

Cosmetics with new rules – What's changing in 2025?

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On 19 March 2025, Decree-Law no. 23/2025 ("**Decree-Law**") was published, ensuring the implementation of Regulation (EC) no. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, which came into force on 11 July 2013. The Decree-Law establishes the standards that cosmetic products available on the market must fulfil in order to guarantee the functioning of the internal market and the protection of human health.

The Decree-Law in question covers the following main aspects:

- (i) Obligations of operators in the economic sector of cosmetic products (manufacture, import or distribution of cosmetic products): operators are legally obliged to register their activity with INFARMED, I.P. (“**INFARMED**”), as well as ensuring compliance with the requirements relating to facilities, equipment, personnel and procedures. This obligation aims to ensure the conservation, quality and safety of cosmetic products, among other relevant aspects;
- (ii) Making available loose cosmetic products that are not pre-packaged, packaged at the point of sale or pre-packaged for immediate sale: the sale of loose cosmetic products that are not pre-packaged, packaged at the point of sale or pre-packaged for immediate sale is permitted only to retailers. It is essential that the products contain the necessary information to correctly identify the original product, namely the ingredients and the batch code;
- (iii) Labelling and information: the labelling and information provided to the consumer, regardless of the form and/or format in which it is provided, must be in Portuguese;
- (iv) Reporting of adverse reactions: health professionals and other professionals who use cosmetic products in the course of their work, as well as consumers, are required to report any adverse reactions related to their use to INFARMED, for registration and regulatory purposes;
- (v) Enforcement and corrective measures: INFARMED is the national authority responsible for enforcing the Decree-Law, as well as ordering the adoption of corrective measures, suspending activities and imposing fines for non-compliance;
- (vi) Penalty regime: the Decree-Law in question contains an extensive list of serious and very serious administrative offences. The fines for these offences can vary between €500.00 and €20,000.00, and €2,500.00 and €44,890.00, respectively. The amount of the fine depends on whether the offender is a natural person or a legal person.

The Decree-Law in question is now in force. Consequently, certain registration requirements for the activity can be fulfilled within 180 days of the electronic platform’s operational launch. Access to the platform will be available on the INFARMED website.

Thinking about tomorrow? Let’s talk today.

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