

Decree of the Chairman of Egyptian Drug Authority No. (122) of 2022 on Cosmetics Notification and Trading

Chairman of Egyptian Drug Authority,

Having perused

- Law on Suppression of Fraud and Counterfeiting Promulgated by Law No. (48) of 1941 and its Executive Regulation;
- Law on Pharmacy Profession Practice Promulgated by Law No. (127) of 1955 and its amendments;
- Law on Reorganizing Importation, Manufacturing, and Trading of Drugs, Medical and Chemical Devices Promulgated by Law No. (113) of 1962 and its amendments;
- Law on the Protection of Intellectual Property Rights Promulgated by Law No. (82) of 2002 and its Executive Regulation;
- Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019 and its Executive Regulation;
- Law of Customs Promulgated by Law No. (207) of 2020;
- Minutes of the Authority's Board of Directors' meeting held in its session dated 20/7/2020;
- Material submitted by the Authority Chairman Assistant for the Affairs of Continuing Professional Development;
- Having considered the interest of work; has decided;

Decided

(Article One)

This decree shall be implemented with regard to Cosmetics Notification and Trading. For its provisions, the following terms shall have the meanings set out for each term hereunder:

- 1) **The Law:** It is the Law of establishing the Egyptian Drug Authority promulgated by Law No. (151) of 2019.
- 2) **The Executive Regulation:** The executive regulation of the law establishing the Egyptian Drug Authority promulgated by Prime Minister Decree No. (777) of 2020.
- 3) **The Authority:** The Egyptian Drug Authority.
- 4) **Cosmetics:** Any product that is composed of a substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips, and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors." The references for assessing these products are (COLIPA) guidelines, the European Cosmetic Regulations (Regulation (EC) No. 1223/2009), and their cosmetics-related amendments.
- 5) **Material:** It refers to any chemical ingredient as well as its compounds in their normal states, or those obtained by a manufacturing process, including any added ingredient that is necessary to maintain its stability, and any impurities resulting from the used manufacturing process, except for any solvent that can be separated without affecting material stability or changing its composition.

- 6) **Mixture:** It is a solution formed by mixing two or more substances.
- 7) **Notification:** It is the process of registering cosmetics and personal care products in the Egyptian Drug Authority's electronic database.
- 8) **Cosmetics Trading:** It refers to one or more of the law-regulated processes of cosmetics' production, distribution, possession, sale display, storage, usage, preservation, packaging, transportation, delivery, import or export.
- 9) **Recalling:** It is the process by which a cosmetic product is removed from the supply chain and during this process, the consumer or user is advised to take the appropriate action. Recalling may be voluntarily by an initiative of the company, or mandatory by a decision of the Egyptian Drug Authority in accordance with procedures applicable in this regard.
- 10) **Sample Collection for Analysis:** It is one of the procedures of the cosmetics notification system. This procedure involves collecting one or more samples after launching the product. This process aims to ensure the cosmetic product conformity.
- 11) **Laboratory Decision:** It refers to documents issued by the Authority laboratories stating analysis results.
- 12) **Cosmetics-owning Company:** It is the company that manufactures a product, whether in the case of local manufacturing or local manufacturing under-license; or in the case of contracting with a third party to manufacture a product, whether in the case of toll manufacturing or toll manufacturing under license. It is the company that circulates the product in the market under its name or its trademark, or it is the company authorized to conduct registration in the case of imported finished products.
- 13) **Cosmetic Preservatives:** They are substances added to a cosmetic product to inhibit microorganisms' growth thereon.
- 14) **Coloring materials for Cosmetics:** They are substances added to a cosmetic product to color the product, the whole body, or some of its parts, by absorbing or reflecting the visible light. The raw materials used to dye the hair of the head by oxidation are also considered one of the coloring materials.
- 15) **UV Filters:** They are materials used to protect skin from some ultraviolet rays by absorbing, reflecting, or scattering ultraviolet rays.
- 16) **Undesirable Side Effect:** It is an adverse reaction that affects human health within the limits of the normal use of a cosmetic product.
- 17) **Undesirable Serious Side Effect:** It is the negative effect that leads to requiring medical follow-up, suffering a temporary or permanent functional disability, causing congenital abnormalities, and even amounting to death.
- 18) **Impurities:** They are secondary components of a certain substance or of raw materials that can arise from:
- Original components.
 - Manufacturing processes.
 - Chemical composition or interaction inside the product, which can occur under normal storage conditions.
 - Possible transmission from the final packing and packaging materials to the product.
 - Possible chemical changes caused by the instability of the product, which is in contact with the final packing and packaging materials.
- 19) **Contaminants:** They are substances unintended to be added, which can arise from sources outside the chemical processes or unforeseen conditions such as poor storage of raw materials or instability of primary product packing and packaging materials.

