EHDS and health data interoperability: implications for medical devices and high-risk AI

The Regulation (EU) 2025/327 on the European Health Data Space (EHDS) is the new European legal framework aimed at improving access to and sharing of health data.
The main beneficiaries of this regulation include:

- Patients: simplified access to their own health data and greater control over it.
- Healthcare providers: access to more complete data for better care.
- Research: improved use of data for innovations in the healthcare sector.

How is the EHDS Regulation structured, and what are its main areas of focus?

The regulation is structured as follows:

- Title I – General Provisions: establishes common rules for electronic health record systems and specifically defines two key terms for categorizing the use of health data: primary use and secondary use. These are defined respectively as:
    - the processing of electronic health data for the provision of healthcare to assess, maintain, or restore the health status of the individual to whom the data relate.
    - the processing of electronic health data for purposes other than those for which the data were initially collected or generated.
- Title II – Primary Use: provides additional rights to patients and establishes the technical infrastructure required for their implementation. Member States must ensure that the necessary national infrastructure is operational and that healthcare providers are connected to it.
- Title III – Electronic Health Record (EHR) Systems: addresses manufacturers and other economic operators who make EHR systems available on the market. It sets requirements regarding interoperability and logging capabilities of these systems. It also establishes market surveillance mechanisms for EHR systems, assigning Member States the task of designating competent authorities and regulating their activities.
- Title IV – Secondary Use: targets data holders and users. It imposes obligations on data holders to make data available and regulates how users may access and use the data. It also

establishes Health Data Access Bodies (HDABs) and the infrastructure required for their operation.

How does the regulation facilitate the exchange and use of health data across Europe?

An important aspect of the regulation is the presentation of the MyHealth@EU and HealthData@EU infrastructures:

- MyHealth@EU is the European infrastructure for digital health services. It enables cross-border exchange of health data among EU countries. A key innovation of the regulation is that health data belongs to the citizen, who has the right to access, manage, and share it in a simple and secure manner.
- HealthData@EU allows the use of anonymized health data for purposes beyond individual patient care, contributing to medical progress and the improvement of public health, as well as the development of new drugs, therapies, and medical devices. This facilitates more effective research and better organization of healthcare services.

Does the regulation concern only EHR system manufacturers?

At first glance, the regulation may seem to impose obligations only on EHR system manufacturers and their importers and distributors, but this is not the case: manufacturers of medical devices and in vitro diagnostic (IVD) devices must also take into account the provisions of Article 1(5) and Article 27. Article 27 stipulates that when devices declare "interoperability" with harmonized software components of electronic health record systems, the provisions of Article 36—introducing the "Common Specifications"—must be applied. These specifications aim to ensure technical uniformity, safety, and consistency in the integration of devices within European digital health infrastructures.

The main obligations for manufacturers include technical adaptation of their devices to the required standards (e.g., HL7 FHIR), demonstration of compliance through appropriate documentation, establishment of ongoing update processes in line with evolving specifications and ensuring that interoperability features do not compromise data security or clinical reliability. Article 53 should also be considered, as it may directly affect the regulatory framework for medical devices, particularly regarding additional obligations for data access, sharing, and reuse, with potential impacts on design and product lifecycle.

It is important to note that similar principles also apply to high-risk artificial intelligence systems, which, under the European AI Regulation, must meet strict requirements for safety, transparency, traceability, and technical compliance. Therefore, both medical devices and IVD manufacturers, as well as developers of high-risk AI solutions, are required to ensure a high level of regulatory compliance to safeguard healthcare quality, data protection, and the trust of patients and professionals.

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