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Life Sciences & Healthcare News

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Health Data: the European Health Data Space Regulation has been published in the EU Official Journal

On 5 March 2025, the new EU Regulation 2025/327 introducing the European Health Data Space has been published in the EU Official Journal. The Regulation aims to improve individuals' access to their personal electronic health data, and it provides for a health-specific data environment that will ensure cross-border access to digital health services and products within the EU.

Through the new Regulation, patients will have the possibility to access, control and share their data with healthcare providers (so-called "primary use"), even though they are located in different Member States.

In addition, the Regulation sets out the rules for the reuse of certain data (e.g. genomic data) for research, innovation, policy-making, and regulatory activities (so-called "secondary use" of data).

Following the publication in the EU Official Journal, the Regulation came into force on 25 March 2025, while the provisions contained therein will progressively become applicable starting from 26 March 2027.

Health Data: Italian health data ecosystem implemented by the new Italian Ministerial Decree

The Ministerial Decree issued by the Italian Ministry of Health with the Ministry of Economics, published in the Italian Official Gazette on 5 March 2025, introduced the so-called Italian "health data ecosystem" ("**HDE**"), an innovative digital system for collecting and analysing health data that will provide advanced and innovative services, particularly for patients and healthcare professionals.

The HDE creates a health data space on a national level (unlike the European Health Data Space, which will provide a European interconnected system), that will interact with other Italian digital health tools, such as electronic health records, the national health card system and the national register of assisted individuals, in order to centralise the collection of data and improve the quality of healthcare.

Similarly to the European Health Data Space Regulation, access to the HDE will be granted for purposes related to patients' assistance (so-called "primary use") and for research, innovation, policy-making, and regulatory activities (so-called "secondary use" of data).

Pursuant to Article 25 of the Ministerial Decree, HDE services shall be available within 31 March 2026.

Health Technologies: on 12 January 2025 the EU Regulation concerning health technology assessment came into force

On 12 January 2025, the EU Regulation 2021/2282 concerning health technology assessment (the "**HTA Regulation**") became applicable. The HTA Regulation marks an important step forward in the creation of a harmonised system for the evaluation of healthcare technologies, such as medicines and medical devices, in the European Union.

The new rules apply to companies seeking marketing authorisation for their products and is also aimed at reducing regulatory burdens. In particular, the HTA Regulation:

> introduces a single EU-level submission file for joint clinical assessments, avoiding duplication of assessments at a national level;
> establishes faster procedures requiring Joint Clinical Assessments to be completed within 30 days after the authorisation of the medicine;
> provides for the systematic consultation of patients and clinicians during the preparation of the assessments as well as the involvement and consultation of the HTA stakeholders.

Initially, starting from 12 January 2025, the new rules will apply to marketing authorisation applications for new cancer medicines or advanced therapy medicinal products (ATMP). These rules will be extended to orphan medicines in January 2028 and as of 2030 will cover all new medicinal products. Selected high-risk medical devices will also be assessed as of 2026.

Cybersecurity: implications of the cybersecurity EU Directive “NIS 2” and the relevant national decree in the Life Sciences & Healthcare sector

Legislative Decree No. 138/2024 (the “**NIS2 Decree**”) implemented Directive (EU) 2022/2555 (the NIS2 Directive), which established measures for a universal high-level of cybersecurity in the EU. The NIS2 Decree came into force on 16 October 2024 and introduced a series of obligations, requirements and deadlines, also providing for a system of liability in the event of non-compliance.

Various categories of companies operating in the Life Sciences & Healthcare sector also have to comply with the provisions of the NIS2 Decree. In particular, the NIS2 Decree applies to entities in the Life Sciences & Healthcare sector that:

> employ more than 50 people and have an annual turnover or a balance sheet total exceeding 10 million euros; and
> operate in the sectors identified as “highly critical” and “critical” under the NIS2 Decree, which include healthcare providers, EU reference laboratories, entities that carry out R&D activities relating to medicinal products, manufacturers of certain types of pharmaceutical products and manufacturers of medical devices and in vitro diagnostic medical devices.

The NIS2 Decree introduces a series of obligations and technical measures for the subjects targeted by the regulation and provides for a precise timeline for compliance. The requirement to register on the Italian cybersecurity agency platform by 28 February 2025 was an important milestone.

We will monitor the adoption of further implementing decrees which are needed for the complete application of the NIS2 Decree and will define certain aspects in detail.

AI in Life Sciences & Healthcare: new guidelines concerning the definition of artificial intelligence system have been adopted by the EU Commission

On 6 February 2025 the EU Commission published guidelines concerning the definition of artificial intelligence system established by Regulation (EU) 2024/1689 (the "**AI Act**") to assist providers and other relevant persons in determining whether a system constitutes an AI system within the meaning of the AI Act, thereby facilitating the effective application and enforcement of the AI Act.

In order to facilitate understanding, the EU Commission has divided the broader definition of AI system provided by Article 3(1) of the AI Act ("*AI system means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments*"), into seven main sections and provided clarification on the interpretation of each one.

The guidelines also have an impact on the Life Sciences & Healthcare sector; in fact, the guidelines provide several examples of AI systems already used in the industry, such as AI systems implemented by pharmaceutical companies and used for drug discovery or medical device diagnostic systems trained on medical imaging.

The guidelines provide a useful tool for the regulatory assessment of the stakeholders in order to determine whether the system used falls within the definition of an AI system, with the consequent applicability of the AI Act.

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