Central Administration of Pharmaceutical Products
General Administration of Human pharmaceuticals registration

Guideline

Regulatory Guideline on

Organizing the Rules and Procedures of the Simulation-Based Registration of Human Pharmaceutical Products in accordance with Egyptian Drug Authority Chairman Decision No. 311 of 2025

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Introduction:

This Guideline is concerned with organizing the rules and procedures for the simulation-based registration of human Pharmaceutical products in accordance to EDA Chairman Decision No. (311) of 2025 issued by the Chairman of the Egyptian Drug Authority. This guide applies to Locally manufactured and Imported Human Pharmaceutical Products to obtain a Simulation-Based Pharmaceutical Product registration license.

Scope of Work:

Companies recorded in the Egyptian Drug Authority's Electronic Companies Record have the right to submit the registration request approval for the Simulation-Based registration of human Pharmaceutical products in accordance with the procedures and rules set out in detail in this guideline, provided that the reference product meets the following conditions:

1. **Has a valid Registration/Re-registration License, or a valid preliminary approval to proceed with re-registration procedures, in accordance with the applicable regulatory rules of the Egyptian Drug Authority.**
2. **Fulfilled all technical studies covering the quality, efficacy, and safety of the products submitted for registration.**
3. **Marketed in the Egyptian market.**

Definitions:

- **Law: The Law establishing the Egyptian Drug Authority by Law No. (151) of 2019.**
- **Executive Regulations: The Executive Regulations of the Law establishing the Egyptian Drug Authority issued by Prime Minister's Decision No. (777) of 2020.**
- **Authority: The Egyptian Drug Authority.**
- **Human Pharmaceutical Product: Any product or preparation containing any substance or group of substances used for the purpose of treatment, prevention, or diagnosis in humans, or claimed to have any other medical effect, or intended to restore, correct, or modify physiological functions by exerting a**

pharmacological, immunological, or metabolic action in public health, in

accordance with applicable references and standards, as well as any products or substances that may be developed in line with scientific advances and/or international standards and references.

Human Pharmaceutical products are classified into locally manufactured human Pharmaceutical products and imported human medicinal products.

- **<u>Simulation-Based Registration:</u> A set of technical, administrative, and legal procedures resulting in the applicant obtaining a registration License for a Pharmaceutical product under a new trade name, provided that a similar Pharmaceutical product exists and is registered in the Authority's database and is owned by the same applicant company.**
- **<u>Original Product:</u> For the purposes of implementing this Decision, it is the product registered in the Egyptian Drug Authority database and holding a valid registration License, re-registration, or Preliminary approval to proceed with registration procedures.**
- **<u>Simulated Product:</u> A product registered in the Authority's database that is similar to the original product registered in the Egyptian Drug Authority in terms of composition, formulation, and intended use, except for the trade name and pack size.**
- **<u>Company – Applicant – Marketing Authorization Holder – Marketing License Holder in Egypt:</u> A legal entity established under the relevant laws of the Arab Republic of Egypt, such entity shall be registered in the Company profile established at the Egyptian Drug Authority. It shall be permitted, in accordance with the provision of the effective laws and regulating decisions in this regard, to submit the registration for registration of human Pharmaceutical products and to carry out all necessary procedures for registration the product from submitting its registration request until obtaining the (Marketing authorization license)**
- **<u>Date of Release to Market:</u> The date of final release of production batches for locally manufactured human Pharmaceutical products or the release of imported shipments of imported human Pharmaceutical products.**

Company Obligations

- **Compliance with the provisions of Intellectual Property Protection Law No. (82)**

of 2002 and its Executive Regulations, without any responsibility on the part of the Egyptian Drug Authority.

- **The company applying for simulation-based registration has the right to benefit from the technical studies of the original product, provided that it complies with the following conditions:**
  1. **Use of the same composition of the original product.**
  2. **Importing the active pharmaceutical ingredient (API) from the same supplier as the original product.**
  3. **Manufacturing at the same manufacturing site as the original product.**

- **Only one final simulation-based registration License shall be issued per original pharmaceutical product registered under the company's name.**

- **The company shall comply with all registration license requirements in accordance with the original product.**

- **The company owning the product shall notify the Egyptian Drug Authority of any change or addition to the registration license of either the original or simulated product throughout the validity period of the license.**

- **No variations shall be made to the simulated product other than those approved in the original product registration license, except for size and design of the pack.**

- **The company holding a simulation-based registration license may manufacture a maximum of one production batch annually for local distribution, provided that obtaining prior approval from the Central Administration for Operations, including batch quantity and production and distribution schedules. It is prohibited to split the authorized batch quantity or withhold the produced quantity from the local market.**
  - **The application for approval from the Central Administration for Operations shall be submitted via the following link: https://forms.gle/fHeVVGucQavzFAL67**
  - **Approval shall be issued within 3 working days, provided that all required documents are fulfilled and the service consideration for approving simulated product manufacturing for local distribution is paid.**
  - **The company shall send a batch distribution statement after manufacturing to the following email: Drug Factory Inspection Inspect.df@edaegypt.gov.eg, and the General Administration for Market Surveillance shall monitor this batch in the market.**

- **The company shall obtain exportation approval for the manufactured quantity of the simulated product in accordance with the procedures published on the official website of the Egyptian Drug Authority, in accordance to EDA Chairman Decision No. 216 of 2020 and the regulatory guide governing the exportation of pharmaceutical products and medical devices, provided that the following conditions are fulfilled:**

