EHDS regels, architectuur & standaarden



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Agenda

- Wat zijn de doelen van de EHDS?
- Wat omvat de EHDS?
- Hoe vertaal je de EHDS naar architectuur?
- Hoe kun je die architectuur implementeren met standaarden?
- Vragen

Wie ben ik?

Wim de Koning

- BASTION365
  - CEO & Founder
  - Secure Data Sharing & Decision Intelligence
- Schrijver Wegiz Normen
  - NEN7541 (Beeld)
  - NEN7545 (eOverdracht)
- Bestuurslid IHE Nederland
  - Implementatie EHDS

IHE Nederland

- SDO & Kennisnetwerk
  - Zorgverleners & ICT Leveranciers
  - Samenwerking met ISO
- Profielen
- Methodiek (ISO/TR 28380)
- Connectathons
  - Conformance Testing

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EHDS Regulation[1] (EU) 2025/327

- **Facilitating Access to Electronic Health Data**
  - *“common rules, standards and infrastructures and a governance framework”*
  - *“primary and secondary use”*
- **Specify the Rights of Natural Persons**
- **Improve the functioning of the internal market**
  - “uniform legal and technical framework for EHR systems”

1) “A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States”. Art. 288 TFEU

EHDS Instruments (Primary Use)

Implementing Acts

Regulation (EU) 2025/327

Primary Use

Rights of natural persons
Art. 3–18
Art 14 Format
Art 15 Categories

Art 19 Authorities
Art 23 MyHealth@EU

EHR Systems

Art 25 Harmonised software Components of EHR systems

Art 36 Interoperability

Annex II

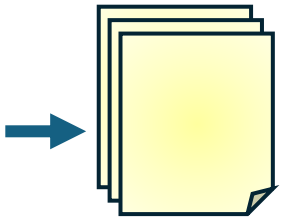
"Enforcement"

