



EGIZ

'Samen vooruit met Wegiz'

WELKOM





European Health Data Space

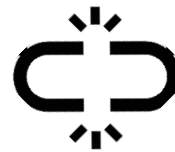


Main problems

Individuals have difficulty accessing and controlling their health data



Healthcare professionals have difficulty accessing health data



Providers of digital health services and products face barriers



Policy makers and regulators cannot easily access health data



Limited innovation takes place on the basis of health data

User perspectives

Empower citizens to have control over their health data



Better diagnosis and treatment, improved patient safety, continuity of care and improved healthcare efficiency

Health data from apps and medical devices



Health data in registries



Electronic health records

Enable healthcare professionals to have access to relevant health data



Assist policy makers and regulators in accessing relevant health data



Facilitate access to health data for innovators in industry



Grant access to health data for researchers



Better health policy, greater opportunities for research and innovation

The scope of EHDS

Strengthens the rights of individuals in relation to greater control over their electronic health data:

Access, share health data with health professionals nationally or cross-border, add information, rectify errors, restrict access, know what health professional accessed data, issue and accept health data in a common European format, strengthen interoperability.

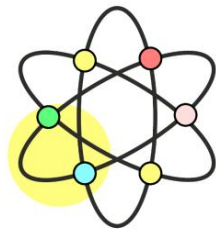


Rules for electronic health record systems (EHR systems)

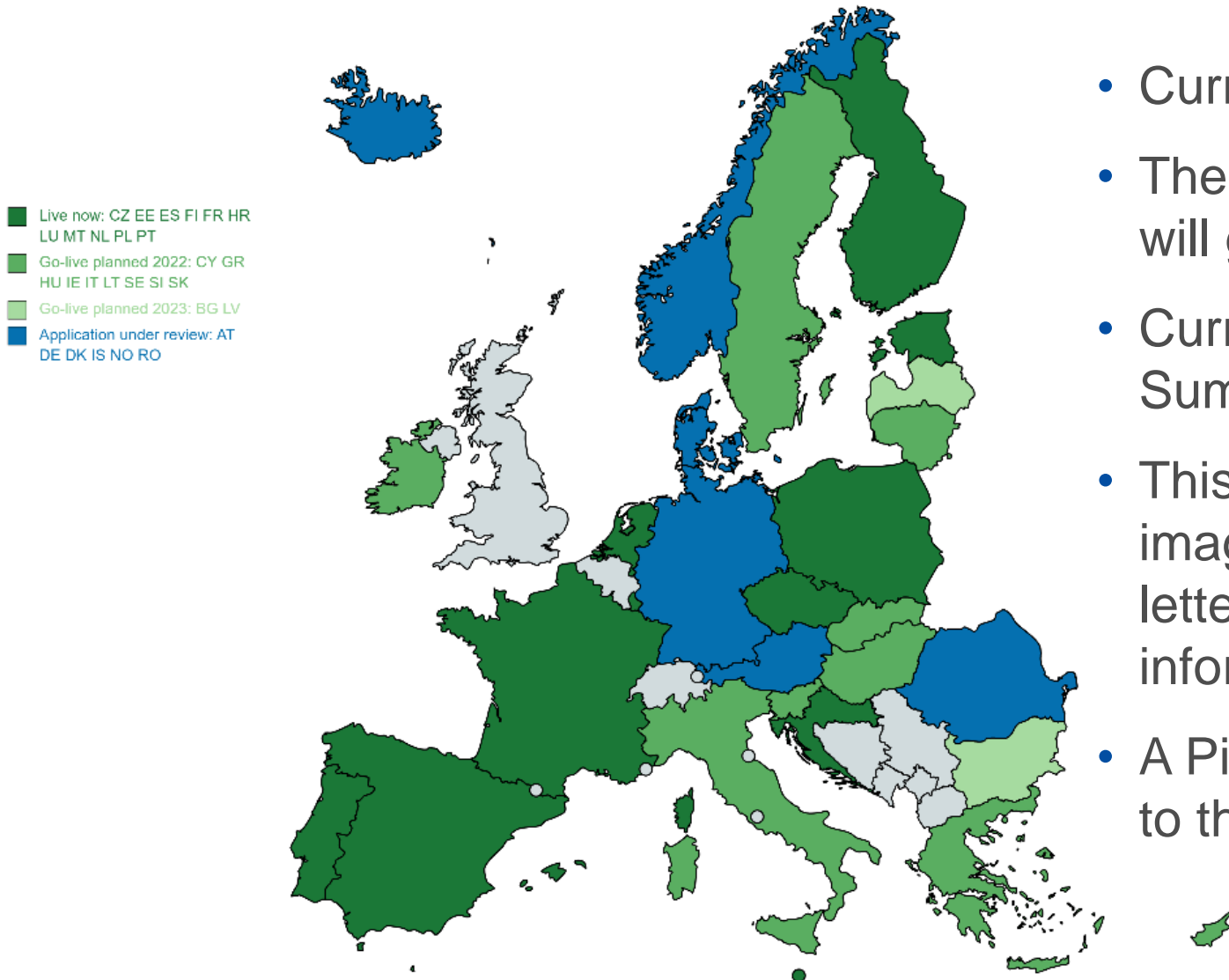
Rules and mechanisms supporting the secondary use of electronic health data

