

**EDA Chairman Decree No. (311) of 2025**  
**Concerning the Regulation of the Rules and Procedures for the Registration of**  
**Human pharmaceutical Products under the Simulation System**  
**for Export Purposes**

**The Chairman of the Egyptian Drug Authority,**

Having reviewed:

- Law no. 163 of the year 1950 on mandatory pricing and determining profits, as amended;
- Law on Practicing Pharmacy enacted subject to Law no. 127 of the year 1955, as amended;
- Law no. 113 of the year 1962 on re-structuring importation, manufacturing, and trading of medical chemical, supplies, and pharmaceuticals;
- Law on the Protection of IPR no. 82 of the year 2002, and executive regulations thereof;
- Law on the Protection of Competition and the Prohibition of Monopolistic Practices enacted pursuant to Law No. 3 of the year 2005, and executive regulations thereof;
- EDA Law enacted subject to Law no. 151 of the year 2019, and executive regulations thereof;
- Presidential decision no. 4 of the year 2025 on the constitution of the Board of Directors of the Egyptian Drug Authority;
- EDA' s BOD Minutes of the Meeting, session no. 1 dated 20/07/2020;
- Ministerial decisions no. 113 of the year 2004, no. 191 of the year 2005, no. 296 of the year 2009, no. 499 of the year 2012, no. 575 of the year 2012, no. 645 of the year 2012, no. 342 of the year 2014, no. 425 of the year 2015, no. 820 of the year 2016, no. 600 of the year 2018, and 645 of the year 2018 on the rules and procedures for granting marketing approvals to pharmaceutical products, pricing human pharmaceutical products, and re-structuring certain provisions on the rules and procedures for registration of human pharmaceutical products;
- EDA Head decision no. 216 of the year 2020 on the rules and procedures for exporting medical supplies and products governed by the provisions of Law no. 151 of the year 2019;
- EDA Head decision no. 315 of the year 2021 governing scientific offices;
- EDA Head decision no. 150 of the year 2022 on re-structuring rules and procedures for re-registration of human medical products;
- EDA Head decision no. 780 of the year 2022 on relying on reference health authorities to register and analyze imported products bearing the registration and marketing certificate by a country of reference approved by the Technical Committee for Pharmaceutical Control;
- EDA Head decision no. 783 of the year 2023 on withdrawing and analyzing samples of human and veteran medical products, herbal products, disinfectants, cosmetics, pesticides, raw material, medical botanical products and similar, in accordance with the latest scientific discoveries;
- EDA Head decision no. 786 of the year 2022 on cancelling or suspension of registration procedures for human medical supplies or marketing license based on the evaluation of safety and efficacy;
- EDA Head decision no. 450 of the year 2023 on unifying rules and procedures for registration of human medical products;

- The letter of Cabinet Secretary issued under no. 9849-5 on 07/04/2025 on the Cabinet approval in its session no. 37 held on 26/03/2025 to the bill governing rules and procedures for registration of human medical products by way of simulation for the purpose of export;
- The content presented by the Head of Central Administration for Pharmaceutical Products;
- To the benefit of the practice;

**(Article 1)**

- The provisions of this decision shall apply to the rules and procedures governing the registration of human pharmaceutical products under the simulation, in compliance with international standards and for mutual benefit. The Decision emphasizes the adoption of credible measures toward manufacturing, the streamlining of registration timelines, and the acceleration of procedural completion to facilitate product export, following the review of the required technical studies and the provision of necessary support to companies for product development. All of this aims to ensure the quality, efficacy, and safety of pharmaceutical products in both the local and international markets.

**(Article 2)**

For the purpose of implementing this Decision, the following phrases shall have the meanings attributable thereto:

- Law: Law on the Establishment of EDA enacted subject to Law no. 151 of the year 2019.
- Executive Regulations: the executive regulations for the Law on the Establishment of EDA enacted subject to the Cabinet decision no. 777 of the year 2020.
- EDA: Egyptian Drug Authority
- Human pharmaceutical Product: any product including one or more active substances used for the purpose of treatment, protection, or diagnosis of humans, or that can be described as having any other medical effect for the purpose of recovery, correction, or amendment of physiological functions through a pharmacological, immunological, or metabolic effect as per the references and standards applicable. Human pharmaceutical products are classified into human locally manufactured products and imported products, as further detailed in the regulatory guide issued pursuant to this Decision.
- Registration under the Simulation System: a set of technical, administrative, and legal procedures upon which the applicant would get a marketing authorization license for the pharmaceutical product under a new commercial name, provided that a similar medical product shall be registered within EDA database and owned by the same applicant.
- The Original Products: for the purpose of application of the present Decision, the original product is the product registered within EDA database bearing a valid marketing authorization license, renewal Marketing authorization license, or preliminary approval.
- Simulated Product: the product registered within EDA database similar to the original product registered within EDA database in terms of ingredients, composition, and use, except for the commercial name and package size.
- Company, applicant, marketing authorization holder, marketing licensee in Egypt: It is a legal entity established in accordance with the relevant laws of the Arab Republic of Egypt. Such entity shall be registered in the company profile established in the Egyptian Drug Authority. It shall be permitted, in accordance with the provisions of the effective laws and the regulating decisions in this regard, to submit registration applications for registering the human pharmaceutical products and performs all the required procedures for registering the product, starting from submitting its registration request until getting the Marketing Authorization License (MA).

