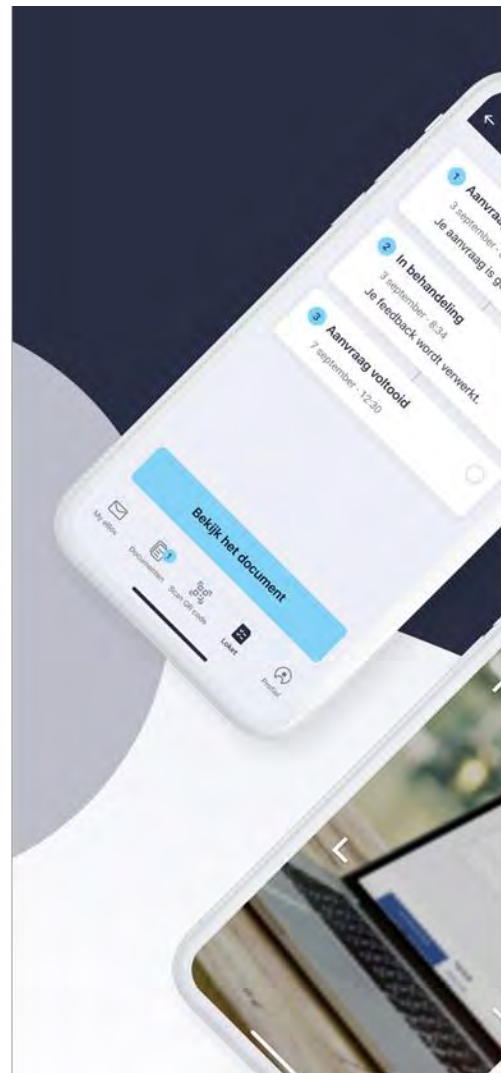
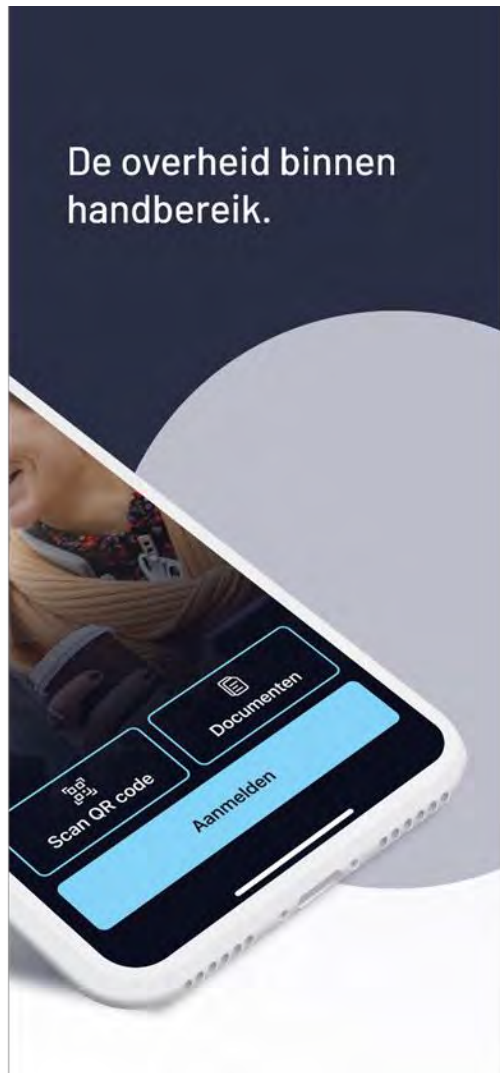
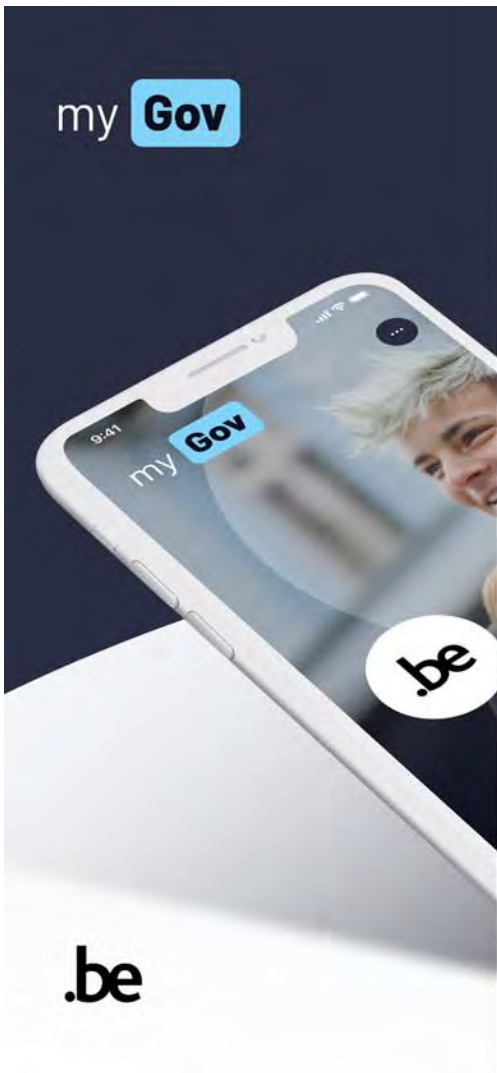
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- | based on this information, MS A can apply the national access authorisation rules adopted in accordance with European regulations
- | all functionalities of the EUDI wallets are valorized to simplify exchange processes
- | citizens must be confident that personal health data is only accessible to health professionals who have a healthcare relationship with them and the data minimization principle enshrined in GDPR must be respected => cross-border exchange of data should be established without the NCPs necessarily having access to personal health data

