

## **Decree of the President of the Authority No. (450) of 2023 on Unifying the Process of Regulating the Rules and Procedures of Registration of Human Pharmaceutical Products**

**President of the Egyptian Drug Authority,**

Having perused:

- The Law on Pharmacy Profession Practice Promulgated by Law No. (127) of 1955, and its amendments;
- Law No. (113) of 1962 on Reorganizing Importation, Manufacturing and Trading of Drugs, Medical and Chemical Devices, and its amendments;
- The Law No. (82) of 2002 on Protecting the Intellectual Property Rights and its executive regulations;
- Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019 and its Executive Regulation, and its executive regulations;
- The Arab Republic of Egypt President's Decree No. (18) of 2020 on the Constitution of the Board of Directors of the Egyptian Drug Authority;
- The Ministerial Resolution No. (94) of 2004 on Modifying some Provisions of Analysis Consideration;
- The Ministerial Resolution No. (113) of 2004 on the Rules and Procedures of Granting the Marketing Approval for the Pharmaceutical Products;
- The Ministerial Resolution No. (499) of 2012 Regarding Pricing of Human Pharmaceutical Products;
- The Ministerial Resolutions Nos. (640) of 2012 and (777) of 2020 on Re-organizing the Service Consideration;
- The Ministerial Resolutions Nos. (575), (645) of 2012 and (342) of 2014 on Modifying some Provisions of the Rules and Procedures of Registering Human Pharmaceutical products;
- The Ministerial Resolution No. (425) of 2015 on Re-organizing the Rules and Procedures of Registration of Human Pharmaceutical Products;
- The Ministerial Resolution No. (820) of 2016 on Regulating the procedures for Registering Local Human Pharmaceutical Products Submitted by the Common Technical Document System;
- The Ministerial Resolution No. (600) of 2018 on Modifying some Provisions of the Ministerial Resolution No. (425) of 2015 on Re-organizing the Rules and Procedures of Registration of Human Pharmaceutical Products;
- The Ministerial Resolution No. (645) of 2018, on Regulating the Acceptance of Applications for Registration of Human Pharmaceutical Products which exceed the Prescribed Number of the Similar Boxes of the Medicines;
- The decree of the President of Egyptian Drug Authority No. (315) of 2021, On Regulating Scientific Offices;
- The Decree of the President of Egyptian Drug Authority No. (150) of 2022, on Re-organization the Rules and Procedures for Re-registration of Human Pharmaceutical Products;

- The Decree of the President of Egyptian Drug Authority No. (786) of 2022, on Suspension and Canceling the Procedures for Registering Human Pharmaceutical Products or the Marketing License Based on the Evaluation of Safety and Effectiveness;
- The Decree of the President of Egyptian Drug Authority No. (783) of 2022 on the Procedures for Withdrawing and Releasing the Pharmaceutical Products and its Regulatory Guideline;
- The Decree of the President of Egyptian Drug Authority No. (780) of 2022;
- The Minutes of the Authority's Board of Directors meeting held in its session on 20/07/2020;
- Material presented by the Chairperson the Central Administration of Pharmaceutical Products; and
- Having considered the interest of work;

**Has decided  
(Article One)**

This decree shall be implemented with regard to Unifying the process of Regulating the Rules and Procedures of Registration of Human Pharmaceutical Products. For the purposes of its provisions, the following terms shall have the meanings set out for each term hereunder.

- **The Law:** Law on Establishing the Egyptian Drug Authority Promulgated by Law No. (151) of 2019.
- **The Executive Regulation:** The executive regulation of the law on establishing the Egyptian Drug Authority promulgated by Prime Minister's Decree No. (777) of 2020.
- **The Authority:** The Egyptian Drug Authority.
- **The Human Pharmaceutical Product:** Every preparation or product containing any substance or group of substances used for the purpose of treatment, prevention or diagnosis in humans, or it may be described as it have another medical effect, used for the purpose of restoring, correcting, or modifying physiological functions through a pharmacological, immunological, or metabolic effect in public health. The aforementioned effects shall be done in accordance with applicable references and standards. As well as any products or materials that may be developed in accordance with the developments in science and/or international standards and references.

