Central Administration of Pharmaceutical Products
General Administration of Human pharmaceuticals registration

Guideline

Regulatory Guideline on

Organizing the Rules and Procedures of the Re-registration of Human pharmaceutical Products in Accordance with the EDA Chairman Decree No. (150) of 2022

Code: GL.CAPP.030
Version No.: (7)
Issue Date: 30/12/2025
Effective date: 1/1/2026

Table of Contents

First: General Rules:

- ❒ This guideline shall apply to reorganizing the rules and procedures of the Re-registration of Human pharmaceutical Products that are locally manufactured or imported for the purpose of local marketing or tenders.

- ❒ Human pharmaceutical products that are manufactured locally or imported shall be re- registered every ten years upon a request submitted by the company during the last year of the marketing authorization license's validity to the General Administration of Human Pharmaceuticals Registration at the Central Administration of Pharmaceutical Products, otherwise the product's marketing shall be suspended.

- ❒ The License holder shall apply for getting a preliminary approval to fulfill and complete the technical studies, requirements and approvals necessary for re-registration.

- ❒ In the case of exceeding the specified period for submitting the re-registration application (preliminary approval for re-registration procedures), the submitted applications shall be reviewed based on an integrated report including the reasons for exceeding the specified period and the significance of the product. These applications shall be processed on a case-by-case basis and be presented to the EDA Chairman through the General Administration of Human Pharmaceuticals Registration at the Central Administration of Pharmaceutical Products.

- ❒ The product that has a preliminary approval to proceed with the re-registration procedures shall be granted a grace period of a maximum of 4 years starting from the expiration date of the marketing authorization license's validity. The purpose of that grace period is to fulfill and complete the technical studies, requirements, and approvals required to get the re-registration marketing authorization license. During the mentioned period, the importation, manufacturing and marketing shall be permitted and authorized in accordance with the regulating rules, unless any contradicting regulations, updates or decisions have been issued.

- In the case of exceeding the specified period for re-registration, the submitted applications shall be reviewed based on an integrated report including the reasons for exceeding the specified period, the significance of the product, the degree of fulfilment of the technical studies and the requirements necessary to complete the re-registration procedures, in addition to the proofs demonstrating the company seriousness. These applications shall be processed on a case-by-case basis and be presented to EDA Chairman through the General Administration of Human Pharmaceuticals Registration at the Central Administration of Pharmaceutical Products.

- **Criteria for accepting the petitions of extending the grace period of re- registration prior to their submission:**

1- The product shall be included in the valid list of drug shortages issued by EDA.
2- The product shall have other concentrations of the same box in the local market.
3- Other cases approved by the Technical Committee for Drug Control.

- The company shall submit the final re-registration dossier which includes all documents issued for the product, which guarantee the quality, efficacy and safety of the products and active ingredients.

- In the case of approval, the product shall be re-registered for another ten years starting from the date of approval of the Technical Committee for Drug Control. The company may submit a petition for reconsidering the final decision of the Technical Committee for Drug Control within 60 working days starting from the decision issuance date, provided that the petition shall include all the technical justifications and shall be supported by the documents and information on which the company relies. The petition shall be adjudicated within 60 working days from the date of its submission.

- The applicant shall submit a report on safety, quality and efficacy of the registered product within the last three months of the fifth year from the date of marketing authorization license. In case of non-compliance, the marketing of the product will be suspended based on a report from the relevant Central Administrations.

- All license holders have products under re-registration in the period prior to the effective date of the EDA Chairman Decree No. (150) of 2022, shall be obligated to complete the procedures and fulfill the requirements, approvals, technical studies and attachments necessary for re-registration in accordance with the following grace periods:
  - Products under re-registration in accordance with Ministerial Decree No. (425) of 2015: They shall have a period of (4) years from the expiry date of the marketing authorization license's validity, or preliminary approval, or the approval of Scientific Committees or approval of the Technical Committee for Drug Control, whichever is the later:
  - Products under re-registration in accordance with Ministerial Decree No. (296) of 2009: They shall have a period of (4) years starting from the effective date of this Decree on April 27th, 2022.
  - Products under re-registration in accordance with the decision of the Sub-Committee or the Ministerial Decree No. (645) of 2012 or Ministerial Decree No.
    (370) of 2006: They shall have a period of two years from the effective date of this Decree on April 27th, 2022.

