DRAFT Regulation on Good Distribution Practices for Cosmetic Products

The proposed Regulation defines the principles and standards of good distribution practices for cosmetic products.
The provisions of this proposal shall apply to entities distributing cosmetic products in Portugal or to Portugal from another Member State, with the necessary adaptations.

TRIS Notification No:	2025/0748/PT (Portugal)
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16 years after the publication of Regulation (EC) No 1223/2009 of the European Parliament and of the Council, of 30 November 2009, on the requirements with which cosmetic products available on the European Union market must comply in order to ensure the functioning of the Internal Market and a high level of protection of human health (Cosmetic Products Regulation), the Portuguese Government published Decree-Law No. 23/2025, of 19 March, which ensures the implementation, in the national legal system, of this Regulation.

Acknowledging that the Cosmetic Products Regulation prevents divergent transpositions by the Member States (MS), the Portuguese Government nevertheless considers that the Cosmetic Products Regulation confers to the Member States the competence to regulate various matters and does not prejudice the possibility for the MS to regulate the establishment, in national territory, of economic operators in the cosmetics sector.

Thus, the National Authority proposes, within the provisions of paragraph 3 of Article 7 of Decree-Law No 23/2025, the Good Distribution Practices which obliges distributors operating in the wholesale trade, as well as retailers selling directly to the end user, to respect in the distribution of cosmetic products, to be defined by regulation of INFARMED, I. P., taking into account the necessary adaptations to the role and sector of activity of each of these economic operators.

AIC – Associação dos Industriais de Cosmética, Perfumaria e Higiene Corporal is the sectoral employers' association that represents companies that manufacture, import and distribute cosmetic products in Portugal. The sector includes large, medium, small and micro companies, international, multinational and national. In

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the pursuit of its statutory objectives, AIC was, from the beginning, actively involved in this national legislative process and had the opportunity to express its opinion on the first text of the INFARMED, I.P. proposal and, although the text now submitted to TRIS already includes some of the proposed suggestions, AIC cannot fail to express its concern about some of the requirements included in the proposal now under consideration.

1. On the adoption of Good Distribution Practices for Cosmetic Products, including for Retailers

AIC considers that since there is a specific and harmonized regulatory framework in the European Union for cosmetic products (Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009) and since this legal framework, unlike what happened for industrial manufacturing activities, did not consider important to establish the Good Practice regime for the distribution of cosmetics in the European Union, the unilateral establishment of a regulation on Good Distribution Practices for Cosmetic Products may result in negative discrimination against companies operating in this area in the national territory, imposing specific requirements and additional costs for establishing business in Portugal and access the Single Market, which are not justifiable from the point of view of consumer safety.

The burden on distribution in Portugal will be especially heavy and unjustified if the obligation to comply with Good Distribution Practices is applied to Retailers, as follows from the definition of Distributor. Retail, namely small retail and traditional retail, even if they are specialized stores, are not able to meet most of the requirements recommended in the presented proposal.

INFARMED, I.P. is well aware that this dissymmetry is real and is not resolved or even mitigated by the fact that it is expressed that the provisions of this regulation apply to entities that carry out the activity of distributing cosmetics to the national territory from another Member State (cf. 1.2) or digitally (cf. 2.1): INFAMED, I.P. has no authority to do so.

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AIC asks the Commission to draw the attention of the Portuguese Authorities, especially INFARMED, I.P., to the need to maintain national initiatives at a level that does not discriminate against the economic activity of companies, for the simple fact that they are operating in the national territory, namely Retailers.
AIC also requests that it should be clarified how INFARMED, I.P. will verify the compliance with Good Distribution Practices for Cosmetic Products to Distributors not based in the national territory or who operate by digital means.

If necessary, the Commission should keep the proposal submitted by INFARMED, I.P. on stand-still until the impact is assessed by the Member States under the Cosmetic Products Regulation.

2. About the deadline for entry into force of Good Distribution Practices

AIC has already explained to INFARMED I.P. that the period for entry into force of 30 days after the publication of Good Distribution Practices in *Diário da República* (cf. 2) is manifestly short.