# Principles regarding electronic prescriptions

- | creating a prescription is done in accordance with the law of the MS where the prescription is created
- | executing a prescription is done in accordance with the law of the MS where the prescription is executed

# MyGov.be: Belgian EUDI wallet



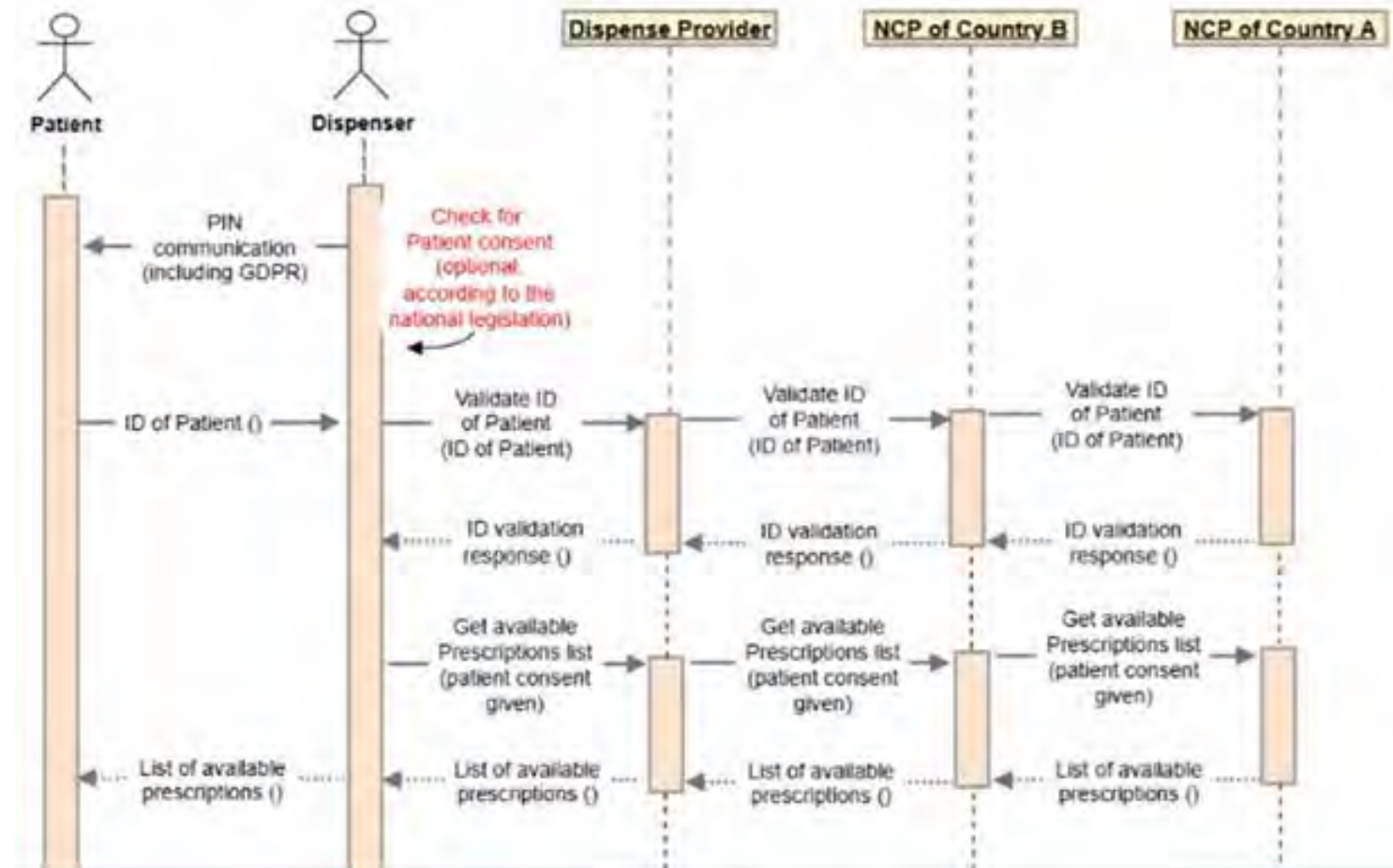
# MyGov.be: Belgian EUDI wallet

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- | digital wallet compliant with the European eIDAS Regulation 2.0
- | actual features
  - | digital identity authentication based on information in the National Register
  - | access to eBox citizen
  - | uploading and storage of legally valid digital documents, with the option of offline verification
  - | scanning of digitally signed QR codes, also available in PDF format
- | digital documents that can already be uploaded
  - | COVID vaccination certificates
  - | isi+ card for children
  - | birth and marriage certificates
  - | social status (MyBEnefits)
  - | vehicle registration certificate
  - | identity card data
  - | driving license data

# MyGov.be in support of EHDS

- | the possibility to upload, after digital identity authentication,
- | the European Health Insurance Card (EHIC) at health insurance funds
- | electronic prescriptions via Recip-e
- | anywhere and at any time
- | the possibility to electronically transfer data from both digital documents to the dispensing pharmacy by scanning a QR code
- | less opportunities for fraud thanks to digitally signed QR codes
- | avoids highly complex existing procedures



# Some concerns regarding implementing acts

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- | implementing acts shall permit to meet the requirements of EHDS Regulation while
  - | ensuring feasibility for EU manufacturers, including SMEs
  - | avoiding cost increase for health professionals and MS
- | implementing acts can only lay down detailed rules ensuring uniform conditions for the implementation of the EHDS Regulation, if and when this is necessary, but not (indirectly) add requirements
- | full respect of the principle of
  - | EU declaration of conformity
  - | use of the digital testing environments for the assessment of harmonized software components of EHR systems

=> no other certification mechanisms

# Open source European digital testing environment

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- | is available at the moment of the publication of the implementing acts defining the technical and semantic specifications and allowing conformity testing in the following areas
  - | harmonized components
  - | technical and semantic interoperability
  - | minimal quality (e.g. correct handling of typical use cases)
  - | identification and authentication mechanism
  - | exchange of evidence of the qualification as health professional and of the healthcare relationship
- | need for method for mutual recognition of conformity tests between MS

# To do's

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- | scanning of any necessary legal adjustments
- | well-coordinated Belgian representation in various working groups
- | monitoring good architecture, beyond primary & secondary use
- | good mutual integration of European and Belgian architecture
- | loyal implementation at the right time to maintain credibility/authority
- | sensible use of European funding



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