Art 85 Funding

Art 99 Penalties

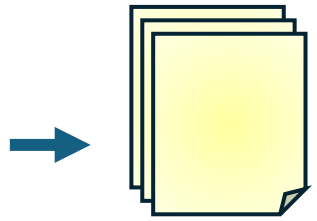
Art 100 Compensation

Art 105 Entry into force

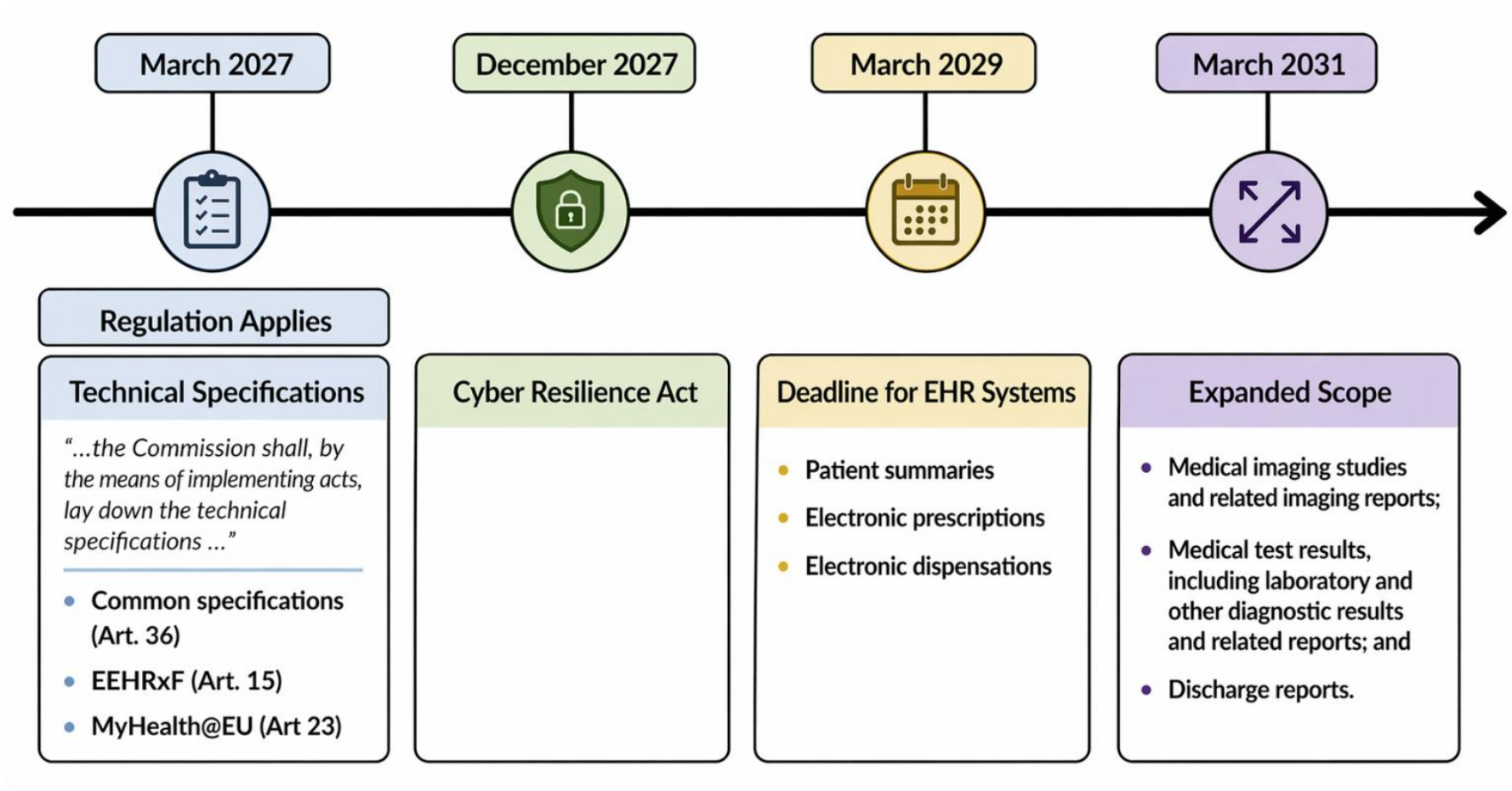


Foundational Acts

GDPR | **eIDAS** | **NIS 2** | **CRA**



EHDS Timeline



Rights of Natural Persons ('Use Cases')





- **Access their personal electronic health data (Art 3)**
- **Electronic Health Data Access Services (HDAS) (Art 4)**
- Insert information in their own EHR Art 5)
- Right of natural persons to rectification (Art 6)
- **Data portability for natural persons (Art 7)**
- Restrict access (Art 8)
- Obtain information data access(Art 9)
- Opt out in primary use (Art 10)
- **Access to health data by health professionals[11] (Art 11)**
- **Health professional access services (HPAS) (Art 12)**
- Registration of personal health data (Art 13)

Interoperability Component for EHR Systems[1]

- Secure Interoperability between EHR Systems using state-of-the-art standards
  - Also with Medical Devices, AI Systems, Wellness Systems Claiming Interoperability
  - Push & Pull API
  - EEHRxF Support
- Security, Confidentiality, Integrity, Protection, Identification
- **Uphold the rights of natural persons**
- No restrictions on sharing
- Reliable Identification & Authorization of Health Professional
- Access Logging of Identity, Categories, Date-Time, Origin