AIC considers that the deadline should be extended, not because the state of non-compliance compared to the proposed requirements is serious, but because the economic agents targeted in the proposal for Good Distribution Practices need time to adapt to the obligations foreseen, namely to prepare the written procedures appropriate to the various operations carried out, such as the procedures applicable to storage and dispatch, the treatment of complaints, withdrawals and recalls from the market, communication of undesirable effects, identification within the supply chain and transport and, subsequently, operationalize all phases of their activity in accordance with the procedures.

AIC considers justified the request to change the entry into force of Good Distribution Practices to 180 days after the publication of the Good Distribution Practices for Cosmetic Products in *Diário da República*.

AIC expects the Commission to support its proposal to extend the entry into force deadline to 180 days, as a way to minimize the impacts on the sector.

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3. On the extent of the obligations and responsibilities of Distributors

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 unambiguously lays down the requirements leading to a high level of safety for the end-user of a cosmetic product, available on the Internal Market.

In pursuit of this objective, the Cosmetic Products Regulation clearly states that no cosmetic product may be placed on the market in the European Union unless a Responsible Person exists and is duly identified and establishes the requirements applicable to the definition of this Responsible Person (cf. Article 4 of Cosmetic Products Regulations).
In addition, the Cosmetic Products Regulation exhaustively establishes the obligations of the different economic entities that operate in the supply chain of cosmetic products in the European Union, that is, the obligations committed to the Responsible Person and the obligations committed to Distributors.

Article 5 of the Cosmetic Products Regulation states that the Responsible Person must ensure compliance with:

- Article 3 - Safety
- Article 8 - Good manufacturing practice
- Article 10 - Safety assessment
- Article 11 - Product information file
- Article 12 - Sampling and analysis
- Article 13 - Notification
- Article 14 - Restrictions for substances listed in the Annexes
- Article 15 - Substances classified as CMR substances
- Article 16 - Nanomaterials
- Article 17 - Traces of prohibited substances
- Article 18 - Animal testing
- Article 19 - Labelling (paragraphs 1, 2, 5, 6)
- Article 20 - Product claims
- Article 21 - Access to information for the public
- Article 23 - Communication of serious undesirable effects
- Article 24 - Information on substances.

The Responsible Person shall cooperate with the Authorities, at their request, in any action to eliminate the risks arising from cosmetic products that they have made available on the market.

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In particular, the Responsible Person shall provide the National Competent Authority, upon its request and in a language that it can easily understand, with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product. In the event that the Competent Authority does not have easy access to the product information file, because the Responsible Person is not based in its country, Article 30 of the Cosmetic Products Regulation establishes cooperation between competent authorities regarding the verification of cosmetic product information file.
The Responsible Person is also obliged to comply with the provisions of Article 7 of the Cosmetic Products Regulation - Identification within the supply chain.

Article 6 of the Cosmetic Products Regulation establishes that Distributors must, in the context of their activities, when making a cosmetic product available on the market, act with due diligence in relation to the applicable requirements.

Thus, before making a cosmetic product available on the market, Distributors make sure that:

- The labelling shall mention the information provided for in points (a) *the name or registered name and the address of the person responsible*; (e) *the batch number of manufacture or the reference for identifying the cosmetic product*, and (g) *a list of ingredients* in paragraph 1 and in paragraphs 3 and 4 of Article 19;
- The language requirements provided for in Article 19(5) are fulfilled;
- The date of minimum durability specified, where applicable under Article 19(1), has not passed.

Distributors shall provide the National Competent Authority, at its request and in a language that it can easily understand, all the information and documentation necessary to demonstrate the conformity of the product with the requirements listed above.

Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Cosmetic Products Regulation.

Distributors shall cooperate with the Competent Authorities, at their request, in any action to eliminate the risks posed by products which they have made available on the market.

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Distributors are also obliged to comply with the provisions of:

- Article 7 - Identification within the supply chain;
- Article 13 - Notification (nos. 3, 4 and 7);
- Article 23 - Communication of serious undesirable effects;
- Article 26 - Non-compliance by distributors.

As the responsibilities and obligations for the Responsible Person and Distributors are thus broadly defined, it was with great surprise that AIC received the proposal for Good Distribution Practices for Cosmetic Products presented by INFARMED, I.P. in which it is re-expressed the intention to extend to Distributors, obligations that are unequivocally attributed to the Responsible Person in the Cosmetic Products Regulation.