- The company shall submit an application to the General Administration of Human Pharmaceuticals Registration at the Central Administration of Pharmaceutical Products after paying the service consideration for submitting the application for each product as from the effective date of this Decree on April 27th, 2022 for 6 months without prejudice to the payment -or completing the payment- of the specified re-registration service consideration as per the type of the product (locally manufactured products - imported or locally packaged products). In the case of exceeding the specified grace period granted to update the preliminary approval for proceeding with re-registration procedures, the companies may submit a request for being granted an additional grace period in order to submit the update application and provide the fulfilled required documents to update the preliminary approval for proceeding with re-registration procedures after paying the prescribed service

consideration for being granted an additional grace period to submit the fulfilled and complete documents required for every month of delay.

- ❒ All relevant regulatory administrations in the Egyptian Drug Authority, within their respective areas of competence, shall be committed to announce on the submission links: all the attachments required to receive the applications and the studies necessary to complete and submit the final re-registration dossier. And without prejudice to the original grace period specified for re-registration, each head of a relevant central administration shall, within their respective areas of competence, determine the grace periods required for the procedures of receiving and evaluation as well as presentation to the various committees and the grace periods granted to the company to fulfill the requirements and complete required documents in accordance with the nature of the procedure, provided that the granted grace period shall not be less than 30 days and not more than 120 days. Each relevant administration shall issue a checklist including the method of applying for getting the requested service, the required documents, paperwork, procedures, specified dates, grace periods, the submission links and the prescribed service consideration, whenever necessary.

- ❒ The production grace period of the locally manufactured products intended for local marketing as well as the importation grace period of the imported products that have a re-registration marketing authorization license shall be calculated based on the expiry date of the last batch produced. These grace periods shall not be applied to the registered products for export only or tender and export.

- ❒ In the case of a variation of quantity or quality of any of the active ingredients that aligns with reference products or scientific references or scientific committees' recommendations, all the specified procedures for registration as a new product shall be applied while keeping its place in the box. The marketing of the product shall be permitted after being presented to the Technical Committee for Drug Control until fulfilling the registration procedures of the new composition in accordance with the rules.

Second: Applying for getting preliminary approval for re-registration procedures

The preliminary approval for re-registration procedures shall be issued after license holder submits an application that shall include - at least- the following documents:

- ❒ Re-registration application form
- ❒ A copy of the marketing authorization license
- ❒ A copy of the latest scientific reference for the pharmaceutical dosage form and the composition
- ❒ A valid Certificate of Pharmaceutical Product of the product in the country of origin "CPP" for imported finished products, imported bulk products and under license products.
- ❒ Documents demonstrating the continuity of manufacturing and marketing of locally manufactured products for local marketing or documents demonstrating the importation of the imported products for local marketing
- ❒ Documents stating the payment of the re-registration service consideration.

Third: Documents, approvals and technical studies required after issuing preliminary approval for re-registration procedures as per the relevant administrations.

(1) Central Administration of Pharmaceutical Care

(A) General Administration of Pharmaceutical Vigilance

- ❒ The company shall be committed to submit the pharmacovigilance file including all required documents in accordance with the principles of good pharmacovigilance practices and the governing rules and regulations within 6 months from the issuance date of the preliminary approval for re-registration procedures.

- ❒ In the case that pharmacovigilance file is not approved, or the documents are not fulfilled, the General Administration of Human Pharmaceuticals Registration shall be addressed to present the pharmacovigilance file to the Technical Committee for Drug Control to take a reasoned decision thereon.

(B) General Administration of Pharmaceutical References and Medical inserts

- ❒ The company shall be committed to apply for approving and updating the medical leaflet that shall be attached to the re-registration dossier in the case that more than 5 years have passed since the last approved medical leaflet or in the case that warnings

❒ or updates that require approving and updating medical leaflets are issued.

(2) Central Administration of Drug Policies and Market Access

(A) General Administration of drug information centers – Pricing Policies and Pharmacoeconomics Administration

❒ The company shall be obligated to provide any of the following documents regarding the products submitted for re-registration:

a. A valid pricing certificate.

b. An expired pricing certificate: It shall be along with the documents indicating submission of an application for renewing the validity of the pricing certificate and accompanied by a commitment made by the company's legal representative on the company's header, notarized by a valid bank signature, stating the approval of issuing the re-registration marketing authorization license in accordance with the current price and demonstrating the company's commitment to submit the updated pricing certificate immediately upon getting it unless a re-registration marketing authorization license is issued prior to the issuance of the updated pricing certificate.

c. A pricing certificate that has an unspecified validity: It shall be along with the documents indicating submission of an application for renewing the validity of the pricing certificate and accompanied by a commitment made by the company's legal representative on company's header, notarized by a valid bank signature, stating the approval of issuing the re-registration marketing authorization license in accordance with the current price and demonstrating the company's commitment to submit the updated pricing certificate immediately upon getting it unless a re-registration marketing authorization license is issued prior to the issuance of the updated pricing certificate.

