Notice to Applicant

Mechanisms for registering the second brand products in Egypt 2026

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Introduction

Second-brand products are of great significance due to their comparable technical quality to original products and their lower cost, which helps ease the financial burden on patients. Additionally, they play a vital role in boosting and supporting the local manufacturing sector, particularly in the production of biological products. In light of this, it is essential to implement clear guidelines and procedures for their registration. This will ensure their safe and effective availability to Egyptian patients, while also promoting a balanced approach that upholds product quality, accessibility, and long-term sustainability.

Definitions

Second Brand: It is a locally manufactured product produced by a local company that has obtained registration and manufacturing rights from a foreign company that owns the original product, which has been licensed by the Egyptian Drug Authority. The local product must be identical in all technical specifications to the original product of the parent foreign company and be marketed under the local company's trade name. Its registration file is based on the technical data approved in the original product file registered by the Egyptian Drug Authority.

Regulatory framework and procedures for second-brand product registration

Eligibility criteria for the original product:

- The product must either hold a valid final marketing authorization license or submitted for re-registration.
- The original product must be registered using a full registration dossier, in compliance with Egyptian Drug Authority Decree No. 343 of 2021 regarding the regulations and procedures for registering biological products as well as any other relevant decisions in force.
- The original product must not be a second brand of any other product.

- Any ongoing or pending post approval changes that are under review or require assessment will be considered during the registration process.

Eligibility criteria for the second brand product:

- The product must match the original product from the parent foreign company in all technical specifications, including the active substance, strength, formulation, dosage form, and the manufacturing sites for the active ingredient, finished product, and primary packaging. However, similarity in the primary packaging site is not required if this process is carried out locally.
- The product should provide a price advantage compared to the original product, that benefit will be evaluated and approved by the Pricing Committee, taking into account the product's importance and relevant economic factors.
- The second brand product must carry a trade name owned to the local manufacturing company.
- The secondary packaging must be carried out by a local manufacturer site. Registration of the second brand product will be rejected if secondary packaging preformed outside Egypt.
- If the local manufacturer site act as the primary packaging site, it must provide the required studies in accordance with ICH Q5E guidelines and submit samples for registration analysis to the Egyptian Drug Authority's laboratories prior to the issuance of the marketing authorization license.
- The agreement between the local and foreign manufacturer sites must outline the technology transfer process, specifying that the primary packaging should be completed within **thirty months** from the date of registration of the second brand product. Additionally, other manufacturing steps for the product must be completed within **four years** from the date of registration of the second brand product.

Second brand product registration procedures:

1- The registration application for the second brand product must be submitted via the designated electronic inquiry system. A legalized copy of the contract should be submitted with the application, along with an authorization letter from the original product's owner, granting the applicant company permission to utilize all documents, studies and data from the original product's registration dossier.

A- If the product is manufactured abroad and undergoes local secondary packaging, the registration file must be submitted within **60 working days** from the product's pricing date, in accordance with the regulatory guidelines outlined in the Egyptian Drug Authority's Decree No. (343) of 2021"Code EDREX.GL.Bioinn.001", This is after the product has received pricing license.

"In this case, the product is exempt from the following requirements:"

- Presentation to the specialized scientific committee for biological products.
- Evaluation of stability studies.
- Evaluation of data related to the manufacturer outside Egypt by the central administration of inspection on pharmaceutical institutions, documents specific to the local manufacturer's site only should be submitted & evaluated.
- Registration analysis of the product.

B -If the primary packaging step will be conducted at a local manufacturer site, the registration file must be submitted within **two years** from the product's pricing date, in line with the regulatory guidelines outlined in the Egyptian Drug Authority's Decree No. (343) of 2021 "Code EDREX.GL.Bioinn.001". The company that owns the product abroad must

also provide a declaration confirming that the manufacturing processes have been consistently followed and that the locally packaged product matches the original product in all technical specifications. Additionally, the necessary studies must be submitted following the ICH Q5E guidelines, along with samples for registration analysis at the Egyptian Drug Authority's laboratories.

"In this case, the product is exempt from the following requirements:"

- Presentation to the specialized scientific committee for biological products.
- Evaluation of data related to the manufacturer outside Egypt by the central administration of inspection on pharmaceutical institutions, documents specific to the local manufacturer's site only should be submitted & evaluated.

2- The package insert; inner and outer package will be reviewed for approval.

3- Pharmacovigilance requirements submitted by the applicant will be evaluated.

4- The product will be submitted to the Technical Committee for Drug Control within **20 working days** for the normal track and within **10 working days** for the fast track, starting from the date all approvals are received from all relevant evaluation parties, to finalize the decision on the product's registration.

Post approval changes

- The foreign company that owns the product abroad must submit a declaration committing to implement all changes made to the original product onto the second brand product. Consequently, any approved changes to the original product will automatically apply to the second brand product without requiring re-evaluation. The local manufacturer is responsible for providing all necessary documentation and paying the required fees.

- If the change involves the primary packaging process conducted locally, the local manufacturer is required to provide a comprehensive statement explaining how the proposed change will be implemented. Furthermore, the procedures outlined in the guideline on the regulation of post-approval changes to a registered Biotherapeutic products in Egypt (Code: EDREX.GL.Bioinn.008) must be followed. This includes payment of the required fees and compliance with all relevant requirements set by the Biological Products Inspection Administration.

General rules

- Products registered as a second brand product, with the same pharmaceutical form, concentration, and packaging as the original product in the local market, are granted a period of **thirty months** from the date of registration to start local packaging (Primary Packaging). Products will not be re-registered if the company fails to comply with the aforementioned timeframes for transferring manufacturing technology
- Re-registration of a previously registered product as a second brand product is not allowed unless the second brand product meets all technical requirements, has the same active ingredient and concentration, and is identical to the original product in terms of composition, pharmaceutical form, and active ingredient manufacturing sites after the completion of manufacturing technology transfer procedures.