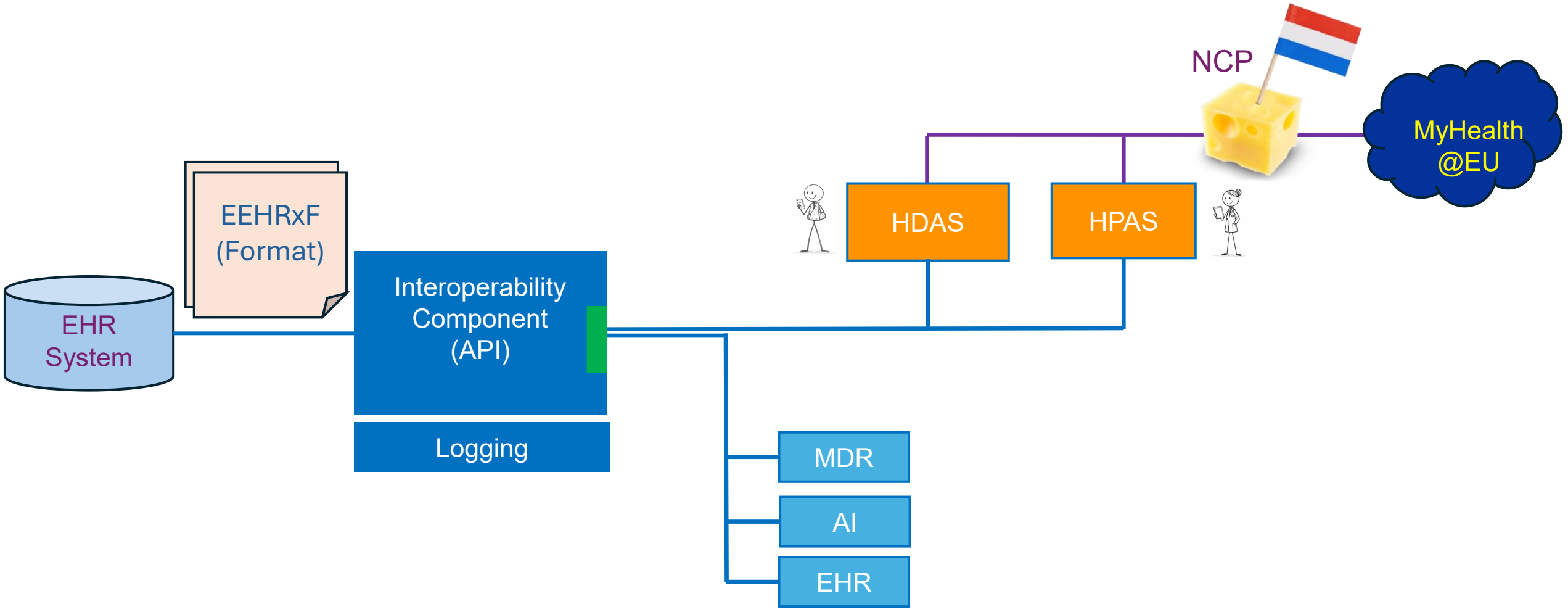
[1)] EHDS Art 36 en Annex II

EHDS Architecture: Key ‘Actors’

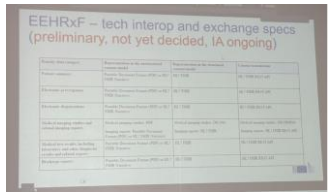
- EHR System [2(k)]
- Interop Component for EHR systems[2(n)]
- Logging Component for EHR systems[2(o)]
- HDAS: Electronic health data access service [2(h)]
- HPAS: Health professional access service[2(i)]
- myHealth@EU
- EEHRxF: European electronic health record exchange format[15]
- Priority Categories (of health data)[14]

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EHDS Architecture



API Specifications?

