Guideline

Central Administration of Pharmaceutical Products
General Administration for Cosmetic Registeration

Regulatory Guide for Cosmetics Notification for the Year 2023

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1. Introduction

This guide is concerned with the regulatory rules and procedures for cosmetics notification in the Egyptian Drug Authority in accordance with the law of establishing the Authority promulgated by Law No. (151) of 2019.

2. Procedures for Applying for Notification

1- The company shall submit the complete notification request via the electronic platform of the Egyptian Drug Authority. After prior reviewing of notification requirements, a notification number shall be automatically issued within 10 working days for the normal track and within 3 working days for the fast track from the date of fulfilling the notification requirements and paying the prescribed fees, provided that the product notification shall be valid for ten years from the date of its issuance.

2- The notification file shall be renewable and the applicant shall submit his request during the last year of the notification file validity. The new notification period shall be calculated from the date of the notification expiry date. The same procedures shall be applied, provided that there has been no change in the product components or its data.

3- The notification file shall be considered cancelled when it expires without being renewed. In the event of a desire to import or market a product, the notification process shall be pursued again.

4- In case of any variation is made to the product data that has been notified, the company shall update that data in accordance with the attached list of variations (*Annex 8*).

3. Locally-Manufactured Cosmetics Intended for Export only

In the case of applying for cosmetics notification of locally-manufactured cosmetics that are intended only for export, the notification shall be optional. In the event that the company desires to notify the aforementioned product, the following procedures shall be applied:

The notification request shall be submitted via the electronic platform of the Egyptian Drug Authority, provided that the notification shall be carried out in

accordance with the requirements referred to in the previous section. After prior reviewing of notification requirements, a notification number shall be automatically issued within 3 working days from the date of fulfilling the notification requirements and paying the prescribed fees, provided that the product notification shall be valid for a period of ten years from the date of its issuance. Such product shall be permitted to be locally circulated only after its notification is cancelled and it is notified as a new local product.

4. Notification Requirements

The company must create an account on the Electronic Company Profile of the pharmaceutical information system at the Egyptian Drug Authority and obtain the user's name and password of its account.

The file of the cosmetic product that complies with the Authority's technical and regulatory rules and guidelines shall be notified. The company in charge of the cosmetic product shall submit the notification request in accordance with the following procedures and requirements:

1. The foreign or local factory in which the product will be manufactured shall be notified for one time via the electronic platform of the Egyptian Drug Authority by listing the Manufacturing List and obtaining approval within 3 working days.

2. A notification request shall be submitted via the electronic platform at the Egyptian Drug Authority and shall indicate the following information:

a. The product trade name.

b. The company name and address to facilitate communication, getting access to any information about the product, and authorizing the product-owning company to notify products in the event that the applicant is different from the manufacturer.

c. A product composition form containing the scientific names of the substances included in the composition and specifying the quantities and percentage, be

w/w% (weight per weight) or w/v% (weight per volume) and the function of each substance.

d. The artwork of the product.

e. A payment receipt of fees and services fees and any other dues in accordance with the law and rules of the Egyptian Drug Authority.

f. The shelf life of the product.

g. A free sale certificate from the country of origin, in the case of imported cosmetic products. The certificate shall be sealed by the competent accreditation authority and authenticated by the Egyptian embassy or consulate in the country of origin. It shall indicate that the product is freely sold in a reference country. It shall be submitted only in the case of seeking recourse of circulation reference (i.e. in the case that the parent company or manufacturer belongs to a non-reference country, but the product is freely sold in a reference country. In this case, the criterion is the circulation reference by the free sale certificate). Circulation reference shall be determined in accordance with the headquarters of the parent company owning the product or the country in which the cosmetic product is manufactured or circulated.

h. Notification authorization from the product-owing company abroad to the agent in the Arab Republic of Egypt. The Authorization shall be sealed by the accreditation authority and authenticated by the Egyptian embassy or consulate in the country of origin (in the case of imported products).

i. The manufacturing contract for the products of toll manufacturing indicating the storage location (the factory store or the accessory storehouses of the factory), provided that it shall be licensed by the authority. The contract shall be sealed by the accreditation authority and authenticated by the Egyptian embassy or consulate in the case of contracting for manufacturing with a license from abroad.

j. In the case of the claims mentioned on the outer package, a scientific reference or scientific studies shall be provided to prove the effectiveness of the substance for its intended purpose of use.