Mandatory cross-border infrastructures for primary and secondary use of health data

- MyHealth@EU
- HealthData@EU



MyHealth@EU



- Currently 11 Member States are live
- The number of connected Member States will grow rapidly in the years ahead
- Currently there are 2 services: Patient Summary and ePrescription
- This is being expanded to include Medical images, Laboratory results, Discharge letters, Rare disease data and other health information categories
- A Pilot project will explore Patient Access to their health data in MyHealth@EU

Primary use of health data

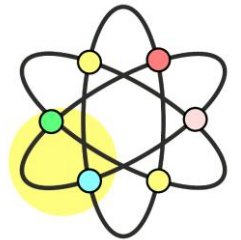
- The legislative proposal will introduce:



- Rights of individuals and healthcare professionals to access health data through **health data access services**



- Minimum requirements for specific health data categories in EHR systems through **self-certification**, registered in an EU database and voluntary labelling of wellness apps



- **Mandatory deployment** of MyHealth@EU with a transition period for different services
- Designation of national digital health authorities, working in EU comitology towards binding **Delegated and Implementing Acts**



Governance

- **Article 14** of Directive 2011/24/EU **is deleted** (Art. 71)
- a new **European Health Data Space Board** (*high level representatives of digital health authorities (primary) and new health data access bodies (secondary) from all the Member States, the Commission, observers etc*). The Commission will chair these meetings. Among other tasks, it will assist Member States in coordinating practices, issue written contributions and to exchange best practices, facilitate cooperation of Member States etc

Governance



- **Comitology committee** – to provide an opinion on draft implementing acts (*now – more than 20 empowerments for implementing acts in the text*). They include one representative from every EU country and are chaired by the Commission.
- **Expert groups** - the Commission will prepare and adopt **binding delegated acts** (*now - more than 10 in the text*) after consulting experts groups, composed of representatives from each EU country.
- **Joint controllership groups** - for two cross-border digital infrastructures (one for primary and another one for secondary uses of health data). The composition, organisation, functioning and cooperation of the sub-groups shall be set out in the rules of procedure adopted by those groups.

Entering into force

- The Regulation will start applying **one year** after its adoption by the co-legislators.
- The proposal foresees **transition periods** for the application of different elements of the proposal, especially related to the primary use of health data
 - Patient Summary and ePrescription should be introduced **1 year** after entry into force
 - Medical images, lab results and hospital discharge reports should be introduced **3 years** after entry into force

Next steps

The Regulation is currently being negotiated by the Council of the EU and European Parliament.

More information can be found online: [European Health Data Space \(europea.eu\)](https://europea.eu)

To get involved, please reach out to hugo.van-haastert@ec.europa.eu

Thank you!