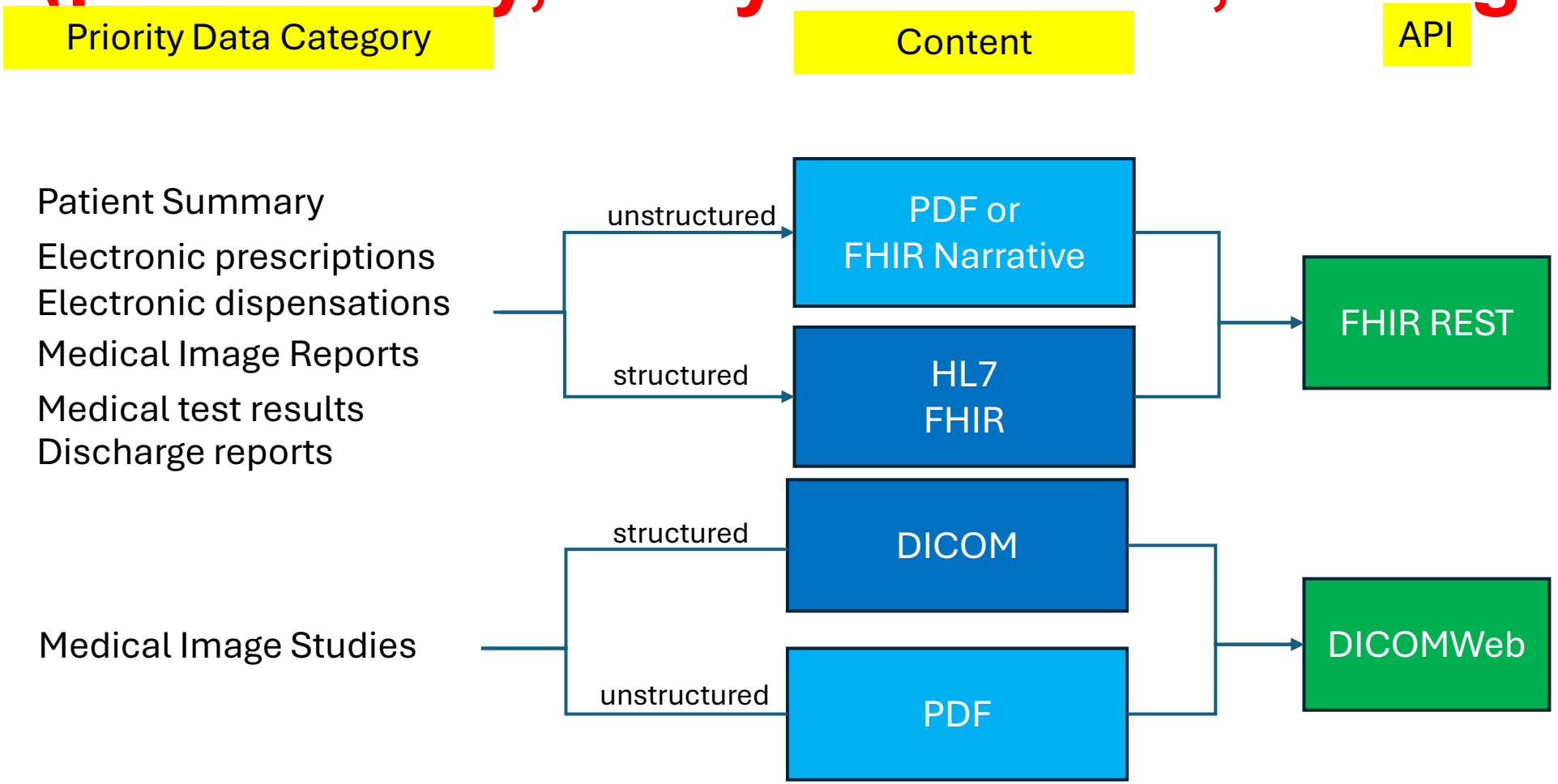


EEHRxF – tech interop and exchange specs (preliminary, not yet decided, IA ongoing)

Priority data category	Representation in the unstructured content model	Representation in the structured content model	Content transmission
Patient summary	Portable Document Format (PDF) or HL7 FHIR Narrative	HL7 FHIR	HL7 FHIR REST API
Electronic prescriptions	Portable Document Format (PDF) or HL7 FHIR Narrative	HL7 FHIR	HL7 FHIR REST API
Electronic dispensations	Portable Document Format (PDF) or HL7 FHIR Narrative	HL7 FHIR	HL7 FHIR REST API
Medical imaging studies and related imaging reports	Medical imaging studies: PDF Imaging reports: Portable Document Format (PDF) or HL7 FHIR Narrative	Medical imaging studies: DICOM Imaging reports: HL7 FHIR	Medical imaging studies: DICOMWeb Imaging reports: HL7 FHIR REST API
Medical test results, including laboratory and other diagnostic results and related reports	Portable Document Format (PDF) or HL7 FHIR Narrative	HL7 FHIR	HL7 FHIR REST API
Discharge reports	Portable Document Format (PDF) or HL7 FHIR Narrative	HL7 FHIR	HL7 FHIR REST API