3. A product shall be notified as one product even if it has multiple colors, fragrances and volumes, in the event that certain products have the same name and the same purpose but they differ in color or/and fragrance, they shall be notified in one request and shall have one notification number. Only one artwork shall be notified and the company shall be committed to the artwork with differences in color, fragrance, and volume.

4. In the case of a kit product that represents several products, similar or different, that are sold together in one outer package or that may be sold separately, it shall be permitted to notify each product of this kit with a separate notification number and then to submit a request for notifying the kit to obtain one combined notification number, if the company so desired.

5. In the case of a hair dye kit containing a dye product and other different products that are sold together in one product kit, all shades of a certain color shall be notified under one of the four color groups (Black, Brown, Red, Yellow) with one notification number for the group with all its shades. Each product included in the kit shall be notified with a separate notification number and then a request for notifying the kit shall be submitted to obtain one combined notification number, if the company so desired.

6. As for a separate dye product, all color shades under each of the four color groups (Black, Brown, Red, Yellow) shall be notified with one notification number for the group with all its shades.

7. In the case that the company desires to add a private label to the account of chains of hotels, hypermarkets or advertising companies, the company shall add the private label in the notification file in accordance with the list of variations set forth below in (*Annex 8*).

5. Making variations on the notified or registered products

A request for variation to be made on a product shall be submitted via the electronic platform of the Egyptian Drug Authority, provided that all requests submitted shall be evaluated and adjudicated within 10 working days for the normal track and 3 working days for the fast track. The list of variations (*Annex 8*) shall be adhered to.

6. Illustrative information of the product artwork

The artwork of cosmetic products shall include the information below in a clear legible and indelible type.

a. Product name and trademark (if any).

b. Applicant Company and manufacturer name in the case of local products, toll-manufacturing products, and products of toll manufacturing with a license from abroad. In case of imported products, applicant's name shall be written.

c. The product country of origin

d. The notification number or what stands therefor (barcode**)**.

e. The product quantity in the package as specified at the time of packing: The product quantity in the package shall be expressed using international units of weight or volume (UI standards). An exception is made in the following cases: products containing less than 15 ml or 15 gm, single-use products and free samples.

f. Terms of use, warning statements and precautionary information shall be clearly expressed on the artwork, taking into consideration the following:

i. Terms of use and warnings for a group of ingredients notified in the list (i) of Annexes from No. (3) to No. (6) of the present Regulatory Guide shall be printed on the primary package label, secondary package, a leaflet, an attachment, or an attached insert. In addition, any other information deemed necessary for the safe use or disposal of the product shall be given (provided that it shall be basically written in Arabic for the locally manufactured products).

ii. These requirements shall also apply to the products intended for professional use, particularly in haircare. The method of the product use shall be carefully

considered as well as the possibility of increased risk due to prolonged exposure or unusual conditions of use.

iii. If it is impossible for practical reasons to print this information on the product artwork, the information shall be mentioned in a leaflet, an attachment or an attached insert and reference must be made in this case either by concise information or by the symbol No. (3) - see *Annex 7* which concerns information that shall appear on the primary or secondary package.

g. Product's purpose of use and instruction for use: The product's purpose of use shall be clearly printed on the primary or secondary package unless it is clear enough to be observed spontaneously and it can be obviously detected through its way of presentation (provided that it shall be mandatory in Arabic for locally manufactured products).

h. Printing the list of ingredients on the primary or secondary package or through an attached leaflet: The list must be headed by the term "Ingredients" and the ingredients' names must be written in English (An ingredient is any substance or mixture that is intentionally used in a cosmetic product during its manufacturing process). The following items shall not be regarded:

i. Impurities in the used raw materials.

ii. Auxiliary technical materials that are used in preparing cosmetics but that do not exist in the final product.

iii. Materials used in extremely minute quantities as solvents or as fragrance vehicle and aromatic compounds. Fragrances and aromatic compounds along with their raw materials shall be referred to by the terms "perfumes" or "fragrance." In addition, reference shall be made to the presence of the materials to which the term "others" is applied (fragrance solvents and aromatic compounds shall not be written with the ingredients except for allergy-causing ingredients in accordance with the EU regulations) in the Regulatory Guide for Cosmetics Notification on the list of ingredients alongside the terms "perfumes" or "fragrances".