The human pharmaceutical products are divided into locally manufactured human pharmaceutical products and imported human pharmaceutical products, as stipulated in detail in the regulatory guideline of this decree.

- **The company - the applicant for registration - the owner of the marketing license 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 electronic registry of the companies established in 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 obtaining the registration notification.
- **The owner of the marketing license for the product in the country of origin - the owner of the marketing license for the product in a country other than the country of origin:** It is the foreign legal entity owning the product and in whose name the product certificate is issued in the country of origin, or that owns the rights to market it abroad.
- **Pharmaceutical similars box:** It is a box consisting of a set of pharmaceutical forms for each product. The number inside the box and the distribution of the pharmaceutical form shall be distributed in accordance with the rules regulating that matter. Hereinafter referred to as "the box".

- **Circulating 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 of imported consignments of human pharmaceutical products.

**Abbreviations:**

- **EMA:** European Medicines Agenc.
- **US FDA:** US Food and Drug Administration United States Food and Drug Administration.
- **CTD:** Common Technical Document.
- **CPP:** Certificate of Pharmaceutical Products.

**(Article Two)**

After presentation to the Authority's President, the number of similars inside the drug similars box shall be determined starting with the original product of the active ingredient according to the rules specified in detail in the regulatory guideline issued for implementing the provisions of this decree. The pharmaceutical forms shall be updated in the box upon emerging a new pharmaceutical form and after presenting to the Technical Committee for Drug Control.

**(Article Three)**

**First: Regular Registration:**

The company shall submit a registration request for registration of human pharmaceutical products, provided that the procedures and regulatory deadlines shall be committed, according to the following cases:

**1. First case:**

The company shall submit a registration request for registration of human pharmaceutical products based on the number allowed in the similars box. Submitting the Common Technical Document (CTD) is a condition for completing the final registration file as stipulated in the regulatory guideline.

**2. Second case:**

The company shall submit a registration request for registration of human pharmaceutical products based on the number allowed in the similars box and according to the Fast Track Registration. Submitting the Common Technical Document (CTD) is a condition for fulfilling the final registration file. The registration request shall follow one of the next tracks:

**Track (A):** The Imported human pharmaceutical products that have obtained the approval of both international reference bodies (US FDA) and (EMA), shall be registered by the Authority within a period of one month from the date of receiving the fulfilled and unified registration file.

**Track (B):** The Imported human pharmaceutical products that have obtained the approval of both international reference bodies (US FDA) and (EMA) , shall be registered by the Authority within a period of two months from the date of receiving the fulfilled and unified registration file.

**Track (C):** The Imported human pharmaceutical products or those locally manufactured, shall be registered by the Authority within a period of six months from the date of receiving the fulfilled and unified registration file.

All aforementioned procedures shall be implemented in accordance with the provisions contained in the regulatory guideline of this decree.

**3. Third case:**

The company shall submit a registration request of human pharmaceutical products but in exceeding the specified number of drug similars boxes referred to in (Article Two). The Common Technical Document (CTD) shall be submitted as a condition for completing the final registration file. **The request shall take one of the following tracks:**

**The tracks include:**

**Track (A):** The products enlisted in any of the lists of shortfalls of approved and valid human pharmaceutical products at that time based on the needs of the market determined by the Authority. These lists of shortfalls shall be published once every three months, provided that the process of production and circulation shall be initiated within six months from the issuance date of the registration notification for local human pharmaceutical products. The process of production and circulation shall be initiated within three months from the issuance date of the registration notification for imported human pharmaceutical products.

**Track (B):** The Human pharmaceutical products locally manufactured on rare production lines specified by the Authority, shall initiate the production and circulation within one year from the issuance date of the registration notification.

**Track (C):** The Human pharmaceutical products submitted by owners of licensed factories within ten years from the issuance date of the decree, shall initiate the production and circulation within one year from the issuance date of the registration notification, provided that the circulation date shall be the date of final release of the manufactured batch. The validity of this track shall end within two years from the issuance date of this decree.