Source: EU Cie Presentation, April 24, 2026 @ IHE Connectathon

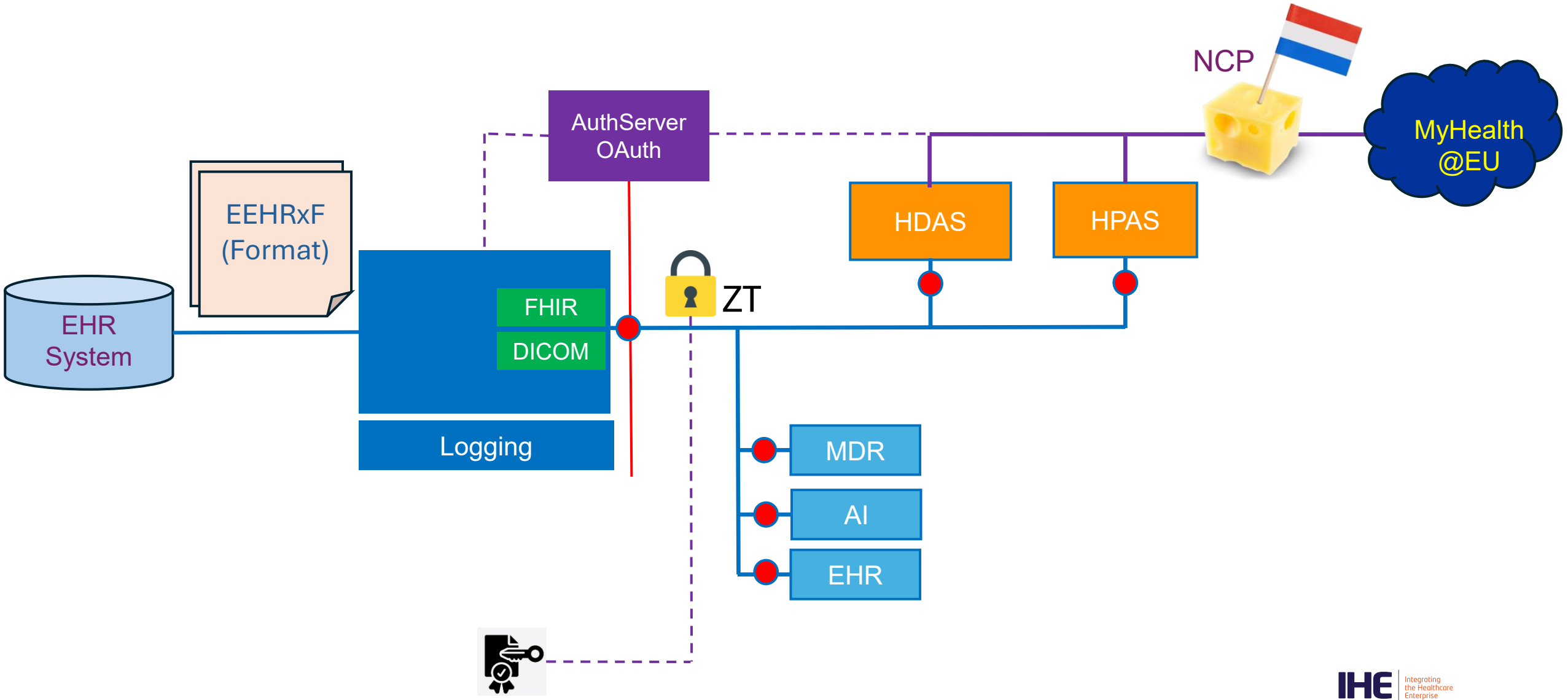
EEHRxF – tech interop and exchange specs (preliminary, not yet decided, IA ongoing)



EHDS API Security

- Protect RESTful API's
  - FHIR
  - DICOMweb
- Zero Trust Principles
  - mTLS
  - Authorization on each request
- Identification & Authentication
  - Art 36 / Annex II
  - Art 12 HPAS
  - Art 16 Identification Management
    - eIDAS (EU) 920/2014