This intention is clearly expressed:

> *2.1.4- Refrain from distributing or making available cosmetic product packaging that presents any of the following situations:*
>
> > *(d) A cosmetic product containing prohibited or unauthorised ingredients in accordance with Regulation (EC) No 1223/2009;*
> >
> > *(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;*
>
> *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.*
>
> *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*

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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.

AIC considers that:

- It is not up to Distributors to verify that the ingredients listed on the labeling comply with the obligations imposed by Regulation (EC) No 1223/2009, with regard to the need of an ingredient to be authorized, nor if it complies with any restriction that applies to it or even if it is prohibited. Distributors, once informed by the Responsible Person or by INFARMED, I.P., will act with due diligence in any action to eliminate the risks arising from products they have made available on the market.

- It is not up to Distributors to verify the claims of cosmetic products, namely whether or not they comply with the requirements of Cosmetic Products Regulation. According to the provisions of Cosmetic Products Regulation, the claims of cosmetic products can be considered from two perspectives: the claim implies that the product ceases to be a cosmetic product, because it is not compliant with the respective definition, or the claim violates the requirements set out in Article 20 of Cosmetic Products Regulation. The Responsible Person is responsible for the compliance with the applicable requirements, taking into account the available guidelines on the subject, namely the *Manual of the Working Group on Cosmetic Products (Sub-Group on Borderline Products) on the scope of application of the Cosmetic Products Regulation (EC) No 1223/2009 (art. 2(1)(a)) and the Guidelines to Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products.*

- It is not up to Distributors to assess whether or not a claim is admissible or misleading for the consumer, because the Distributor is not responsible for placing the product on the market, nor does it have access to the Product Information File. In case of doubts as to whether a product is a cosmetic product or about any of the claims of a cosmetic product, Distributors should contact the Responsible Person.

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- It is not the responsibility of Distributors to verify the legal and regulatory compliance of the cosmetic product, including its notification on the *Cosmetic Products Notification Portal (CPNP).* Nor to verify that this conformity is documental proven. The Distributor does not have access to the Product Information File. Documental demonstration of legal and regulatory compliance is the responsibility of the Responsible Person when requested by the Competent Authorities.

AIC also considers that the Distributor who proceeds with the first sale of a cosmetic product in the national market cannot be considered by INFARMED, I.P. as the Responsible Person for that product. In particular, the first Distributor has no obligation to demonstrate to the National Authority, in a documented manner or other, the compliance of ingredients, labelling and claims with the requirements laid down in Regulation (EC) No 1223/2009 and Regulation (EU) No 655/2013 and other applicable legislation.

The extension of the obligations of the Distributors proposed by INFARMED, I.P. is absolutely unacceptable by AIC, since, in its opinion, it violates the provisions of Regulation (EC) No. 1223/2009, with regard to the obligations and responsibilities of the Distributors, going so far as to equate the Distributor who proceeds with the first sale of the cosmetic product in Portugal, as a Responsible Person.
AIC expects the Commission to explicitly inform INFARMED, I.P. of the need to amend/delete any section of the Good Distribution Practices for Cosmetic Products proposal that results, explicitly or implicitly, in this extension.

4. About segregation in storage

The proposal for Good Distribution Practices for Cosmetic Products refers in section *«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.»*

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AIC does not understand why it is possible to store cosmetic products with medicines, medical devices, food supplements and biocides (e.g. hand disinfectants, surface disinfectants, insecticides, insect repellents, rodenticides) and not with other products such as soaps, detergents or cleaning products or articles for human hygiene such as toilet paper and tissues, etc.

It is strange that cosmetic products have to be stored segregated from all products except medicines, medical devices, food supplements and biocides.

AIC opportunely drew the attention of INFARMED, I.P. to the fact that the obligation of "segregation" would require taking actions to organize the warehouses, including the construction of physical barriers, an unnecessary cost since usually and naturally the products are stored separately.

AIC asks the Commission to inform INFARMED, I.P. that in the storage and transport of cosmetic products, it is sufficient to apply the principle of "separation".

5. Detailed consideration and proposed amendments

Attached is the detailed assessment of the text of Good Distribution Practices for Cosmetic Products proposed by INFARMED, I.P. with comments / amendments of AIC.