A list of ingredients shall be arranged in a descending order according to the weight of the ingredient at the time it is added to the cosmetic product. The ingredients

whose concentrations are less than 1% may be incorporated in any order following those whose concentrations are more than 1%. In the case of aesthetic cosmetic products that are marketed in several colors, arrangement of colors other than those intended to color hair may be made in any order in the list after other ingredients, provided that the phrase “may contain” or the symbol "+/-" shall be added and the CI terms (Color Index) must be used.

- An ingredient must be identified by its common name, that is its International Nomenclature of Cosmetic Ingredients (INCI) name, as shown in the EU Common Ingredient Nomenclature.
- In the event that this information is not possible, for practical reasons, to be printed on the artwork of the cosmetic product, the information must be mentioned in an attached leaflet.
- Reference must be made to this information either by concise information or by the symbol No. (3) - see *Annex 7* concerning information that shall appear on the primary or secondary package.
- The aforementioned requirements shall be either by Arabic and/or English languages unless otherwise stated.
- In the case of free samples, small-size products containing less than 15 ml or 15 gm or the products designed for one-time use, the information shall be provided in the form of a flier, an adhesive tape or a leaflet attached to the product, or it shall be printed on the secondary package or the bundled package, so that it shall be evident to the consumer.
- Ingredients on artwork shall conform to the notified composition form.

i. **Terms of storage and warnings:**

They shall be determined in accordance with the composition form of each product in compliance with the EU regulations.

7. General Requirements

1- The company shall not be allowed to make any variation during the re-notification process and it shall make sure that all variations have been made before applying re-notification of the product.

2- Considering that the claims shall be appropriate for the indications of use and the composition form in addition to observing the claims guide for cosmetics notification on the Authority's website.

3- Notification of the products containing non-biodegradable microbeads shall be rejected.

4- In the case of presence of ingredients in the composition form that have special requirements in accordance with the European directives, clarification letter for these requirements shall be submitted.

5- In the event that the ingredients on the artwork differ from the notified composition form, a clarification letter for this difference shall be submitted.

6- In the case of notifying a hair dye kit, the group name must be written alongside the product name by the method of Short & Long Name.

8. Annexes

Annex No. (1): An illustrative list of cosmetic products

Cosmetics that can be circulated or imported (manufactured locally or imported) in the Arab Republic of Egypt only after they are notified in the electronic database of the Egyptian Drug Authority.

The following list is not exclusive. Therefore, the definition of cosmetics stipulated in Article (2) of the decree of the Authority chairman regarding the regulatory rules for the notification and trading of cosmetics shall be applied to other products that are not included in this list.

- Creams, emulsions, lotions, gels and oils used for skin (hand, face, feet, etc.)
- Face masks (except for chemical peeling products that have active ingredients that exceeds permitted limits)
- Dye bases (liquids, creams and powders)
- Makeup powders, after-bath powders, hygienic powders, etc.
- Personal hygiene products (salts, foams, oils, etc.)
- Depilatories.
- Deodorants and antiperspirants.
- Hair care products:
    - Hair tints and bleaches;
    - Hair waving products;
    - Hair straightening and fixing products;
    - Hair Styling products;
    - Cleansing products (lotions, powders, all types of shampoos including anti-dandruff shampoos);
    - Hair strengthening and revitalizing products;
    - Hairdressing products.

- Eye cosmetics (eye shadows, mascara, eyebrow and eyeliner pencils, eyelash cream, eye kohl, etc.).
- Shaving products (creams, foams, lotions, etc.).
- Products for making-up and removing make-up from the face and eyes.
- Products intended for external application on the lips.
- Oral care, dental care, and teeth whitening products.
- Nail care and make-up products.
- Products for external intimate hygiene.
- Sunblock products.
- Sunbathing products/ sunless tanning of the skin.
- Skin-whitening products.
- Anti-wrinkle and anti-aging products.

Annex No. (2): list of substances prohibited in cosmetic products

Ingredients and substances listed in Annex II of the mandatory guidelines mentioned in the European Cosmetic Products Regulation (EC) No. 1223/2009 and its amendments shall be banned in cosmetics.

Annex No. (3): list of substances which cosmetic products must not contain except subject to the restrictions laid down

Ingredients and substances listed in Annex III of the mandatory guidelines mentioned in the European Cosmetic Products Regulation (EC) No. 1223/2009 and its amendments may not be used in cosmetics without compliance with the stated restrictions.

