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DATA PRIVACY, CYBERSECURITY AND TECHNOLOGY LAW

Regulation 2025/327 on European Health Data Space: Spacing out the preparation steps for compliance

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Regulation 2025/327 on European Health Data Space: Pacing the Path to EHDS Compliance

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Introduction

The EU has taken a major step forward in its vision for a unified data economy. The first-ever legal text on European Data Spaces, forming part of the European Data Strategy, has now been published, adding a crucial piece to the evolving framework for data governance in the EU. The newly adopted **Regulation 2025/327 on the European Health Data Space (EHDS)** entered into force on 26 March 2025. This landmark Regulation lays the groundwork for how health data will be accessed, shared, and reused across Member States, ushering in a new era for digital health in Europe.

Because the EHDS requires the development of complex technical and procedural frameworks, its implementation will be **phased** between 26 March 2027 and 26 March 2035. During this period, Member States will gradually put the necessary structures in place. While maintaining harmonized EU-wide implementation, they may also adopt national rules for certain aspects falling within the Regulation's scope.

With 105 Articles introducing a wide range of new obligations, stakeholders should take full advantage of the transitional period to prepare early and align their systems and practices.

Key highlights

The Regulation brings important changes across three main areas:

Primary use of electronic health data: Strengthens individuals' access to and control over their personal electronic health information.

Secondary use of electronic health data: Tackles legal fragmentation and creates a level playing field for the reuse of health data for research, innovation, policymaking, patient safety and personalised medicine.

The market of Electronic Heath Record Systems (EHR systems): Promotes interoperability and supports the development of a digital single market for EHR systems across the EU.

Stakeholders affected

The implementation of the EHDS Regulation calls for coordinated action from both private and public sector entities, making collaboration between the two essential. It sets out obligations that apply to the activities of the following sectors:

- **Manufacturers of EHR systems and other economic operators** involved in placing them on the market or putting them into service.
- **Healthcare providers.**
- **Manufacturers of wellness applications.**
- **Health Data Holders,** with the exception of natural persons and microenterprises.
- **Health Data Users.**

In this newsletter we will focus on the key obligations for i) EHR market actors, and ii) stakeholders involved in secondary use of health data.

New requirements for EHR systems

The Regulation introduces a range of new obligations for stakeholders involved in the supply chain of EHR systems. These requirements vary depending on the actor's role, whether as a manufacturer, importer, or distributor.

For manufacturers of EHR systems:

Manufacturers must:

- Ensure compliance with the **harmonised software components** of EHR systems, to guarantee interoperability with the European Electronic Health Record Exchange Format **(EHRxF)** and enable log generation, as detailed in the European Commission's implementing acts (to be adopted by 26 March 2027).
- Prepare and maintain technical documentation demonstrating compliance.
- Provide specific information to users and distributors.
- Draw up an EU declaration of Conformity and affix CE marking.
- Keep a register of complaints and cooperate with market surveillance authorities.
- Appoint an authorised representative (if the manufacturer is established outside the EU).

For importers and distributors of EHR systems:

Importers and distributors are required to:

- Verify that EHR systems conform with the harmonised software components and their common specifications.
- Ensure that required information is made available to users.
- Notify relevant stakeholders in the event of a risk.
- Cooperate with market surveillance authorities.
- Assume the manufacturer's obligations under certain circumstances (for instance, when they place a system on the market under their own name).

It is also worth noting that the Regulation interacts closely **with existing EU legislation on medical devices and artificial intelligence (AI) systems** ensuring coherence across the broader digital health regulatory landscape.

New obligations in the context of secondary use

The EHDS Regulation establishes a common EU-wide framework for accessing electronic health data for secondary use, aiming to unlock the vast potential of health data for societal and economic benefit across the EU. To support this, it establishes a dedicated infrastructure, 'HealthData@EU', which will enable secure and harmonised cross-border access to health data for secondary purposes such as research, innovation, policymaking, patient safety, and personalised medicine.

The first step towards compliance for any organisation is to assess whether its activities qualify under the Regulation's definitions of a '**data holder' or/and a 'data user'**. Depending on their role across the health data ecosystem, different obligations will apply within the health data ecosystem.

For Health data holders:

Health data holders must:

- Determine whether the data they hold fall within the 17 categories of health data eligible for secondary use including data from electronic health records, medical devices, wellness applications, clinical trials, and research questionnaires or surveys (after their initial publication).
- Notify the competent **Health Data Access Body** (**HDAB**) by providing a description of their datasets falling within the above categories (the "data catalogue").

- Provide access to the requested data to the HDAB within a specific timeframe (generally within 3 months).
- Review and update their data catalogue annually, correcting any inaccuracies, when necessary.
- Make non-personal data available through trusted open databases to facilitate transparency and reuse.

IP protected data: When a dataset includes material covered by intellectual property rights, trade secrets or data exclusivity under EU medicines law, the data holder must inform the HDAB. After the HDAB issues a data permit, the data holders may still be obliged to share the protected data for approved secondary use, subject to the Regulation's strict safeguards.

For Health data users:

Health data users are required to:

- Process electronic health data strictly in accordance with the legal requirements and the conditions set out in the data permit issued by the HDAB.
- Pay fees, when required by the HDAB.
- Comply with transparency obligations, including disclosing the results or outputs of secondary use activities and identifying the source of the data used.
- Notify the HDAB of any significant finding relating to a individual's health, when that person's data are included in the dataset.

Health data users' responsibilities are equally relevant to the entrepreneurial and research ecosystem, as the definition of "data user" covers a wide range of stakeholders engaging in research, ranging from private educational and research institutions to SMEs, startups, and larger companies involved in development, innovation, and AI training.

Enforcement measures and fines

The HDAB is empowered to enforce compliance with the EHDS Regulation and may impose **significant** fines on health data holders and users who fail to meet their obligations.

The fines can reach **EUR 20.000.000 or, in the case of an undertaking, 4 % of its total worldwide** annual turnover (whichever is higher).

Conclusions – Final remarks

The EHDS Regulation represents a major leap forward in Europe's digital transformation — aiming to unlock the power of health data to improve patient care, disease prevention, innovation and economic growth. To achieve this vision, the Regulation sets out a robust and trusted framework for the safe, ethical and transparent use of health data, ensuring high standards of data protection, security and confidentiality. Its provisions build on existing EU data legislation, including the Data Governance Act, Data Act and GDPR, while introducing a new layer of obligations tailored to the health sector.

At the same time, the EHDS also introduces a complex set of compliance requirements for all stakeholders in the health data ecosystem. Early and structured preparation will be essential to seize opportunities while minimizing compliance risks once the Regulation is fully in force.

As the EU lays the foundations for a truly connected health data landscape, the next few years will be decisive. Those who prepare early will not only ensure compliance, they 'll be ready to lead the digital health revolution.

Our firm will continue to monitor EU and national developments as the EHDS framework takes shape. In the next two years, the EU's implementing acts and national measures will specify key obligations, while Member States, including Greece, advance technical preparations to bring the new system to life.

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