Documents Required for Variations of Cosmetic Products

For the Year 2025

Code: EDREX: GL. CAPP.041
Version No:1
Issue Date: 04/08/2025
Effective date: 07/08/2025

Table of Contents

1. Introduction

To ensure compliance with regulatory standards and legal requirements, please note the following guidelines regarding the documents required for cosmetic product variations.

2. Scope

This regulatory guide applies to cosmetic products that hold registration or listing notifications, when there is a need to change product data during the validity period of the notification.

3. Definitions

1.Cosmetic Products: Any product containing one or more substances intended to be used on the external parts of the human body (skin, hair, nails, lips, etc.) for cleaning, perfuming, protection, or enhancing appearance.

2.Notification: The process of recording cosmetic and personal care products in the electronic database of the Egyptian Drug Authority (EDA).

3.Cosmetic Variations: Any modification made to a registered or listed cosmetic product, its attachments, or both, during the validity period of the registration/listing notification.

1.1 Procedures

1.1.1 1. Transfer of Agency

In case the product owner wishes to transfer the agency of registered or listed products, the following documents shall be submitted:

1.1. Original Registration/Listing Notification of the product.

1.2. Termination Letter for the old agent:

- A letter from the product owner (**License Holder**), as recorded in the registration notification, must be provided stating the termination of the product registration rights for the old agent (**Termination Letter**).
- The letter must be authenticated by the Chamber of Commerce and the Egyptian Embassy in the country of origin.
- All data must be verified to match what is stated in the registration notifications.

1.3. Authorization Letter for registration:

- A letter of authorization for registration (**Authorization Letter**) from the product owner (**License Holder**), as recorded in the registration notification, must be provided for the new agent, provided that the letter is authenticated by the Chamber of Commerce and the Egyptian Embassy in the country of origin.
- The letter must include a match of all data with the registered data in the registration notifications and the commercial register of the new agent.

1.4. Declaration Letter:

- In the event of a clerical error in any of these required documents, a **Declaration Letter** must be provided by the product owner (**License Holder**) clarifying the clerical error and providing the necessary correction in a clear and accurate manner, authenticated by the Chamber of Commerce in the country of origin.

. Adding a Manufacture:

2.1. The original Registration/Listing Notification of the product must be provided.

2.2. In case of:

2.2.1. Adding a factory for imported products:

- A letter from the product owner abroad must be provided, stating that the product is manufactured in the factory intended to be added.

2.2.2. Adding a non-reference factory for imported reference products: In the case of imported products registered as reference and controlled reference products (i.e., manufactured in a reference country), and if the company wishes to add another non-reference factory:

- A **Free Sale Certificate** must be provided, authenticated by the Chamber of Commerce and the Egyptian Embassy in the reference country where the product is marketed, and stating the product name and that it is freely sold in the reference country.

2.2.3. Adding a factory for local products:

- A valid manufacturing contract with the factory stated in the Registration Notification must be provided, along with an annex to the contract mentioning the product name, provided both are authenticated by the Legal Affairs department.
- A valid manufacturing contract with the new factory to be added must be provided, along with an annex to the contract mentioning the product name, provided both are authenticated by the Legal Affairs department.
- Providing the technical operation license for the new factory, proving its production line for the product.

1. Transfer of Ownership

In case the company wishes to transfer the ownership of local products, whether registered or listed:

3.1. The original Registration/Listing Notification of the product must be provided.

3.2. A waiver document authenticated by the Real Estate Registration Office must be prepared, including the following information:

- The name of the assigning company and its commercial registration number, ensuring these details exactly match what is recorded in the assigning company's commercial register.
- The name of the assignee company and its commercial registration number, ensuring these details exactly match what is recorded in the assignee company's commercial register.
- The names of the products intended to be waived in English, mentioning their registration or listing numbers. These must match the registration or listing notifications issued by the Egyptian Drug Authority (EDA).
- In case of any error in the data mentioned in the waiver, it must be corrected and the amendment authenticated with the "Eagle Seal" from the Real Estate Registration Office.

3.3. The authenticated waiver document is to be submitted to the Egyptian Drug Authority for legal and technical review at the **Reception window** before submitting the final **Hard file**.