❒ For the cases that require renewal, the company shall be obligated to submit an application for renewing the pricing certificate validity in a period of 3 months before the expiry of the pricing certificate. The company shall be also obligated to price all packages prepared for local marketing which are intended to be stated with their prices in the re-registration marketing authorization license.

- The locally manufactured products intended to be marketed for tender and export as well as the packages prepared for tender and export shall not be subjected to the requirement of submitting a pricing certificate.

(B) General Administration for Importation and Custom Release

- It is permissible to allow importation and sealed medical customs release of
  - Pharmaceutical active ingredients/ packing and packaging materials used in the manufacturing of locally manufactured products.
  - Imported products (finished products/ packaging importation)

  that are concerned with the registered products and submitted for re-registration in accordance with registration / re-registration marketing authorization license or valid preliminary approval for re-registration, or the documents indicating the status of the product regarding re-registration based on the statement issued by the Central Administration of Pharmaceutical Products.

- The company shall be obligated to submit the documents required for the issuance of the approval/importation plan and the sealed medical customs release letter made in accordance with the regulatory guideline for the rules and procedures regulating import and medical customs release of medical products, their ingredients and packing and packaging requirements.

(3) Central Administration of inspection on pharmaceutical institutions General Administration of Factories Inspection

- Production lines of products imported from non-reference countries and not marketed in a reference country are inspected in accordance with the Risk based Inspection planning issued by the General Administration for Factories Inspection.

(4) Central Administration for Drug Control

- The license holder has products under re-registration shall be obligated to submit an application to update the analysis file to the Administration of Human Pharmaceutical Variation at the General Administration of Human Pharmaceuticals Registration at the Central Administration of Pharmaceutical Products, in order to

issue the necessary transfer letter.

- ❒ The status of the product shall be studied by the Central Administration of Drug Control to issue a certificate of updating the analysis file of a registered human pharmaceutical product. The final analysis report of the product and the final composition approved by the Central Administration of Drug Control as well as the finished product specifications shall be attached to the certificate.

- ❒ In the cases requiring re-analysis at the Administration of Evaluation and Approval before issuance of the re-registration marketing authorization license: sealed samples of the product shall be provided to be analyzed at the Central Administration of Drug Control, the Administration of Evaluation and Approval via the Central Administration of Operations, without stopping the release of the production batch from which the sample has been taken based on a written commitment made by the company's legal representative on the company's header, notarized by a valid bank signature, and stating the company's full responsibility. That procedure shall be followed up by the Central Administration of Operations.

- ❒ In the case that the company wants to apply for fulfilling re-registration requirements at the Central Administration of Pharmaceutical Products utilizing a final report issued by the Administration of Evaluation and Approval within a year from the date of the approval of the final report at the Central Administration for Drug Control, the license holder may apply to get a statement from the Central Administration for Drug Control indicating that the product final report issued by the Administration of Evaluation and Approval has been updated as part of the procedures for reviewing the product's file before analysis.

(5) Central Administration of Pharmaceutical Products

(A) General Administration of Stability

- ❒ The company is obligated to apply to the General Administration of Stability to approve the long-term stability study for re-registration in case there is no long-term stability study approval subsequent to the marketing authorization license.

(B) Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals

- ❒ The company is obligated to apply to the Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals to approve the bioequivalence study or in-vitro dissolution according to the rules.

- ❒ Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals may exempt a product from re-conducting the bioequivalence study or in-vitro dissolution based on the type of the product and the variations it undergoes in the case that the conducted studies fulfill all the requirements, rules, and updated decisions regulating conducting these studies at the time of evaluation.

(C) Evaluation Unit of Scientific Evaluation and Drug Development

- ❒ For products that have lost their reference status, the company is required to submit an application to the Scientific Evaluation and Pharmaceutical Development Unit at the General Administration of Human Pharmaceuticals Registration within six (6) months from the date of issuance of preliminary approval for re-registration procedures.

  The mentioned unit is allowed to approve the continuation of the re-registration process, provided that the reasons for the loss of reference status are not related to safety or efficacy, and based on a statement issued by the General Administration of Pharmacovigilance regarding whether any safety or efficacy signals have been detected for the product.

  If the above conditions are not met, the General Administration of Pharmacovigilance shall be contacted to evaluate the product's safety, taking into account the number of years the product has been marketed in the Egyptian market, as well as evaluating pharmacovigilance files and reviewing a safety assessment of the product during its marketing period.