- 20) **Single-use Products:** They are products used immediately after opening and designed to be used once only.
- 21) **Free Samples:** They are free products distributed to the end users.
- 22) **Primary Package:** It is the package designed in such a way that it comes into direct contact with the contents of a product or a formulation.
- 23) **Secondary Package:** It is the package designed to contain one or more of the primary packages and it may include protective materials depending on the technical conditions.
- 24) **Warehouse:** It is a place licensed by the Egyptian Drug Authority and prepared by the company in charge to be used for storing cosmetics.
- 25) **Toll Manufacturing (Toll companies):** They are companies that manufacture cosmetics notified in their names in a manufacturing site that is not owned by them and they are licensed by the Egyptian Drug Authority to produce these cosmetics through a toll manufacturing system.
- 26) **Good Manufacturing Practices (GMP):** They refer to quality procedures implemented to ensure that cosmetics are produced in a sound technical manner and that they also conform to the regulatory rules for good manufacturing practice issued by the Authority in accordance with international specifications and standards implemented in this regard, which particularly include:
 «Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products», and «ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP)».
- 27) **Good Storage Practices (GSP):** They are quality procedures implemented to ensure that the various types of warehouses or stores apply the Good Storage Practice rules in accordance with international standards adopted in this regard as well as the rules issued by the Egyptian Drug Authority.
- 28) **Good Laboratory Practice (GLP):** They are practices and procedures followed in laboratories in accordance with the international rules and World Health Organization guidelines adopted by the Egyptian Drug Authority.
- 29) **Technical Operating License:** It is the certificate issued by the Egyptian Drug Authority for licensing the authorized production lines in the facility.
- 30) **Raw Materials:** They are active or inactive substances used in producing cosmetics, except for materials used in packing and packaging. Raw materials are divided into local and imported raw materials in accordance with the cosmetics composition statement issued by the company, factory or any of the companies registered in the raw material importers' record for local manufacturing or for manufacturing for export without circulating in the local market.
- 31) **Cosmetics (Bulk):** They are imported products that are fully manufactured overseas and only packaged within the Arab Republic of Egypt.
- 32) **Premix:** They are imported products that are partially manufactured overseas and that are subject to the rest of the manufacturing processes, packing, and packaging before being launched in the market.
- 33) **Batch Register:** It is a documentary ledger that is kept in every licensed manufacturing site. It shall not contain any crossing out, erasure, or modification. This ledger shall record the production details of each batch.

34) **A Certificate of Analysis (CoA):** It is a certificate, that is issued in the case of local production by the Quality Control Department of the factory or by one of the Authority-approved laboratories with which the factory has a contract or which is provided by the supplier in the case of raw materials or an imported finished product. The product name, its batch number, and its production and expiry date shall be recorded in this certificate, which shall also state the results of the tests that were carried out on the raw material or the finished product, whether they were physical/chemical or microbiological tests. The certificate shall record that the raw material or the finished product conforms to standard specifications. This certificate has two types. First, the certificate of analysis of the raw material received by the factory from the supplier or the factory of the raw material. Second, the certificate of analysis of the finished product is provided by the local factory that manufactured the product.

35) **Unsafe Product:** It is a product that does not meet all the safety requirements and the applicable quality standards due to having a bacterial content, containing prohibited substances, or restricted substances that exceed the permitted percentages.

36) **Cosmetic Products' Vigilance:** It is the process of continuous and systematic technical monitoring of cosmetic products' safety by collecting, evaluating, and monitoring received reports on undesirable incidents observed during or after cosmetics normal use or those incidents that are expected to arise from the normal and reasonable use of cosmetic products by the end user.