**Track (D):** The Human pharmaceutical products submitted by owners of factories under construction, shall initiate the production and circulation within two years from the issuance date of the registration notification, provided that the circulation date shall be the date of final release of the manufactured batch. The validity of this track shall end within two years from the issuance date of this decree.

**Track (E):** The human pharmaceutical products locally manufactured for the purpose of local circulation and export abroad, at least 25% of the production as set out in the regulatory guideline, shall initiate the production and circulation within nine months and shall export within thirty months from the issuance date of the registration notification.

The procedures for the human pharmaceutical products submitted according to the various tracks stipulated in this case, shall be completed in accordance with the procedures and conditions of the **first case**.

**Second: Irregular Registration:**

a- In cases of emergency, any product may be circulated after being excluded from some of the conditions required for the registration stipulated in this decree as well as if it exceeded the specified number of similars box, based on a detailed technical memorandum prepared by the Central Administration of Pharmaceutical Products approved by the Authority's President, provided that the concerned person shall submit the registration file upon completing it in accordance with the applicable procedures for granting a license for emergency use.

b- The registration of human pharmaceutical products for which decrees are received from the Authority's President according to the scientific, technical or market need or emergency circumstances as well as if it exceeded the specified number of similars box, the registration procedures of them shall be completed in accordance with the rules regulating this matter and in accordance with the procedures contained in the regulatory guideline of this decree.

**(Article Four)**

It is required for the issuance of the registration notification of imported human pharmaceutical products, to be circulated for one year at least in the country of origin or any of the reference countries approved by the Technical Committee for Drug Control at the Authority. The imported human pharmaceutical products submitted for registration according to the second case referred to in (Article Three) of this decree shall be excluded from this condition, provided that the company shall be allowed to submit a registration request during this period.

**(Article Five)**

The imported human pharmaceutical products submitted for registration and the human pharmaceutical products imported from non-reference countries or not circulated in any of the reference countries shall be presented to the Technical Committee for Drug Control to take what it deems appropriate decree, if they have available place in the similars box.

**(Article Six)**

All human pharmaceutical products submitted for registration which have no scientific reference in the same pharmaceutical form, dosage or method of usage shall be referred to the specialized scientific committees, provided that the scientific files for the product shall be submitted by the company to the aforementioned committees. In case of approval by the committees from a scientific point of view, the company shall be notified to complete the product registration procedures. For the products which were scientifically rejected, they shall be presented to the Technical Committee for Drug Control to be adjudicated, provided that the committee's decision of rejecting the registration shall be reasoned.

**(Article Seven)**

**The company shall be committed to submit the registration file to the General Administration of Human Pharmaceutical Registration in accordance with the following procedures:**

**a- Locally manufactured products intended for local circulation or export and tenders:** They shall be granted a grace period of thirty-three (33) months starting from the issuance date of the pricing notification or from the date of the issuance of the pharmacovigilance approval, whichever is later. These deadlines shall apply to all locally manufactured products intended for local circulation or export and tenders under registration, with the exception of the third case (a) local products, which shall be granted a grace period of twenty-one (21) months starting from the issuance date of the pricing notification or from the issuance date of the pharmacovigilance approval, whichever is later, as stipulated in the regulatory guideline.

**b- For imported products submitted for the registration according to the first case and third case (a):** They shall be granted a grace period of six months (6 months) starting from the issuance date of the pricing notification or from the approval of the General Administration of Pharmacovigilance, whichever is later.

**c- For the products submitted for the registration according to the second case:** The deadlines stipulated in the regulatory guideline for this decision shall be committed.

**d- For the products submitted for registration for the purpose of export:** The company shall be granted thirty-three (33) months as a maximum starting from the issuance date of approval of proceed with the registration procedures or from the date of approval of the scientific committee in the case of non-referenced products, whichever is later.

In the case of exceeding the previous deadlines, the procedures specified in the regulatory guideline for this decree shall be committed.