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Deliberation n.º xxx/CD/2025	AIC Position
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	

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Decree-Law No. 46/2012 of 24 February 2021, 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.	**AIC asks the Commission to draw the attention of the Portuguese Authorities, especially INFARMED, I.P., to the need to maintain national initiatives at a level that does not discriminate against the economic activity of companies, for the simple fact that they are operating in the national territory, namely Retailers.** **AIC also requests that it should be clarified how INFARMED, I.P. will verify the compliance with Good Distribution Practices to Distributors not based in the national territory or who operate by digital means.** **If necessary, the Commission should keep the proposal submitted by INFARMED, I.P. on stand-still until the impact is assessed by the Member States under the Cosmetic Products Regulation.**
(2) This deliberation shall take effect 30 days after its publication in the Official Gazette.	AIC considers justified the request to change the entry into force of the Good Distribution Practices to 180 days after the publication of the Good Distribution Practices for Cosmetic Products in *Diário da República*. **AIC expects the Commission to support its proposal to extend the entry into force deadline to 180 days, as a way to minimize the impacts on the sector.**
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.	**AIC asks the Commission to clarify how INFARMED, I.P. will verify the compliance with Good Distribution Practices for Cosmetic Products to Distributors not based in the national territory.**

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	If such clarification is not possible, AIC asks the Commission to remove the reference to Distributors not based in the national territory.
(2)- Basic requirements	The extension of the obligations of Distributors proposed by INFARMED, I.P. in this section is absolutely unacceptable by AIC, since, in its opinion, it violates the provisions of Regulation (EC) No. 1223/2009, with regard to the obligations and responsibilities of Distributors, going so far as to equate the Distributor who proceeds with the first sale of the cosmetic product in Portugal, as a Responsible Person. **AIC expects the Commission to explicitly inform INFARMED, I.P. of the need to amend/delete any section of the Good Distribution Practices for Cosmetic Products proposal that results, explicitly or implicitly, in this extension.**
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:	**AIC asks the Commission to clarify how INFARMED, I.P. will verify the compliance with Good Distribution Practices for Cosmetic Products to Distributors not based in the national territory or who operate by digital means.** **If such clarification is not possible, AIC requests the Commission to remove the reference to Distributors not based in the national territory or acting by digital means.**
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;	**AIC asks the Commission to maintain the obligations and responsibilities of Distributors as set out in the Cosmetic Products Regulation and not to allow new requirements to be introduced, in any way.** It is the understanding of AIC that requirement 2.1.2. is in line with Article 6 of the Cosmetic Products Regulation: *"Distributors shall ensure that, while a product is*

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	under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in this Regulation."
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;	AIC considers that it is not up to Distributors to verify that the ingredients listed on the labeling comply with the obligations imposed by Regulation (EC) No 1223/2009, with regard to the need of an ingredient to be authorized, nor if it complies with any restriction that applies to it or even if it is prohibited. Distributors, once informed by the Responsible Person or by INFARMED, I.P., will act with due diligence in any action to eliminate the risks arising from products they have made available on the market. **AIC requests the Commission to delete this paragraph.**
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;	AIC considers that it is not up to Distributors to verify the claims of cosmetic products, namely whether or not they comply with the requirements of Cosmetic Products Regulation. According to the provisions of Cosmetic Products Regulation, the claims of cosmetic products can be considered from two perspectives: the claim implies that the product ceases to be a cosmetic

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	product, because it is not compliant to the respective definition, or the claim violates the requirements set out in Article 20 of Cosmetic Products Regulation. The Responsible Person is responsible for the compliance with the applicable requirements, taking into account the available guidelines on the subject, namely the *Manual of the Working Group on Cosmetic Products (Sub-Group on Borderline Products) on the scope of application of the Cosmetic Products Regulation (EC) No 1223/2009 (Article 2(1)(a)) and the Guidelines to Commission Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products.* AIC considers that it is not up to Distributors to assess whether or not a claim is admissible or misleading for the consumer, because the Distributor is not responsible for placing the product on the market, nor does it have access to the Product Information File. In case they have doubts as to whether a product is a cosmetic product or about any of the claims of a cosmetic product, Distributors should contact the Responsible Person. **AIC requests the Commission to delete this paragraph.**
g) A cosmetic product whose regulatory compliance cannot be supported by documentary evidence;	AIC considers that it is not up to Distributors to verify the legal and regulatory compliance of the cosmetic product, including its notification on the Cosmetic Products Notification Portal (CPNP). Nor to verify that this conformity is documental proven. The Distributor does not have access to the Product Information File. Documental demonstration of legal and regulatory compliance is the responsibility of the Responsible Person when requested by the Competent Authorities. **AIC requests the Commission to delete this paragraph.**
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,	In order to make it clear that there is no extension of the obligations and responsibilities of the Distributors, section 2.1.5- should read:

