

## **Deliberation n.º xxx/CD/2025**

### **Whereas:**

With the publication of Decree-Law No23/2025 of 19 March, the implementation of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 (hereinafter Regulation (EC) No1223/2009) which lays down the rules that cosmetic products available on the market must comply with, in order to ensure the functioning of the internal market and a high level of protection of human health, was ensured in the domestic legal order.

The aforementioned law also establishes an obligation to register the activity of economic operators who manufacture, import or carry out the first sale in the distribution of cosmetic products in national territory, and also enshrines provisions for the establishment and operation of economic operators in the cosmetic products sector;

Taking into account the distribution stage as fundamental in the integrated system for the supply of cosmetic products, new rules are foreseen for distribution, aiming to ensure the quality and safety of these products throughout the entire marketing chain in the domestic market.

It is therefore important to implement good practices in the distribution of cosmetic products that must be complied with by distributors operating in the wholesale trade, as well as by retailers, and it is up to INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (National Authority of Medicines and Health Products, I.P.) to define them by means of a regulation;

Thus, the Governing Board of INFARMED, I.P. - National Authority for Medicines and Health Products I.P., pursuant to the provisions of Article 2(1) and Article 7(3) of the [Decreto-Lei n.º 23/2025](#), of 19 March and Article 5(2)(c) of Decree-Law No. 46/2012 of 24 February 2012, in its current wording, hereby resolves as follows:

(1) To approve the Regulation on Good Distribution Practices for Cosmetic Products, attached to this resolution, of which it forms an integral part.

(2) This deliberation shall take effect 30 days after its publication in the Official Gazette.

## Annex

### **Regulation on Good Distribution Practices for Cosmetic Products**

#### **(1)- Object and scope**

1.1- This Regulation lays down the principles and standards of good distribution practices for cosmetic products.

1.2- The provisions of this Regulation shall apply to entities distributing cosmetic products within the national territory or to the national territory from another Member State, with the necessary adaptations.

#### **(2)- Basic requirements**

2.1- Entities that carry out, in whole or in part, face-to-face or digital distribution of cosmetic products (PCs), in or for Portuguese national territory, must:

2.1.1- Have adequate staff, equipment and facilities and have the capacity to ensure the reception, storage, preservation, transport, distribution and availability of cosmetic products in accordance with the applicable legal requirements;

2.1.2- Ensure, on an ongoing and documented basis, compliance with and maintenance of requirements that ensure a high level of protection of human health, as well as the quality, safety and claims of cosmetic products, and their traceability throughout the distribution chain, in

accordance with the activity carried out and within the scope of the entity's operations in the distribution chain;

2.1.3- Follow and apply the storage precautions indicated on the respective labelling of cosmetic products or recommended by the Responsible Person, where applicable;

2.1.4- Refrain from distributing or making available cosmetic product packaging that presents any of the following situations:

a) Packaging that is not intact, damaged, opened, tampered with or shows signs of tampering, except in the cases legally provided for under Article 8 of Decree-Law 23/2025;

b) A cosmetic product past its minimum durability date;

c) A cosmetic product withdrawn or recalled from the market;

d) A cosmetic product containing prohibited or unauthorised ingredients in accordance with Regulation (EC) No 1223/2009;

e) A cosmetic product that is falsified or counterfeit, or in respect of which suspicions exist;

f) A product whose labelling contains non-cosmetic or therapeutic claims or claims which are likely to mislead the consumer as to its intended purpose;

g) A cosmetic product whose regulatory compliance cannot be supported by documentary evidence;

h) A cosmetic product whose storage conditions, as indicated on the label and defined by the Responsible Person, have not been complied with;

2.1.5- Collaborate diligently and provide INFARMED, I. P., whenever requested and within the deadline established by it, with access to all establishments, facilities, or other locations where cosmetic products are found, as well as to all documentation.