(Article Two)

This decree shall apply to all cosmetics circulated within the Arab Republic of Egypt, including cosmetics that meet a standard specification or that are produced per a standard specification, and it shall also apply to all producers and importers who distribute these cosmetics to ensure that they are easily circulated in the market and to guarantee preserving human health. It is prohibited to circulate or import all aforementioned cosmetics in the Arab Republic of Egypt except after these cosmetics are notified in the electronic database of the Authority in accordance with the Regulatory Guidelines issued in line with the provisions of this decree and after a cosmetic product obtains its notification number. The provisions of this decree shall not apply to the following items: perfumes, eau de toilette, and cologne, bathing soap of all types, be solid or liquid, raw materials or single oil types sold in packages as finished products without medical claims that are subject to the monitoring of the Egyptian Organization for Standards and Quality and that meet the Egyptian Standard Specifications or other standards that are approved for the aforementioned products.

(Article Three)

Cosmetic products shall be safe for humans whenever they are used in normal, ordinary, and expected conditions.

A cosmetic product shall be considered unsafe in the following cases:

- If it contains a prohibited substance or a restrict-use substance that has been added in a way that violates the conditions of its restricted use.
- If the necessary warnings and ingredients are not mentioned on its package as specified in the regulatory guides.
- If it has been improperly transported or stored, thus changing the microbiological properties of the product.

Cosmetic products shall not contain any of the following:

- Prohibited substances that are specified in the Regulatory Guide for Cosmetics Notification.
- Restrict-use substances that are not used in conformity with the specified restrictions in the Regulatory Guide for Cosmetics Notification.
- Coloring substances that are not specified in the Regulatory Guide for Cosmetics Notification. The cosmetics that contain coloring substances used only for hair dye shall be excluded.
- Preservatives that are not included in the Regulatory Guide for Cosmetics Notification.

- Preservatives that are incorporated in the Regulatory Guide for Cosmetics Notification but that are not used in accordance with the conditions prescribed in the aforementioned guide, unless other concentrations of the product formulation are used for specific and clear purposes and are scientifically proven in accordance with the documents provided.

- UV filters that are not included in the Regulatory Guide for Cosmetics Notification or those that are incorporated therein but that are not used in accordance with the conditions specified in the abovementioned guide.

Without prejudice to the provisions of this decree, the cosmetics are allowed to have traces of the substances stipulated in the Regulatory Guide for Cosmetics Notification as impurities of the natural ingredients that shall in no way exceed the industrial limits, provided that their presence shall be technically unavoidable in accordance to Good Manufacturing Practices and that they shall in no way exceed the permissible limits that are in line with the international standards and the rules approved by the Authority.

(Article Four)

The company shall be committed to keeping the data of all distributors it has dealt with and provided them directly with supplies in organized records for five years from the date of supply. It also shall comply with all requirements contained in the relevant regulatory guidelines, **particularly the following:**

Various explanatory data and language requirements shall be provided.

- The earliest possible expiry date of the product shall not be exceeded as per international rules.
- The conditions of storage and transportation shall not contradict the specifications stipulated for that purpose.
- The Authority shall be notified in detail of any symptoms or risks to the consumer's health.
- The company shall cooperate with the Authority in all procedures of following-up products in the markets and shall clarify the applicable measures adopted to eliminate any product-related risks.

(Article Five)

Before importing or circulating any cosmetic product in the Arab Republic of Egypt, the company shall be committed to notifying the cosmetic product in the electronic database of the Authority in accordance with the regulations and requirements set out in detail in the Regulatory Guide for Cosmetics Notification, provided that the company shall adhere to the following:

- 1.The product shall obtain an electronic Notification number, provided that the trading or importation shall take place during the validity period of the product Notification.
- 2.The company shall not circulate the product in the market before completing its Notification procedures.
- 3.A product shall be allowed to be circulated in the Egyptian market in the event that its Notification validity period is expired, provided that the product was circulated before the expiry of the Notification validity period.

