

# Life Sciences & Healthcare News

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## **The Decree establishing minimum requirements for insurance policies has been published on the Official Gazette**

On 1 March 2024 Decree no. 232/2023 issued by the Italian Ministry of Enterprises and Made in Italy (together with the Italian Ministries of Health and Economics), which defines the minimum insurance policy requirements for healthcare facilities and professionals, has been published.

The Decree has been pending for seven years and implements the provisions set forth under Article 10 of Law no. 24/2017 (the so-called Gelli-Bianco Law).

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## **“LEAs” (Essential Levels of healthcare Assistance): the entry into force of the new rates postponed to 1 January 2025**

The Decree of the Prime Minister (D.P.C.M.) dated 12 January 2017 introduced new LEAs (assistance/services to be provided by the National Health Service) in relation to numerous diseases (including medically assisted procreation, rare diseases, celiac disease, eating disorders).

The Ministerial Decree dated 23 June 2023 provided the rates of the abovementioned LEAs, so that such LEAs would have become effective and actually be provided by the National Health Service. The entry into force of the Ministerial Decree was initially scheduled on 1 January 2024, then was postponed to 1 April 2024.

By a recently signed Decree, even if not yet published, the entry into force of the Ministerial Decree has been further postponed to 1 January 2025.

In light of the above, the LEAs introduced in 2017 are not yet effective.

## Treatment of certain personal data for relevant public purposes: amendments to the Italian Privacy Code

Law-Decree no. 19/2024 concerning the PNRR (the Italian National Recovery and Resilience Plan) amended Article 2-*sexies* of Legislative Decree no. 196/2003 (the Italian Privacy Code), which regulates the possibility of processing specific categories of personal data, including health data, for relevant public purposes.

With specific regard to health data, the amendments provided:

- > that such data may also be treated in pseudonymised form through the interconnection of the information systems of the public entities involved, in accordance with their institutional purposes;
- > for the introduction of Paragraph 1-*ter*, which delegates the Ministry of Health to implement the regulation of the interconnection of information systems through Ministerial Decrees.

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## Adaptation of the national medicine traceability system

Through the European Delegation Law 2022-2023, published in the Italian Official Gazette on 24 February 2024, the Italian Government committed to adopt specific measures to adapt national legislation to the European medicine traceability system based on the so-called *datamatrix* (i.e., a unique bi-dimensional barcode) by 9 February 2025. Thus replacing the current stamp system.

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## A website that connects pharmacists and customers for the purchase of prescription-free medicines is lawful

With decision dated 29 February 2024, the European Court of Justice clarified that EU Member States cannot forbid the activity of someone who merely connects authorised pharmacists and potential customers to facilitate the purchase of prescription-free medicines, even if the “facilitator” is not a pharmacist. Indeed, the “facilitator” is not involved in the sale of medicines, but merely acts as an intermediary.



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