Thank you



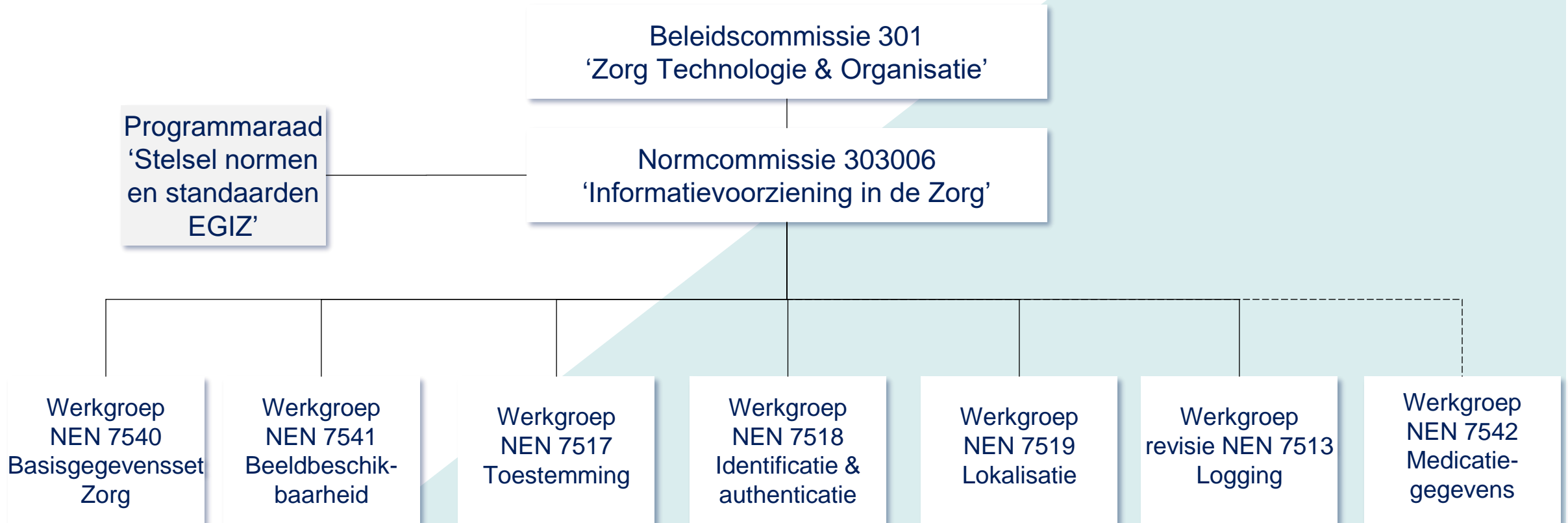
© European Union 2021

Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.

Slide xx: **element concerned**, source: [e.g. Fotolia.com](https://www.fotolia.com/); Slide xx: **element concerned**, source: [e.g. iStock.com](https://www.istock.com/)



Organisatiestructuur normontwikkeling



Fasen normontwikkeling



Informatiebijeenkomst

- Belanghebbenden geïnformeerd over mogelijkheid deelname werkgroep



Ontwikkeling

- Oprichten werkgroep
- Werkgroep schrijft norm



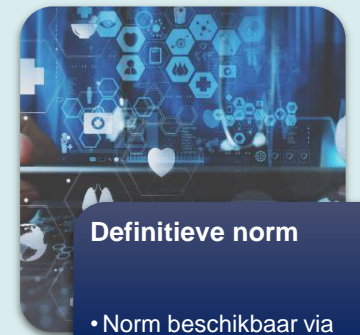
Normontwerp

- Publicatie op normontwerpen.nen.nl
- 3 maanden commentaarperiode



Verwerking

- Werkgroep verwerkt commentaar



Definitieve norm

- Norm beschikbaar via nen-egiz.nl



Status specifieke en generieke normen

Specifieke normen

	Status
NEN 7503 Voorschrijven en ter handstellen medicatie	Gepubliceerd april 2022
NEN 7540 Basisgegevensset Zorg	Binnenkort publicatie normontwerp
NEN 7541 Beeldbeschikbaarheid	In ontwikkeling
NEN 7542 Medicatiegegevens	Informatiebijeenkomst 31 oktober 2022

Generieke normen

	Status
NEN 7517 Toestemming	In ontwikkeling
NEN 7518 Identificatie & authenticatie	In ontwikkeling
NEN 7519 Lokalisatie	In ontwikkeling
NEN 7510 Informatiebeveiliging	Informatiebijeenkomst start revisie 29 september 2022
NEN 7512 Vertrouwensbasis gegevensuitwisseling	Gepubliceerd juli 2022
NEN 7513 Logging	In revisie



BEDANKT

Meer informatie: www.nen-egiz.nl of
www.gegevensuitwisselingindezorg.nl