The company shall notify the Authority of its conformity with the contents of the Notification approval in accordance with requirements and procedures stated in the Regulatory Guidelines issued by the Authority as regards the advertising materials of cosmetic products.

(Article Six)

Cosmetics advertisements shall be subject to the following terms and conditions:

- The product shall be notified in the Authority as per the regulating procedures and during the Notification validity period.
- Whenever the Authority decides to cancel the Notification of a cosmetic product, ban it, or suspend its circulation, it shall be completely prohibited to advertise such product in any form or by any means unless its circulation has been allowed again by virtue of a decision by the Authority.

(Article Seven)

The cosmetics manufacturing company shall commit itself to Good Manufacturing Practices and the manufacturer or importer of cosmetics shall be committed to the principles of Good Storage Practice as well as to the fulfillment of all health requirements in the warehouses or stores in which cosmetics are stored.

(Article Eight)

The company shall submit the full Notification request via the Authority's electronic platform. After the prior review of the notification requirements, the notification number shall be issued automatically. The Notification shall be considered invalid upon the expiry of its validity period without renewing it. The company shall adhere to notification requirements, provide complete product information on the packages, and conform to the variation's rules following the Regulatory Guide for Cosmetics Notification. The company shall keep a Product Information File (PIF) upon launching the cosmetic product in the market in accordance with the Regulatory Guide for the Cosmetics Safety Report. The company shall apprise the Authority of the Product Information File upon its request within five working days from the date of receiving the request or within 48 hours in case of necessity. The Product Information File shall be kept for ten years after the date on which the last batch of the cosmetic product was introduced into the market. The product information file shall include the following data and information in accordance with its last updates:

1. A description of the cosmetic product.
2. A safety report of the cosmetic product.
3. A description of the manufacturing method and a statement of adherence to Good Manufacturing Practices.
4. Proof of the effect claims of the cosmetic product.
5. A certificate by the company that shall verify tests performed on animals by the manufacturer, its agents, or suppliers to develop or evaluate the safety of the cosmetic product or its ingredients have been performed only when there was no acceptable alternative method as per the international standards.
6. The Product Information File shall be made readily available in Arabic or English with a certified Arabic translation to be directed in an electronic form or any other form to the Authority at its address indicated on the approved form.
7. The company shall ensure that the cosmetics have undergone safety evaluation and mandated tests and that the safety report has been prepared in accordance with the applicable rules, provided that this procedure shall be performed before introducing the cosmetic product into the market.
8. The company shall be committed to the following when preparing the safety evaluation report:
 - Safety evaluation, expected normal use of cosmetics, and regular exposure to various components used in the product's final formulation shall be considered.
 - Safety evaluation shall adopt a weight-of-evidence methodology 'relying on a mix of information derived from multiple sources' when reviewing information from all available sources.
 - Cosmetics Safety Report shall be maintained and updated when necessary in light of all new information that may appear later after the product has been put on the market.
 - The person responsible for preparing the cosmetic safety evaluation shall meet the conditions required by the Authority.

(Article Nine)

The company shall submit an application to get pre-importation approval and then follow up by uploading the file on the Authority's electronic platform to obtain the medical customs release in accordance with the Regulatory Guide for the Importation and Medical Customs release of Cosmetics.

(Article Ten)

The Authority shall be responsible for monitoring and periodically inspecting cosmetics factories, their warehouses, and their circulation places to detect violations of the provisions of the applicable law, other relative laws, this decree, and various regulatory guidelines related to cosmetics. The Authority inspectors possessing the capacity of judicial police officers shall be entitled to the competencies and powers necessary for detecting violations and taking various legal measures as regulated by law.

(Article Eleven)

The Authority has the right to cancel a cosmetic product notification, ban a product itself, recall it, or suspend its marketing in the event that the company violates the provisions stipulated in the law, relevant laws, this decree, or the regulatory guides that are issued for its implementation or that are applicable concerning cosmetics. The Authority has the right to take legal measures to implement the stipulated penalties in accordance with the provisions of Law No. (127) of 1955 on Pharmacy Profession Practice, provided that notification cancellation shall be obligatory if a violation is repeated or the risk of the product to the consumer is proven. The company in charge shall bear all the obligations arising from the notification throughout its validity period and for five years after its invalidation.