  The company is allowed to be granted a grace period to fulfill the required data and documents in accordance with the approved timeframes for re-registration, in cases

where the available safety data for the product are insufficient. Files of products for which the required documentation could not be completed shall be submitted to the Technical Committee for Drug Control to issue a reasoned decision in this regard.

Fourth: Submitting the final and complete re-registration dossier

- ❒ The company shall submit the final re-registration dossier (Modules 1 & 3), complete with all required documents as published on EDA website, pertaining to the Administration of Human Pharmaceuticals Regulatory Affairs under the General Administration for Human Pharmaceuticals Registration.
- ❒ The Administration of Human Pharmaceuticals Regulatory affairs, and its affiliated units, shall carry out the initial review of the dossier within the timeframes specified in Annex No. (1), and shall notify the company of the product status, whether the dossier is accepted or not accepted.

- ❒ In case of initial acceptance of the dossier, the Administration of Human Pharmaceuticals Regulatory Affairs and its affiliated units shall distribute the re-registration dossier to the relevant departments and units in order to initiate the technical evaluation procedures within the timeframes specified in Annex No. (1), and shall notify the company of the product status upon completion of the technical evaluation process.

- ❒ In case that requirements are requested from the company, the company shall be notified of the requirements, and the company shall be obligated to submit the required documents within the timeframes specified in Annex No. (2) from the date of sending the assessment report. And in case that the total granted period for submitting the requirements is exceeded, the company is required to pay the service fee for extending the requirements fulfilling period to the General Administration of Human Pharmaceuticals Registration. If an additional extension is granted, the submitted requirements shall be reviewed within the timeframes specified in Annex No. (1).

- ❒ The dossier shall be presented to the Technical Committee for Drug Control within the timeframes specified in Annex No. (1), from the date of submission of the original documents.

- ❒ In case of approval by the Technical Committee for Drug Control, the final re-registration license for the product shall be issued, and the company shall be obligated to comply with the requirements stated in the license. The Central Administration of Inspection on Pharmaceutical Institutions is responsible for monitoring the implementation of these requirements.

- ❒ In case of rejection by the Technical Committee for Drug Control, the company is allowed to submit an appeal to the General Administration of Human Pharmaceuticals Registration against the final decision issued by the Technical Committee for Drug Control within (60) working days from the date of issuance of the decision, through a reasoned application submitted to the Technical Committee for Drug Control and supported by the documents and information on which the company desires to rely on when reviewing the appeal. The appeal shall be presented to the Technical Committee within (60) working days from the date of its submission.

Fifth: Attachments

Annex (1): Timeframes for Review and Evaluation of the Re-registration Dossier

No.	Dossier review steps	Timeframe
1	Initial screening [1]	(20) Working days
2	Dossier distribution and technical evaluation [2]	Technical evaluation and fulfilling the requirements within (60) working days Reviewing the fulfilled requirements for the first time within (30) working days Reviewing the fulfilled requirements for the second time within (30) working days

3	**Presentation to the technical committee and issuing the final re-registration license**	**(30) Working days**

(1) Initial review of the re-registration dossier to ensure the presence of all required technical studies and approvals by the Administration of human Pharmaceuticals Regulatory affairs, in order to verify whether the dossier is complete to proceed with the technical evaluation process or not.

(2) Detailed technical review by the relevant departments and units, and initiation of the evaluation of the technical studies.

Annex (2): Timeframes for the company to fulfill the requirements

No.	The specified departments	Timeframe
1	**All departments and units involved in the technical evaluation**	**The company is obligated to fulfill the requirements within a maximum of (120) days from the date of sending the fulfilled requirements; this period can be divided into a maximum of two intervals.**

Versions

Versions	Issue Date	Subjects of amendments
Version: 1	April 14th, 2022	New Issue
Version: 2	Jan. 5th, 2023	▪ Updating the preliminary approval for re-registration procedures. ▪ Central Administration for Drug Control
Version: 3	June 20th, 2023	▪ General rules ▪ Central Administration for Drug Control ▪ Submitting the final and complete re-registration dossier
Version: 4	September 20th, 2023	▪ General rules ▪ The applicant shall submit a report on safety, quality and efficacy of the registered product within the last three months of the fifth year from the date of marketing authorization license. In case of non-compliance, the marketing of the product will be suspended based on a report from the relevant Central Administrations.
Version:5	November 30th 2023	▪ General Administration of Factories Inspection ▪ Submitting the final and complete re-registration dossier
Version:6	October 30th 2024	▪ Updating the final re-registration dossier concerning the technical studies that must be submitted to get re-registration marketing authorization license.
Version:7	December 30th 2025	▪ Updating the requirements of the final re-registration dossier