

2024 EHTEL Symposium

The EU digital health policy journey

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Also:

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PHASE 1 – Where we came from



2011 →

Digital Health as a service enabler in the Cross-border Healthcare Directive

- EU competence to complement national healthcare policies
- Patient rights when seeking healthcare in another EU country
- Supporting digital technologies to improve healthcare
 - ERNs (European Rare Disease Networks)
 - > eHDSI (eHealth Digital Service Infrastructure) ePresciptions, Patient Summaries
 - > Telemedicine

PHASE 1 – Where we came from

Digital Health and Care 🛚 🗞 🖧

TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Hamessing the potential of data to empower citizens and build a healthier society

2018

Communication on • enabling the digital transformation of health and care in the **Digital Single Market**

2019

Recommendation on a **European Electronic Health Record** exchange format

European health challenges

- Ageing population and chronic diseases putting pressure on health budgets
- Unequal quality and access to healthcare services 88
- 88 Shortage of health professionals

Potential of digital applications and data to improve health

- Efficient and integrated healthcare systems
- Personalised health research, diagnosis and treatment
- Prevention and citizen-centred health services

What EU citizens expect...

90% To access their own health data (requiring interoperable and quality health data)

80%

To share their health data agree

80%

To provide feedback on quality of treatments

Support European Commission:

Ambition:

Citizens securely access their

(doctors, pharmacies...) can

exchange them across the EU.

health data and health providers

Secure access and exchange of health data



- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and

ePrescriptions) and cooperation between participating countries will be strengthened. - Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records. - Recommended exchange format for interoperability of existing electronic health records in Europe.

and personalised medicine

Ambition:

feedback).

Ambition:

Health data pooled for research

Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

- Voluntary collaboration mechanisms for health research and clinical practice (starting with "one million genomes by 2022" target). - Specifications for secure access and exchange of health data. - Pilot actions on rare diseases, infectious diseases and impact data.

Digital tools and data for citizen empowerment and person-centred healthcare



Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing

Graphic created by the European Commission

- Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification. - Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance. - Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.



PHASE 2 – Where we are now

Overview of digital (health) legislation and related issues in the European Union



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2024

The European Health Data Space Regulation recognises:

- Data is a fuel for better health services
- Data needs to be interoperable and in good quality
- Need to balance the power of the use of data with data subject rights
- Need to have wide range of stakeholders on board

EHDS: Patients' rights and researchers' interests

Primary use of health data

Legal base for processing

• Legal base for primary use

Enhanced data access

- Immediate, free of charge
- Access for proxy
- Access service

Data Addition

- Apps
- Personal notes



Secondary use of health data

Legal base for re-use

- Legal base for secondary use
- Health Data Access Bodies
- Data access Permits

Data Quality Assurance

- Data catalogues
- Quality and utility labeling
- Enhanced data returned to HDAB

Transparency

- Access Log
- Annual report

Opt-out

 MS may provide opt-out for sharing EHRs with other care providers

Opt-out

• Right to opt-out of secondary use

Transparency

- Access Log
 - Annual report secondary use

European Health Data Space:

(Preliminary) Implementation Timeline



PHASE 1:

- Establish digital infrastructure
- Adopt preparatory measures to support MS, health data holders and EHR systems manufacturing in meeting their obligations

PHASE 2:

- Regular updating of implement acts
- Maintenance and operation of the systems under the EHDS at EU and MS level

This phase includes setting up the foundational systems and ensuring that all parties are ready to effectively comply with the EHDS requirements.

This phase ensures the sustained functionality and compliance of the digital health infrastructure.



2025 →

The new horizon

- Al to generate synthetic data to mimic real-world patient data and drive innovation in healthcare
- Individuals to be empowered by apps and devices to engage more fully in healthcare and in public health
- Digital technologies to enable disease prevention at larger scale fighting antimicrobial resistance, cancer, and epidemics

PHASE 3 – Direction of travel



2025

- Al Act becomes applicable
- Supporting integration of AI into healthcare, starting the next generation of digital health

PHASE 3 – Direction of travel



Graphic created by the European Commission

2025

- Urgent need to revise the MDR
- Recognising the role of software as a medical device and health apps

PHASE 3 – Direction of travel

2025

- Pharmaceutical package is expected to be adopted
- Moving towards eProduct information, use of real world evidence in marketing application

THE PHARMACEUTICAL STRATEGY FOR EUROPE

Innovative & Addressing unmet affordable medicines medical needs Enhancing preparedness Strengthening EU & reducing shortages competitiveness #EUPharmaStrategy #EUHealthUnion Õ European





The future of digital health in Europe is bright !



Thank you very much

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