(Article Twelve)

Recalling of Cosmetic Products: In the case of necessary recalling of a defective, unsafe, or non-conforming cosmetic product that does not comply with the regulations of the notification system, the Authority shall take the following measures:

- 1-The Authority shall count the suspicious products and identify their places of circulation.
- 2-The Authority shall issue a decision to recall the cosmetic product and explain the reasons for its withdrawal.
- 3-The Company shall be obligated to recall the cosmetic product within a period specified in the Authority decision.
- 4-In the event that the company does not comply with withdrawing the product within the specified period, the Authority shall have the right to recall the product at the company's expense.
- 5-After recalling the product, the Authority shall have the right to take any of the following procedures:
 - a.Making it obligatory for the company to destroy the product at its own expense.
 - b.Giving permission to re-circulate the product after correcting the violation, whenever this is allowable and possible.
 - c.Giving permission to re-export the imported product to the country from which it was imported, without prejudice to the provisions of the applicable laws and resolutions in this regard.
- 6.The company shall submit a statement containing the quantities and information of the recalled products.

(Article Thirteen)

Destruction of the Products: One or more committees shall be formed to destruct the cosmetic products in accordance with the rules set forth in the Regulatory Guide for the Inspection of Cosmetics Factories and Warehouses and Market Control, provided that the violating person or the destruction applicant shall bear the costs of the destruction process, without prejudice to the rules and procedures of the Authority-adopted system of speed warning and recalling of medical products.

(Article Fourteen)

Detection of Undesirable Side Effects of Cosmetic Products:

- 1- In the event of detecting undesirable side effects, the company shall be obligated to follow the regulating rules of cosmetics vigilance, which are issued by the Central Administration of Pharmaceutical Care, notify the Authority of its compliance with these rules and of the corrective measures it takes, if any, as per the dates and procedures set forth in the Regulatory Guide for the Cosmetics Safety Report.

2-The Egyptian Drug Authority shall inform the company of any undesirable side effects reported by consumers or health professionals. The company shall take the necessary procedures and measures as per the dates and procedures set forth in the Regulatory Guide for the Cosmetics Safety Report.

(Article Fifteen)

Stakeholders addressed by this decree may appeal against the decisions issued by the dedicated departments of the Authority regarding the notification and circulation of cosmetics in accordance with the provisions and procedures outlined in the law and the executive regulation.

(Article Sixteen)

The Regulatory Guide for Cosmetics Notification shall be issued within five days from the date of approving this decree by the chairpersons of the central administrations of the Authority, in their respective fields of specialization, as follows:

- The Head of the Central Administration of Pharmaceutical Products shall be responsible for issuing the Regulatory Guide for Cosmetics Notification.
- The Head of the Central Administration of Pharmaceutical Policies and Market Access shall be responsible for issuing the Regulatory Guide for the Importation and Medical Customs Clearance of Cosmetics.
- The Head of the Central Administration of Operations shall be responsible for issuing the Regulatory Guide for the Inspection and Control of Cosmetics and the Regulatory Guide for Licensing Procedures of Operating Cosmetics Factories.
- The Head of the Central Administration of Pharmaceutical Care shall be responsible for issuing the Regulatory Guide for the Cosmetics Safety Report and the Regulatory Guide for Advertising Materials of Cosmetics.
- The Head of the Central Administration of Drug Control shall be responsible for issuing the Regulatory Guide for the Analysis of Cosmetics.

(Article Seventeen)

All companies marketing cosmetics that are subject to the provisions of this decree shall adhere to all the technical provisions and requirements contained herein, as well as to the aforementioned Regulatory Guides, and all technical and regulatory decisions issued by the Authority. The companies shall regularize their conditions within six months from the date of issuing this decree and inform the Authority thereof.

(Article Eighteen)

This DECREE shall be published in Al-Waqa'i' Al-Misriyya 'Egyptian Chronicles, the Supplement of the Official Gazette' and shall enter into force as of its publication date. Any other provisions that may contradict this DECREE shall be null and void.

**Chairman of
Egyptian Drug Authority
Prof /Tamer Mohamed Essam**

Edited on: 27/2/2022