



POLICY BRIEF

15 09 2025
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THE EUROPEAN HEALTH DATA SPACE REGULATION

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The European Health Data Space Regulation	
BACKGROUND AND FIELD OF APPLICATION	<p>A central component of the European Data Strategy is the creation of common European Data Spaces, that are interoperable and secure infrastructures designed to support large-scale data sharing across sectors. Among these, the European Health Data Space (EHDS),¹ established by Regulation 327/2025, introduces a unified framework for the exchange and use of electronic health data, which are considered sensitive personal data under Article 9 GDPR.</p> <p>The EHDS serves two main functions: enabling access to health data for primary use, meaning its processing for healthcare delivery, and for secondary use, which refers to processing for other purposes such as research, innovation, and policy-making.</p>
HIGHLIGHTS	<p>Concerning secondary use, these are the main provisions:</p> <ul style="list-style-type: none"> ○ The EHDS Regulation establishes a legal basis for the secondary use of electronic health data under Article 9(2)(g–j) GDPR, supported by specific safeguards. ○ Secondary use is strictly limited to purposes listed in Article 53(1), such as public health, policy-making, statistics, education, research, and healthcare system improvement. ○ Five categories of use are explicitly prohibited, including discriminatory decision-making, marketing, development of harmful products, and ethically questionable activities. ○ Access to data for secondary use is granted through three procedures: data permits, requests for anonymised statistical data, and approvals via the HealthData@EU infrastructure. The data permit process involves a detailed application and assessment by a health data access body, which evaluates the purpose, necessity, legal basis, and security measures before issuing a permit valid for up to ten years. ○ Data must be accessed through secure processing environments (SPEs) that ensure GDPR compliance and protect intellectual property, confidentiality, and data integrity. These environments are tightly controlled, with predefined protocols and access tracking. ○ Individuals have the right to opt out of secondary data processing, although national laws may allow exceptions for public interest purposes if specific conditions are met, such as the absence of alternative data sources and a justified request from a public entity.
IMPACT	<p>The secondary use of data is particularly important for research projects that involve the development or training of tools requiring health-</p>

¹ Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.



	<p>related datasets for training and validation. The European Health Data Space (EHDS) will facilitate secure access to relevant data, such as medical imaging, which can be used to enhance the performance of AI-based systems for medical decision support, among other applications. While the regulation sets out clear rules and standards that should greatly benefit scientific research in the health sector, its implementation will unfold gradually, and its full impact will depend on how Member States and stakeholders operationalize its provisions over time. The interplay with national rules and implementing decrees, such as those established by Law 132/2025 in Italy (see Policy Brief no. 18), will need to be carefully analysed, even if the expectations for an overall simplification of the legal framework on data sharing are high.</p>
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