

Portugal implements EU regulation on cosmetic products

March 2025

Portugal implements Regulation (EC) 1223/2009 on cosmetic products through Decree-Law no. 23/2025. This legislative act covers the rules applicable to the establishment and operation of economic operators in the sector, as well as matters relating to the product information file, the labelling of cosmetics and the system for reporting undesirable effects of these products.

[Decree-Law no. 23/2025](#) (DL 23/2025) was published in the Official Gazette on 19 March, implementing in Portugal [Regulation \(EC\) no. 1223/2009](#) of the European Parliament and of the Council of 30 November 2009, which establishes the standards that cosmetic products available on the market must comply with. DL 23/2025 establishes the rules applicable to the establishment and operation of economic operators in the cosmetics sector, the communication system of serious undesirable effects of cosmetic products and the sanctions applicable to the non-compliance of the legislation on cosmetic products.

1. National Competent Authority

INFARMED – National Authority for Medicines and Health Products, I.P. is designated as the competent national authority for the purposes of Regulation 1223/2009 and DL 23/2025 and is also responsible for monitoring and supervising compliance with them, as well as applying measures to protect public health and safety.

2. Compliance and Activity Registration

Any product that does not fulfil the definition of cosmetic product established in European legislation is prohibited from being manufactured, placed or made available on the national market as a cosmetic product.

Regarding the registration of activity, DL 23/2025 provides that:

- The activities of manufacturing, importation, or first disposal (within the scope of the distribution activity) of cosmetic products in national territory by entities based in Portugal and distinct from the person responsible are subject to registration with INFARMED.
- The registration of these activities is carried out through an electronic platform, available on INFARMED's website.
- In terms of industrial licensing of manufacturing activity, DL 23/2025, in contrast to the previous framework, refers to the provisions of the Responsible Industry System.

3. Special Obligations

DL 23/2025 imposes special obligations on economic operators depending on the economic activity to which they are engaged, namely:

Activity	Special obligations
Manufacturing, distribution and import	<ul style="list-style-type: none"> ▪ Have adequate facilities and equipment with the capacity to ensure the manufacture, storage and conservation of cosmetic products. ▪ Store and transport cosmetic products segregated from other products, with the exception of medicines, medical devices, food supplements and biocides. ▪ Ensure that returned cosmetic products are marketed on the condition that their conformity has been assessed. ▪ Keep the facilities stowed and organized, as well as have suitable and qualified personnel for the tasks to be performed.
Manufacturing and distribution of cosmetic products in name or private label and modification of cosmetic product already placed on the market or import	<p>In addition to the above, they must also:</p> <ul style="list-style-type: none"> ▪ Have sufficient qualified personnel to carry out manufacturing, importation, storage and control activities, with one of the qualified individuals designated as a contact person for INFARMED. ▪ Have written work procedures that describe all the company's activities. ▪ If the performance of any activity is subcontracted, have written contracts describing the subcontracted activities and defining the different responsibilities.

Also, regarding the activity of manufacturing cosmetic products, it is required that there be a person responsible for production and a person responsible for quality control, with the possibility of accumulating these tasks being forbidden.

Finally, distributors operating in the wholesale trade and retailers selling directly to the end user are bound to comply with the good distribution practices for cosmetic products, which will be defined through an administrative regulation to be approved by INFARMED.

4. Import Activity

It falls upon the importer of cosmetic products, based in Portugal, to present to the customs authorities a declaration issued by INFARMED attesting compliance with the notification requirements provided for in Regulation 1223/2009, in the following situations:

- When the cosmetic product derives from a third country and is placed on the market for the first time; and
- When the import concerns a first batch of a cosmetic product that, despite being previously placed on the market, has been subject to a change in formulation or any other modification that affects its compliance with the aforementioned European rules.

5. Making Products Available Loose

Only retailers may make loose cosmetic products available that are not pre-packaged, cosmetic products packaged at the point of sale at the request of the buyer or pre-packaged directly to the consumer, with resale being excluded.

DL 23/2025 also establishes a set of rules to be followed in the activity of making products available on a loose basis and determines, regarding labeling, that products provided by this means comply with the general labeling requirements imposed on the remaining cosmetic products.

6. Report of Undesirable Effects

About the report of undesirable effects, it is determined that:

- The person responsible and the distributors are obliged to immediately report to INFARMED all serious undesirable effects related to the use of cosmetic products in Portugal.
- Consumers, health professionals and other professionals who use cosmetic products are recognized have the prerogative to report any undesirable effects to INFARMED.

7. Penalty Framework

- There are updates regarding the values of the administrative fines applicable for non-compliance with the legislation on cosmetic products:

Type of Administrative Offence	Administrative Fine
Serious	<ul style="list-style-type: none"> ▪ Natural persons: between €500.00 and €2500.00 ▪ Legal persons: € 5000.00 and € 20000.00
Very serious	<ul style="list-style-type: none"> ▪ Natural persons: between € 2500.00 and € 3740.00 ▪ Legal persons: € 20000.00 and € 44890.00

8. Entry into Force and Transitional Provisions

- DL 23/2025 entered into force on March 24, 2025.
- Regarding transitional provisions, it is established that:
 - i. Economic operators who, on the date of entry into force of DL 23/2025, carry out any of the activities for which it is necessary to register on the INFARMED electronic platform, must do so within a maximum period of 180 days after the entry into operation of this electronic platform.
 - ii. Within the same period, the remaining provisions related to the registration of activity must be implemented.
 - iii. Within 180 days, an interconnection mechanism must be established between INFARMED and the national customs authorities that allows the availability of the declaration issued for the import of cosmetics.
- Decree-Law no. 189/2008 is hereby repealed.

The sole purpose of this newsletter is to transmit relevant information in a general, summary and non-detailed manner, and is not intended to provide any type of legal advice. It does not dispense with or replace consultation of the applicable legislation.

More information:

[Administrative and Constitutional Law](#)

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