2.1.6- The distributor who first sells a cosmetic product on the domestic market must ensure, in a documented manner, that the ingredients, labelling and claims comply with the applicable legal and regulatory

requirements, in particular those laid down in Regulation (EC) No 1223/2009 and Regulation (EU) No 655/2013 and other applicable legislation.

### **3- Staff**

3.1- The distributor must have an organised and documented structure, with responsibilities and functions defined in writing and appropriate to the size of the company and the type of cosmetic product with which it operates, as well as sufficient and qualified staff to ensure compliance with these Good Distribution Practices and other applicable requirements arising from the legislation on cosmetic products.

3.2- Each distributor of cosmetic products must have a contact person with INFARMED, I.P.

### **4- Facilities and Equipment**

4.1- The distributor's facilities and equipment, including transport to customers, must be suitable for the proper storage, conservation and preservation of cosmetic products, and must be sized and adapted to the needs of their distribution and availability.

4.2- The facilities must be organised, sized, adapted, and arranged in such a way as to enable the separation, demarcation and identification of all areas, namely reception, inspection, storage, order preparation, dispatch, returns, withdrawals and recalls, areas for falsified and counterfeit products and rejected products, or other areas applicable to the specific characteristics of cosmetic products.

4.3- The facilities, areas and spaces mentioned in the previous paragraph must be kept clean and sanitised, without debris or accumulation of dust, and special precautions must be taken against pests, spills, breakages and contamination.

## **5- Procedures**

5.1- Distributors of cosmetic products shall have in place a set of appropriate written procedures describing the various operations carried out, including those which may affect the quality and safety of cosmetic products.

5.1.1 The procedures referred to in the previous paragraph shall include, as a minimum, procedures applicable to storage and dispatch, handling of complaints, withdrawals and recalls, reporting of undesirable effects and traceability of products.

5.2- All procedures must be up-to-date, dated and approved by competent persons within the entity, according to the organisational structure, before they are used.

## **6- Documentation and Records**

6.1- The distributor shall keep available for consultation all documentation and records relating to the distribution of cosmetic products.

6.1.1- Records must be kept simultaneously with operations and this information must be preserved for a period of three years.

6.2- For the purposes of communication by distributors operating on the national market with their national customers, with national end-users and with INFARMED, I.P., the Portuguese language must be used, except in the situations provided for by law.

6.3- For all activities contracted or subcontracted by the distributor, including transport or temporary leasing, there must be an agreement in writing, stipulating and defining the responsibilities and obligations of each of the parties relating to cosmetic products.

6.4- In order to ensure the traceability of each cosmetic product, there must be a record of all supplies, transfers, transactions and transport notes made from the establishment in question, which must contain an indication of the date, the identification of the cosmetic product by its trade name, batch

code or reference, the quantity received or supplied, as well as the name, address and contact details of the supplier and recipient.

## **7- Reception and Checking**

7.1- All cosmetic products received, or intended for shipment, as well as all associated documentation, must be properly examined and checked, and their regulatory compliance must comply with applicable European and national legislation, and be duly registered in the Cosmetic Products Notification Portal (CPNP).

7.2- Product shipments received are checked at the distributor's premises for their batch or reference number, labelling, mandatory information, language used, claims and legal compliance, as well as the associated documentation, in proportion to the activity, size and type of product, with the exception of the entity that makes the first sale on the domestic market, which must verify all of the shipments received.

7.3- Cosmetic products that do not contain all the mandatory information and indications in Portuguese must be immediately separated from marketable stock and may not be marketed until they have been brought into conformity.

7.4- Where the distributor has the means to ensure the conformity of the translation provided for in the preceding paragraph, they shall include on a sticker or equivalent indelible label the mandatory translation particulars exactly as they appear on the labelling and in the original language, as provided for in Article 19(5) of Regulation (EC) No1223/2009.

7.5- The translation must be identical in form and meaning, be orthographically and grammatically correct, and be clearly visible without concealing any original text, in accordance with legal requirements.

7.6- The Distributor shall ensure dedicated space for the purpose of translation, prepared equipment, procedures and written records relating to the translation operations carried out, with reference to ISO 22716.