  1. **The original product must not be listed in the drug shortage lists.**
  2. **The manufacturing ratio of the simulated product shall not exceed (25%) of the raw material capacity of the factory if the raw material is imported, unless an increase is justified by ensuring availability of the original product in the local market, availability of production capacity, and submission of an importation plan ensuring continuity of raw material supply.**

Procedures for the Simulation-Based Registration of Human Pharmaceutical Products, Locally Manufactured or Imported

First: Procedures for Obtaining Simulation-Based Registration Request Approval

- **The company shall submit the Simulation-Based registration request approval in accordance with the procedures of the General Administration of Human Pharmaceuticals Registration as announced on the website of the Egyptian Drug Authority (Annex 1). The company shall be notified of confirmation of the initial acceptance of the registration request approval within 3 working days from the date of receipt of a complete application submitted in accordance with the applicable regulations.**

- **The company shall be notified of the product's status within a maximum of 7 working days from the date of confirmation of the initial acceptance of the complete registration request approval, in accordance with the applicable regulations.**

- **In case additional information or documents are required, the company shall be granted a maximum period of one month to submit the requested requirements in accordance with the procedures of the General Administration of Human**

Pharmaceuticals Registration announced on the website of the Egyptian Drug Authority (Annex 1), for the issuance of the registration request approval. Such approval shall be issued within two working days from the acceptance of all required submissions in full. The company shall pay the service consideration required to register the product before the registration request approval

Second: Submission to the Evaluation unit for Trade Names and Mockup for human pharmaceuticals to Obtain Approval of the Trade Name

- The company shall apply to the Trade Names and Mockup Unit for Human Pharmaceuticals within 15 working days from the date of issuance of the

registration request approval in order to obtain approval for the product name. The list of names proposed by the company shall be evaluated within 4 working days from the date of submission to the Trade Names and Mockup Unit for Human Pharmaceuticals.

- The company may apply using the same trade name as the original product, with the addition of the letter "E", or may apply for a new trade name, provided that it complies with the trade-name regulations announced by the Egyptian Drug Authority.

Third: Pricing Policies Administration in Central Administration of Pharmaceutical Policies and Market Access

- The company shall submit an application to the Pricing Policy Administration within a maximum of 15 working days from the date of issuance of the registration request approval. The pricing certificate shall be issued within a maximum of 30 working days from the date of receiving of the complete pricing dossier.

- Products undergoing Simulation-Based registration, as well as any additional pack sizes of such products, shall be priced in accordance with the price proposed by the company, provided that the price does not exceed the price of the reference product (Brand Product) in Egypt or the marketed prices of the

reference product abroad. In all cases, the price of the simulated product shall not exceed the average of the lowest prices of the reference product in five foreign countries.

Fourth: Procedures for Receiving and Review of the Registration Dossier and Issuance of a Simulated Registration License

1. The company shall submit the required documents to obtain a Simulated Product Registration License in accordance with the procedures of the General Administration of Human Pharmaceuticals Registration as published

on the website of the Egyptian Drug Authority, within 30 working days from the issuance of the first pricing certificate. An initial review shall be conducted by the Administration of human Pharmaceuticals Regulatory affairs and its affiliated units within 3 working days, after which the company shall be notified either of the initial acceptance of the registration dossier for evaluation or of any required documentation to be completed.

2. The Administration of human Pharmaceuticals Regulatory affairs and its affiliated units shall review the dossier and communicate with the Trade Names and Mockup Unit for Human Pharmaceuticals and the General Administration of Pharmaceutical References and Leaflets within the Central Administration of Pharmaceutical Care for approval of the outer pack and the updated leaflet, within 15 working days from receipt of the dossier. If additional information or documents are requested, the company shall comply with all requirements necessary for the issuance of the Simulated Product Registration License.

- Where additional requirements are requested, the company shall submit the requested completions to the General Administration of Human Pharmaceuticals Registration within one month from the date on which the request for completion is sent. The Simulated Product Registration License shall be issued within 2 working days from the date of approval by the Technical Committee for Drug Control. The company shall comply with all requirements applicable to the License in accordance with the original product, and this shall be followed up by the Central Administration of Operations.

Annex (1): Documents Required for Obtaining Simulation-Based Registration Request Approval of Human Pharmaceutical Products

Required Documents	Original to review	Hard copy	Soft copy
1. Registration Request Approval, submitted in accordance with the procedures of the General Administration for Human Pharmaceuticals Registration as published on the website of the Egyptian Drug Authority, provided that the form is on the company's official letterhead and stamped.			√
2. A copy of the payment receipt of the service consideration and the registration request approval fees shall be attached.			√
3. Submission of a valid Final Registration License, a valid Re-registration License, or a valid Preliminary Approval to Proceed with Re-registration Procedures.			√
4. A report from the Central Administration of Operations confirming the existence of a valid batch currently marketed.			√
5. A commitment, signed and stamped by the Chairman of the company, stating that the data submitted in the registration request approval is identical with the latest updates of the original product.			√

Annex (2): Timelines for the Review and Evaluation of Simulation-Based Human Pharmaceutical Products

Locally manufactured and Imported Human Pharmaceutical Products	
Registration Request Approval	12 working days
Trade Names and Pricing Evaluation	30 working days
Review and Evaluation and Issuing Simulation-Based Registration License	20 working days