Annex No. (4): list of colorants allowed in cosmetic products

Coloring material listed in Annex IV of the mandatory guidelines mentioned in the European Cosmetic Products Regulation (EC) No. 1223/2009 and its amendments are permitted to be use in cosmetics.

Annex No. (5): list of preservatives allowed in cosmetic products

Preservatives listed in Annex V of the mandatory guidelines mentioned in the European Cosmetic Products Regulation (EC) No. 1223/2009 and its amendments are permitted to be use in cosmetics.

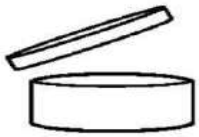
Annex No. (6): list of UV filters allowed in cosmetic products

Ultraviolet filters listed in Annex VI of the mandatory guidelines mentioned in the European Cosmetic Products Regulation (EC) No. 1223/2009 and its amendments are permitted to be use in cosmetics.

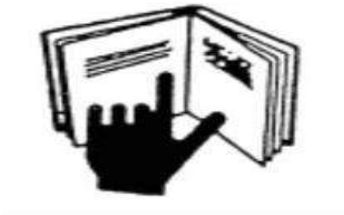
Annex No. (7): Symbols used for inner/outer packages

Symbol (1) The date when the product's characteristics are likely to disappear.

Symbol (2) period after opening.



Symbol (3) refers to information attached or approved about the product.



Annex No. (8): Variations

Do & Tell **(The company can apply for the cosmetics variations after the modification is made to the product)**	**Analysis**
1. Size Addition/Deletion (provided that the added size is designed for selling to the public)	Re-analysis is not required
2. Carton Box Addition/Deletion with a commitment to the registered data mentioned in the inner or/and outer pack	Re-analysis is not required
3. Pack Addition/Deletion with a commitment to the previously approved data in the case of upgrading only	Re-analysis is not required
4. Shelf-Life Extension/Reduction (up to 5 years)	Re-analysis is not required
Tell & Do **(The company shall apply for the Cosmetics Variations before changing the data of the approved product, and that type of variation shall not be applied except after getting Authority's Approval)**	**Analysis**
1. Changing composition form	Re-analysis is required
2. Changing the pharmaceutical form	Re-analysis is required

3. Pack Addition/Deletion with a commitment to the previously approved data in the case of downgrading only	Re-analysis is required
4. Updating the registration type from Imported to Under License and vice versa	Re-analysis is required
5. Adding a country of origin	Re-analysis is required
6. manufacturing transfer	Re-analysis is required
7. Adding manufacturing site	Re-analysis is required
8. Adding colors, fragrances and flavors, provided the additives are permitted in the EU and that they have no cosmetic use or claims other than the approved purpose	Re-analysis is required (Inspection)
9. Name Change	Re-analysis is not required
10. Adding a leaflet	Re-analysis is not required
11. Changing the purpose of use	Re-analysis is not required
12. Applicant's Name/Commercial Name change	Re-analysis is not required
13. Artwork change (except for product promotions)	Re-analysis is not required
14. Deleting a manufacturing site	Re-analysis is not required
15. Deleting a country of origin	Re-analysis is not required
16. Ownership transfer	Re-analysis is not required
17. Adding an artwork (private label) to the account of hotel chains or hypermarkets	Re-analysis is not required

Annex No. (9): Supplementary References

European Cosmetic Products Regulation (EC) No. 1223/2009

ISO 22716 Cosmetics– Good Manufacturing Practices– Good Manufacturing Practice Guides.

Annex No. (10): Violations and applicable measures

	Violation	Applicable measure(s)
1	Submitting documents of doubtful authenticity	Holding the product notification. (Hold)
2	Non-reporting of any variation applied to the product without notifying that change on the Authority's electronic platform	Holding the product notification in case of Tell & Do
3	Deliberate concealment of any document that affects the approval of notification of the product/change	Holding the product notification. (Hold)
4	Failure to respond to any decision or publication, which has been newly issued as a result of any recent change that occurred after notification	Holding the product notification. (Hold)
5	For the flag product (which obtained a notification number with a conditional approval), in the case that fulfilment is not provided within the specified period (two months) or in the case of incorrect fulfilment	Holding the product notification. (Hold)
6	For the hold product (whose notification number was suspended), in the case that fulfilment is not provided within the specified period (six months) or in the case of incorrect fulfilment	Cancelling the product notification. (Block)