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facilities, or other locations where cosmetic products are found, as well as to all documentation.	*«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* ***relating to its distribution activity****.»*
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.	AIC also considers that a Distributor who proceeds with the first sale of a cosmetic product in the national market cannot be considered by INFARMED, I.P. as the Responsible Person for that product. In particular, this Distributor has no obligation to demonstrate to the National Authority, in a documented manner or other, the compliance of ingredients, labelling and claims with the requirements set out in Regulation (EC) No 1223/2009 and Regulation (EU) No 655/2013 and other applicable legislation. **AIC requests the Commission to delete this paragraph.**
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.	

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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.	For administrative simplification, section 5.1- should read: *«5.1- Distributors of cosmetic products shall have in place a set of appropriate written procedures**, which might be available in electronic form only,** 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.	

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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).	AIC considers that it is not up to Distributors to verify the legal and regulatory compliance of the cosmetic product, including its notification on the Cosmetic Products Notification Portal (CPNP). Nor to verify that this conformity is documental proven. The Distributor does not have access to the Product Information File. Documental demonstration of legal and regulatory compliance is the responsibility of the Responsible Person, when requested by the Competent Authorities. **AIC requests the Commission to remove the obligation for the Distributor to verify regulatory compliance with applicable European and national legislation, and registration on 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	AIC considers that it is not up to Distributors to verify the labelling, with the exception of the obligation arising from the application of Article 6 of Cosmetic

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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.	Products Regulation, the mandatory requirements, the claims and the legal compliance of the cosmetic product. Nor to verify that this compliance is documental proven. The Distributor does not have access to the Product Information File. Documental demonstration of legal and regulatory compliance is the responsibility of the Responsible Person, when requested by the Competent Authorities. AIC also considers that the Distributor who proceeds with the first sale of a cosmetic product in the national market cannot be considered by INFARMED, I.P. as the Responsible Person for that product. In particular, this Distributor has no obligation to demonstrate to the National Authority, in a documented manner or other, the compliance of ingredients, labelling and claims with the requirements set out in Regulation (EC) No 1223/2009 and Regulation (EU) No 655/2013 and other applicable legislation, in all of the shipments received. **AIC requests the Commission to amend this paragraph, limiting the obligations of Distributors to those provided in the Cosmetic Products Regulation.**
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.	

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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 toISO 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.	**AIC asks the Commission to inform INFARMED, I.P. that in the storage and transport of cosmetic products, it is sufficient to apply the principle of "separation".**
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.	AIC does not understand the introduction of this requirement. It does not make sense to create separate physical areas in the warehouse just for samples of cosmetic products because they are properly identified on the label and in the computer control system. Even for other product categories (such as medicines and medical devices) there are no separate areas for samples. The creation of separate areas for samples of cosmetic products would, for example, require logistics operators to create separate spaces with increased storage costs. **AIC requests the Commission to delete this subsection.**

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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.	This subsection should read: *«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	

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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.	This subsection should be correctly numbered: 9.3-
10- Returns, Complaints, Withdrawals and Recalls, Counterfeit and Rejected Items	AIC is surprised that regarding returns, complaints, withdrawals, recalls, counterfeit and rejected items, no mention is made to the need for the Distributor to contact the Responsible Person and act in accordance with its instructions. Except in cases where withdrawals and/or recalls are determined by INFARMED, I.P. and addressed directly to the respective Distributor.
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	

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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	AIC considers that, when a Distributor intends to destroy a cosmetic product that is in its possession, this product immediately has the status of waste and the Distributor is obliged to apply the relevant legislation. Therefore, it is not up to INFARMED, I.P. to decide on the deadline for the destruction of the waste. **AIC requests the Commission to amend this subsection to read:** *«10.5- Rejected and/or expired products may not be available, and must be identified and physically segregated in the establishment and be destroyed* ***where possible, in accordance with the applicable waste management legislation and/or the legislation on the destruction of unsold consumer products (Ecodesign Regulation)****.»*

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