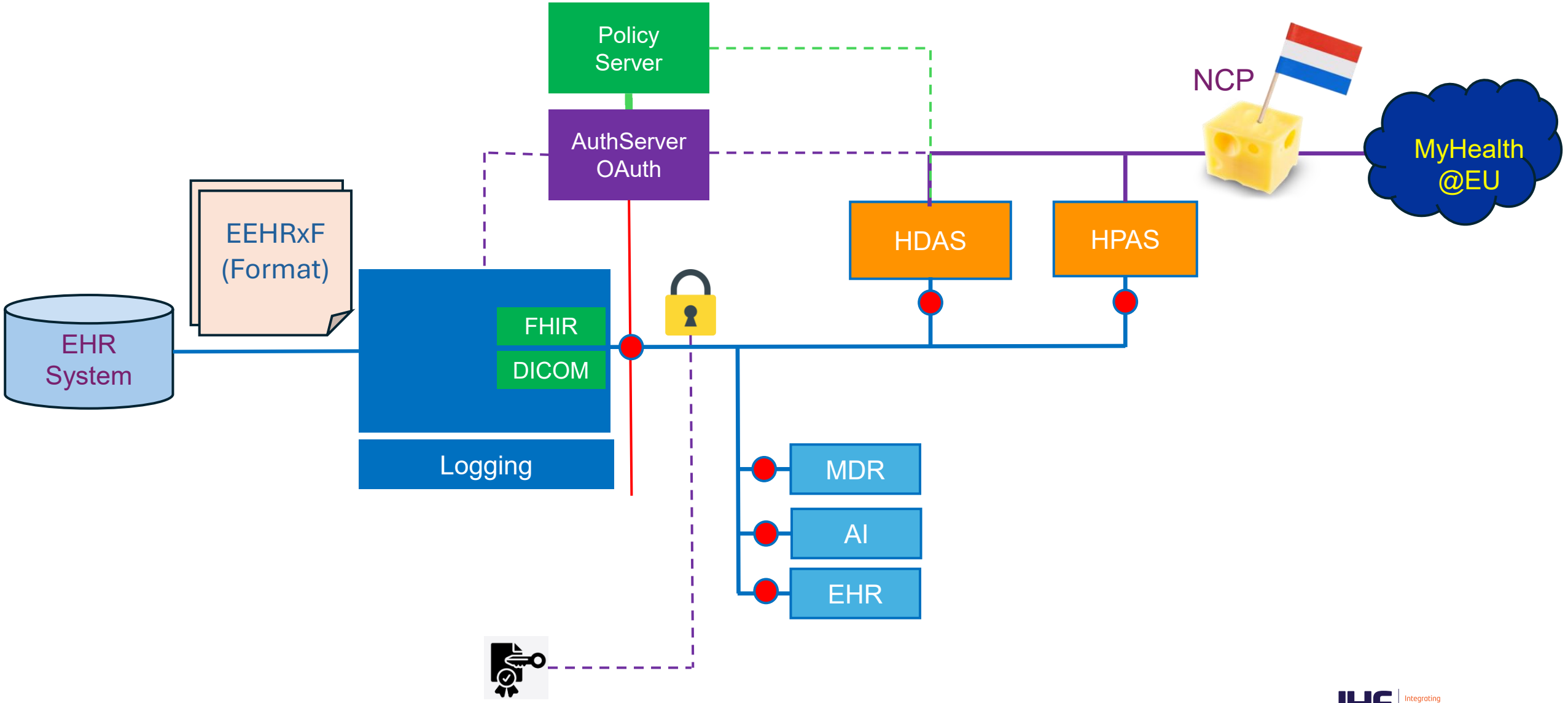
EHDS API Security



EHDS Privacy Layer (Authorization)

- Art 10: Opt out from access in primary use[10]
  - Blocks HDAS[4] & HPAS[12] Access
- Art 8: Restrict access of Healthcare Providers[8]
  - All or parts of their personal electronic health data
  - Access restrictions shall NOT be visible to healthcare provider[11.5]
- Art 4: Enabled via HDAS Proxy Services
  - Interoperable between member states[4.4]
  - Specifications in EU implementing acts[4.4]

EHDS Compliance



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Standards and Specifications

- Reg EU No 1025/2012 on European Standardisation
- ‘standard’ means a technical specification, adopted by a recognised standardisation body
    - International standard: ISO, IEC, ITU
    - European standards: CEN, Cenelec, ETSI
    - National standard: NEN
- Technical specification:
    - document that prescribes technical requirements to be fulfilled by a product,
    - Can be eligible for referencing[1]
    - If compliant with Annex II
- Harmonised Standard
    - EU standard with legal effects
    - presumption of conformity with legal requirements
- Technical specification may not replace or compete with a standard

1) (EU) 2015/1302 for 23 IHE Profiles

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Which ‘Standards’?



- HL7 FHIR IG’s
  - IPS, EPS,



- DICOM Conformance Statement
  - DICOM only
  - Legally binding



- IHE Profiles (Integration Statement/Seal)
  - EU Referenceable
  - Verified Interop (Connectathon)



- EU Common Specifications
  - Presumption of legal conformity
  - Usually interop testing

IHE ‘EHDS’ Profiles (Safe Bets)

- IHE MHD
  - FHIR RESTful API
  - Wegiz NEN 7541
- IHE WIA/WIC
  - DICOMWeb RESTful API
  - Wegiz NEN 7545
- IHE IPS
  - FHIR R4
- IHE PDQm
- IHE IUA
  - HTTP API Authorization
  - OAuth 2.0
  - *NL/EU extension tbd*
- IHE ATNA
  - Secure Node (TLS)
  - Logging (FHIR)
- *IHE mCSD*
  - *Addressing API (FHIR)*

In conclusion

- EHDS is a complete framework for Health Data Sharing, both National and EU wide.
- It is ‘the law’ with a very tight deadline
- National requirements can be implemented as extensions
- Comprehensive controls for cybersecurity, privacy and patient rights.
- Most economic way to implement national strategy
- Enough to get started, but major details (EU and National) are still missing
- NL national policies very poorly aligned: many, many conflicting projects, policies and government spending
- So start now, but mind the gap!
- We are here to help:

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Questions?

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