**marketing Date:** It is the date of the final release of the production batch of the human pharmaceutical products locally manufactured or the date of the final release of imported consignments of human pharmaceutical products.

**(Article 3)**

Without prejudice to intellectual property rights (IPRs), companies duly registered in the Egyptian Drug Authority's Register of Companies and authorized to submit registration requests for the registration of human pharmaceutical products may apply to register a product under the simulation system, in accordance with the procedures and rules set out in the regulatory guide. Such companies shall undertake to comply with all provisions governing the protection of intellectual property rights, both domestically and internationally.

The original product shall meet the following requirements:

- 1- It holds a valid marketing authorization license or renewal marketing authorization license, or preliminary approval in accordance with the regulatory rules applicable at the Egyptian Drug Authority (EDA).
- 2- It has completed all technical studies demonstrating the quality, efficacy, and safety of the product to be registered.
- 3- It is currently marketed within the Egyptian market.

**(Article 4)**

An applicant company intending to register a product using the simulation method may utilize the technical studies associated with the original product, subject to compliance with the following conditions:

- 1- Using the same composition data of the original product.
- 2- Supplying the raw material from the same supplier providing raw material for the original product.
- 3- Manufacturing at the same facility as the same original product.

**(Article 5)**

- The product registered by way of simulation shall be listed in the EDA database. The applicant shall issue marketing authorization license for the simulated pharmaceutical product, with a maximum of one marketing authorization license per original pharmaceutical product under the company's name. The simulated product shall have the same validity period as the original product and shall be registered under a new commercial name, with the package size determined in accordance with the terms and conditions set out in the guideline issued pursuant to this decision. Products registered by way of simulation shall be issued a pricing certificate and a Certificate of Origin (CCP/Free Sale).

**(Article 6)**

Prices, as well as package sizes for the same products mentioned to support export, shall be determined for products to be registered within the simulation system, in accordance with the price suggested by the company, provided not exceeding the reference price for the brand product in Egypt or the reference price abroad. In anyway, the price of the simulated product shall not exceed the average price for the reference price in five countries, as detailed within the guideline issued pursuant to the Decision.

**(Article 7)**

The company granted marketing authorization license under the simulation mechanism may manufacture one batch per annum for local marketing , in accordance with the price established for the simulated product, subject to obtaining prior approval from the Central Administration for Operations, which shall determine the approved quantity as well as the timelines for production and distribution. The approved quantity shall not be subdivided into portions smaller than the authorized batch, nor shall the company refrain from offering the produced quantity for sale within the local market.

**(Article 8)**

- The company shall obtain export approval for the simulated products produced, provided abiding by the following:

- The original product shall not be listed within the drug shortage list

The percentage of local manufacturing shall not be less than twenty-five percent (25%) for imported products. This percentage may be increased, provided that the availability of the original product in the local market is ensured, the manufacturer's production capacity permits such increase, and an importation plan is submitted to guarantee the continuous supply of active ingredients, in accordance with the terms and conditions stipulated in the guideline issued pursuant to the provisions of this Decision.

**(Article 9)**

According to the detailed memorandum issued by the competent Central Administration, in the event that any of the original products are listed among the products subject to drug shortage, the chairman of Egyptian Drug Authority (EDA) may authorize the distribution of the simulated products available in the local market at the official price of the original product produced by the same company.

**(Article 10)**

- The company shall submit the registration requests of pharmaceutical products by way of simulation by paying the service fees , in accordance with. EDA Fast track registration system.

**(Article 11)**

The applicant shall promptly notify the Egyptian Drug Authority (EDA) of any modifications or additions to the registration marketing authorization license for either the original or simulated products throughout the registration validity period. The marketing authorization license for the simulated product shall be revoked upon cancellation of the original product's registration or in the event of rejection of the re-registration procedures for the original product.

Under all circumstances, only those changes reflected in the marketing authorization license of the original product may be applied to the simulated product, with the sole exceptions of package size and shape.

**(Article 12)**

The Head of the Central Administration for Pharmaceutical Products, in coordination with the Head of the Central Administration for Pharmaceutical Policies and Market Policy and the Head of the Central Administration for Operations, shall issue a guideline specifying the procedures and mechanisms for the registration of medical products by way of simulation.

The guideline shall be issued within fifteen (15) working days from effective date of this decree. It shall include the executive mechanisms necessary for the implementation of all rules and procedures set forth in this Decision and shall clearly outline all requirements, approvals, technical studies, and supporting documentation required for its application. The guideline shall be subject to the approval of the relevant central administrations and shall adhere to the technical regulations in effect at the time of its issuance.

The guideline shall be updated by the issuing authorities whenever necessary, in line with any newly enacted regulatory provisions, legislative developments, or scientific advancements.

**(Article 13)**

This Decree shall be published in the Egyptian Gazette and shall enter into force on the day following its publication. Any provision to the contrary is hereby repealed.

**Chairman of the Egyptian Drug Authority**

**Dr. Ali El Ghamrawy**

**Issued on: 19/5/2025**



هَيْئَةُ الدَّوَاءِ الْمِصْرِيَّةِ