**(Article Eight)**

After fulfilling the requirements of the final registration file, it shall be presented to the Technical Committee for Drug Control to be adjudicated. In the event of approval, a final registration notification valid for ten years (10 years) shall be issued as of the date of the committee's approval, provided that a report on safety, quality and efficacy shall be submitted in the fifth year from the date of registration notification, otherwise the circulation of the product shall be suspended based on a report issued by the relevant central departments as stipulated in the regulatory guideline.

In the event of refusal to register the product, the company may submit a petition to reconsider the final decision of the Technical Committee for Drug Control within sixty (60) working days as of the date of notifying the applicant of the decision, provided that the petition shall fulfill all the technical justifications on which the petition is relied. The petition shall be supported by documents and information which the company wishes to rely on when examining its petition, provided that the petition shall be adjudicated within 60 working days from the date of its submission.

**(Article Nine)**

A report on safety, quality and efficacy of the product shall be submitted in the fifth year from the date of registration notification, otherwise the circulation of the product shall be suspended based on a report issued by the relevant central departments as stipulated in the regulatory guideline.

**(Article Ten)**

**The ownership of human pharmaceutical products may not be transferred in the following cases:**

- 1- The locally manufactured human pharmaceutical products submitted for registration in accordance with the provisions of this decree except after the issuance of the final registration notification, subject to clauses (2) and (3) of this Article.
- 2- The human pharmaceutical products manufactured locally and prepared for local circulation and submitted for registration in accordance with the first or second case of this decree, except after the lapse of three years from the date of circulation.
- 3- The human pharmaceutical products submitted for registration in accordance with the (third) case of the (Article Three) of this decree, except after the lapse of five years from the date of circulating the product.

In all cases, the approval of the Central Administration of Pharmaceutical Products to transfer the ownership shall be obtained.

**(Article Eleven)**

The registration notification shall be canceled by a decision of the President of Egyptian Drug Authority, based on a reasoned report by the chairman of the Central Administration of Pharmaceutical Products, after presentation to the Technical Committee for Drug Control, **in the following cases:**

- a- If the locally manufactured products for the purpose of local circulation in the Egyptian market did not produced or if the import of the products that have a final registration notification didn't take place within (18) eighteen months from the issuance date of the final registration notification, based on a report issued by the Central Administration of Operation, except for the locally manufactured and imported human pharmaceutical products registered in accordance with the third case of (Article Three) of this decree.
- b- If the locally manufactured products for the purpose of local circulation did not produced or if the import of the products that have a final registration notification didn't take place before the last day of the expiry date of the last produced or imported batch, based on a report issued by the Central Administration of Operations.

The products registered for export only or for export and the tenders submitted according to the (first) case of (Article Three) of this decree shall not subject to the production and import deadlines stipulated in paragraphs (a) and (b) of this Article.

- c- The company's failure to submit the accelerated and long-term stability studies for the first three production batches, for locally manufactured products that are circulated locally or for export or tenders within five years from the issuance date of the final notification, according to the report issued by the Central Administration of Operations.

The generic products for which the original product has previously been granted a patent by the Egyptian Patent Office, until the expiration of the period of protection prescribed for the patent, and without prejudice to the provisions of the Law of Intellectual Property Rights Protection Promulgated by Law No. (82) of 2002, shall be excluded from the deadlines mentioned in the previous clauses.

In the event of exceeding the previous deadlines, the company may submit a request to the General Administration of Human Pharmaceutical Registration to extend a deadline, indicating the reasons for the delay and the new period required. The request shall be presented with a detailed report to the Authority's President indicating the reasons for exceeding the periods, the importance of the product in addition to evidence of the seriousness of the company to consider the public interest with regard to the product. The company may be granted an additional period of six months, renewable once for the same period, provided that paying the prescribed service consideration and existing one of the following reasons:

- The number of registered similars for the same concentration and pharmaceutical form that are actually in circulation shall not exceed five similars from other companies, based on a statement of the Central Administration of Operations regarding the circulation.
  - The products enlisted in the valid list of shortfalls issued by the Authority.
  - The product shall be concentrations locally circulated of the same similars box.
  - Other cases approved by the Technical Committee for Drug Control based on a reasoned decision.
- d- The company's non-compliance with the rules governing the transfer of ownership referred to in (Article Ten) of this decree.
- e- In the event of the circulation of the human pharmaceutical product may cause harm to public health, based on a technical memorandum supported by scientific evidence submitted by the chairman of the Central Administration of Pharmaceutical Products after presentation to the Technical Committee for Drug Control.