7.7- Cosmetic products subject to special and/or specific storage measures shall be promptly identified, routed and stored, in accordance with the conditions specified by the Responsible Person in their labelling.

## **8- Storage**

8.1 - Cosmetic products must be stored, transported and made available under the conditions specified by the corresponding Responsible Person, as described in their labelling.

8.2- Cosmetic products must be kept in their original packaging, intact and unopened, and may not be altered, tampered with or subjected to any other intervention, except in the cases provided for by law in accordance with Article 8 of Decree-Law 23/2025.

8.3- Cosmetic products may be stored together with medicines, medical devices, food supplements and biocides, but must be segregated from other products that may contaminate them, and must be properly organised, arranged and identified.

8.4- Samples of cosmetic products, used for promotional, advertising or professional purposes, must be identified and stored in a separate location and duly identified for this purpose.

8.5- For cosmetic products for which the Responsible Person has established special and/or specific storage measures, the necessary and appropriate measures shall be taken to prevent the quality, efficacy and safety of the cosmetic products from being affected by factors such as temperature, humidity, exposure to sunlight or light, among others.

8.6- Distributors shall monitor and record the room temperature using regularly calibrated equipment, or adopt equivalent measures to ensure the detection of deviations or protection from adverse factors, whenever applicable to the characteristics of the products distributed and in accordance with the storage conditions defined by the Responsible Person.

8.7- There should be a system, preferably in digital format, that ensures appropriate stock rotation, according to the rule "first to expire, first to

leave" and secondarily "first to enter, first to leave", subject to periodic checks.

8.8- Cosmetic products considered unfit, and in particular those returned, subject to complaints, recalled and/or withdrawn, falsified and/or counterfeited, rejected, for export and out of date, must be physically segregated from saleable stocks, and separated from each other with appropriate identification.

## **9- Supply, Transport and Availability**

9.1 - All legal requirements and provisions set out in this Regulation relating to the storage and distribution of cosmetic products shall apply, with the necessary adaptations, to the supply, transport and making available of cosmetic products up to delivery at the customer's premises, with the aim of maintaining the quality, efficacy and safety of the products unchanged.

9.2- Cosmetic products must be supplied or transported in such a way as to ensure that, throughout the distribution and making-available chain, they are properly packaged, identified, traced and well preserved, and so that they can be used within the time limits laid down for safe use.

9.4- Without prejudice to the provisions of the preceding paragraph, the original packaging of cosmetic products may only be opened or subdivided in cases legally provided for, namely in the context of the provision of services to the consumer, the sale of products in loose form, and the use of testers made available by retailers. Such operations must be duly traceable, in order to comply with the products' durability dates and hygiene requirements, and to avoid contamination, including microbiological contamination.

## **10- Returns, Complaints, Withdrawals and Recalls, Counterfeit and Rejected Items**

10.1- Any cosmetic products returned by the customer must be registered, and the return operations must be adapted to the storage conditions of each product.

10.1.1- Decisions to reinstate returned cosmetic products to saleable condition must be justified according to the characteristics, integrity and preservation of the cosmetic products.

10.2 - A system for registering and handling complaints received must be ensured that includes investigating the causes, taking into account the activities carried out and the cosmetic products made available, and responding to the complainant by appropriate means.

10.3 - The existence of a system of withdrawals and recalls or the implementation of other corrective market measures, which is maintained and implemented effectively by the distributor, must be ensured. The contact person, or another person designated for this purpose, must always be available to adopt and implement these measures in a timely manner with the affected customers, as applicable, for the segregation of cosmetic products and documentation of the traceability and records of these non-compliant cosmetic products.

10.4- Whenever the distributor detects or has reason to suspect that a cosmetic product is counterfeit or falsified, they must segregate the product and immediately report the occurrence to the respective supplier and the authorities.

10.5- Rejected and/or expired products may not be made available, and must be identified and physically segregated in the establishment and destroyed within 12 (twelve) months