3.4. A valid manufacturing contract with the factory where the company wishes to manufacture must be provided, along with an annex to the contract mentioning the product name, provided both are authenticated by the Legal Affairs department.

4. Transfer of Manufacturing

4.1. The original Registration/Listing Notification of the product must be provided.

4.2. In case the company wishes to **transfer the manufacturing** of a product from one factory to another, **one** of the following documents must be submitted:

- **A waiver from the factory:**
  - A signed waiver from the factory intended to be transferred from must be provided.
  - The waiver must be accompanied by a bank signature verification to guarantee the validity of the signature.
  - The waiver must be authenticated by the Legal Affairs department at the Egyptian Drug Authority (EDA) to ensure its official adoption.
- **OR a registered letter with acknowledgment of receipt:**
  - An official letter must be sent to the factory intended to be transferred from, stating the termination of the contract and the cessation of product manufacturing at their facility.
  - The letter must be sent via registered mail with acknowledgment of receipt to prove it reached the factory.
  - A copy of the letter sent to the factory, stating the termination of manufacturing at the facility, must be attached to the documents submitted to the Egyptian Drug Authority.
- **OR a notification via a process server (Bailiff):**
  - An official notification via a process server must be submitted to inform the factory intended to be transferred from regarding the cessation of product manufacturing at their facility.
  - A copy of the notification must be kept for submission to the Egyptian Drug Authority as part of the required documents.

5. Changing the Product Name

5.1. The original Registration/Listing Notification of the product must be provided. 5.2. In case of:

5.2.1. Changing the name for local Toll-Manufactured products or products manufactured locally under license from abroad (Toll-under license):

- A valid manufacturing contract must be provided, along with an annex to the contract mentioning the new product name, provided both are authenticated by the Legal Affairs department.

5.2.2. Changing the name for Local-Manufactured products and Toll-Manufactured products.

- A list of names must be provided.

6. Converting an Imported Product to a Locally Manufactured Product In case of converting a product from being an imported finished product to a locally manufactured product under license from abroad:

6.1. The original Registration/Listing Notification of the product must be provided.

6.2. An **Authorization letter** from the product owner abroad must be provided, granting authorization to the agent in Egypt to register and manufacture the product. It must be authenticated by the Chamber of Commerce and the Egyptian Embassy in the country of origin, ensuring all data matches the Registration Notification.

6.3. A valid manufacturing contract with the local factory intended for manufacturing must be provided, along with an annex to the contract mentioning the name of the product required to be manufactured, provided both are authenticated by the Legal Affairs department.

6.4. The technical operation license for the local factory must be provided, proving its production line for the product.

General Requirements

1. To make any other change, whether paper-based or on the listing platform, a letter must be submitted explaining the type of change required and presenting the intended amendment clearly and accurately.
2. Changes that require the issuance of a **new Registration or Listing Notification**: Transfer of ownership, transfer of manufacturing (or both), transfer of agency, changing the type of license from an imported product to a locally manufactured product under license from abroad (and vice versa), changing the product name, changing the purpose of use, changing the trade name or the commercial brand of the company, changing the license-holding company, and adding/deleting a manufacturing site (in the case of locally manufactured products).

3. Amendments that require the issuance of approval letters for the paper-based system, or updating product data in the electronic database for listed products without the issuance of paper-based and electronic system approvals, including:

Changes to the composition and mock-up statements, adding an internal leaflet, changing the pharmaceutical dosage form, extending or reducing the product's shelf life, and additions which include: adding/deleting a color, adding/deleting a flavor, adding/deleting a fragrance, adding/deleting a pack size or type, adding/deleting a carton box, and adding/deleting a manufacturing site (in the case of imported products).

References

1. Decision of the Chairman of the Egyptian Drug Authority No. (122) of 2022 regarding the listing and circulation of cosmetic products.
2. Regulatory guide for listing cosmetic product files, No. EDREX:GL.CAPP.009, Version: 1, Issue Date: March 6, 2023.
3. European Cosmetics Regulation (Directive no.: (EC) 1223/2009).