**(Article Twelve)**

The registration request of a human pharmaceutical product shall be canceled in case of the dates and deadlines specified in this decree and its regulatory guideline are exceeded, based on a decision by the chairman of the Central Administration of Pharmaceutical Products, the reports issued by the relevant central departments and after presentation to the Technical Committee for Drug Control.

**(Article Thirteen)**

The provisions of the decisions regulating the registration of the previous human pharmaceutical products shall apply to human pharmaceutical products submitted for registration prior to the implementation of the provisions of this decree, until the time of expiry of its registration notification.

**(Article Fourteen)**

In cases of emergency, any product may be circulated after being excluded from some of the conditions stipulated in this decree which are required for the registration based on a detailed technical memorandum supported by the scientific evidence and market studies prepared by the Central Administration of Pharmaceutical Products approved by the Authority's President.

**(Article Fifteen)**

chairman of the Central Administration of Pharmaceutical Products shall issue the regulatory guideline for this decree within fifteen working days (15) from the date of its effectiveness.

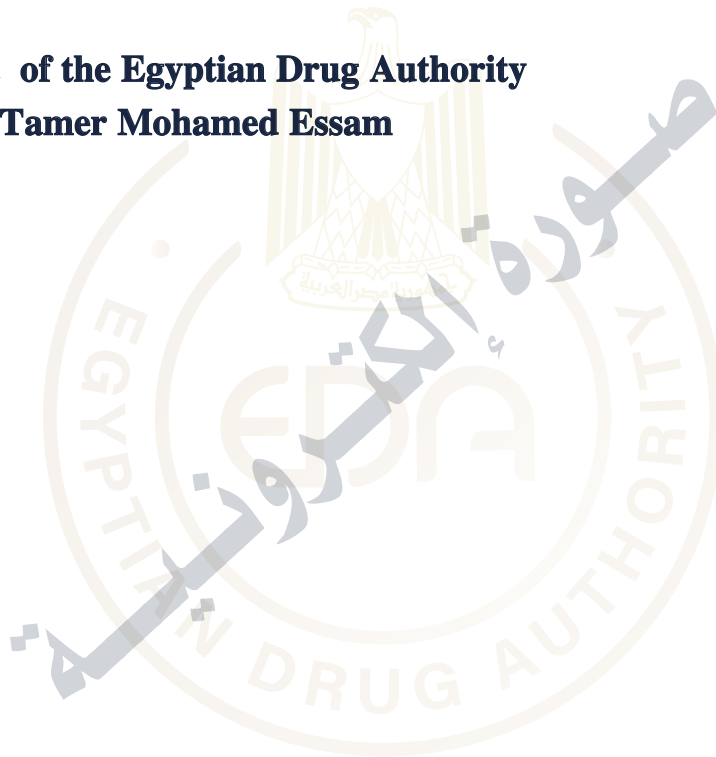
The guideline shall include the executive mechanisms concluding all rules and procedures and explaining of all requirements, approvals, technical studies and attachments necessary to implement the provisions of this decree, after being approved by the relevant central administrations, all within their respective jurisdictions, in accordance with the approved technical rules updated at the time of their approval. The issuing of the regulatory guideline also shall consider its updating whenever required by the business and in accordance with new laws, regulatory rules and developments in science.

**(Article Sixteen)**

This DECREE shall be published in Al-Waqa'i' al-Misriyya and shall come into effect from the day following its publication therein. All provisions that may contradict it shall be null and void.

**President of the Egyptian Drug Authority  
Prof. Tamer Mohamed Essam**

**Written on: 19/7/2022**



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