Decree of the President of Egyptian Drug Authority No. (150) of 2022 on Reorganizing the Rules and Procedures of Re-registration of Human Medical Products

President of Egyptian Drug Authority,

Having perused

- The Law of Suppression of Fraud and Counterfeiting Promulgated by Law No. (48) of 1941 and its Executive Regulations;

- Law No. (127) of 1955 on Pharmacy Profession Practice 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 on the Protection of Intellectual Property Rights Promulgated by Law No. (82) of 2002 and its Executive Regulation;

- Law on Establishing Egyptian Drug Authority Promulgated by Law No. (151) of 2019 and its Executive Regulation;

- Minutes of the Authority's Board of Directors meeting held in its session dated on 20/7/2020;

- Ministerial resolutions Nos. (113 of 2004), (191 of 2005), (296 of 2009), (575 of 2012), (342 of 2014), (425 of 2015), (600 of 2018) and (645 of 2018) on reorganization and amendment of some provisions of the rules and procedures of the registration of human pharmaceuticals products.

- Material submitted by the Chairman of the Central Administration of Pharmaceutical Products;

- Having considered the interest of work;

(Article 1)

This decision shall be implemented with regard to reorganizing the rules and procedures of re-registration of locally-manufactured or imported human medical products with a view to local circulation or tenders. For the purposes of implementing its provisions, the following terms shall have the meanings set out for each term hereunder:

- **The law**: It is the Law of establishing the Egyptian Drug Authority promulgated by Law No. (151) of 2019.

- **The Executive Regulation**: It is the executive regulation for the law of establishing the Egyptian Drug Authority promulgated by Prime Minister Decree No. (777) of 2020.

- **The Authority**: It is the Egyptian Drug Authority.

- **Locally-Manufactured Human Medical Products**: They are the human medical products manufactured by licensed factories within the Arab Republic of Egypt.

- **Imported Human Medical Products**: They are the human medical products that are fully manufactured when being imported from abroad or those that are manufactured abroad but they are packed and packaged in factories licensed within the Arab Republic of Egypt.

- The Company: It is the company owning the product registration in the Arab Republic of Egypt.

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(Article 2)

The locally-manufactured or imported human medical products shall be re-registered every ten years upon a request submitted by the company to the General Administration of the Registration of Human Products at the Central Administration of Pharmaceutical Products **during the last valid year of the registration notification, otherwise the product registration shall be cancelled**. In the case of exceeding the specified period, the submitted applications shall be examined on a case-by-case basis by virtue of a comprehensive report as per the procedures contained in the Regulatory Guide of this decree and shall be presented to the President of the Authority for taking appropriate decision(s) that he deems conducive to the common good.

(Article 3)

The product shall obtain an approval to pursue the procedures of re-registration within a four-year grace period at most to fulfill the requirements of obtaining the final re-registration notification. The grace period shall start from the expiry date of the **registration notification**. During this period, import, production and marketing shall be permitted in accordance with the regulating rules unless a derogating regulation or decision is issued. **In the event of exceeding this grace period**, each case shall be presented separately by virtue of a comprehensive report to be submitted to the President of the Authority for appropriate decision(s) that he deems conducive to the common good, as per the procedures contained in the Regulatory Guide of this decree.

(Article 4)

During the specified period, the company shall submit the final re-registration file complete with all requirements, approvals, and all attachments. The company shall also fulfill the technical studies necessary for the re-registration for all cases. All these actions shall be in accordance with the procedures and rules contained in the Regulatory Guide of this decree.

(Article 5)

After the final re-registration file is duly completed, it shall be presented to the Technical Committee for Drug Control within ninety days. In the case of approval, re-registration is licensed for another ten years starting from the approval date 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 date of issuing the decision, provided that the petition shall offer all the technical justifications and it shall be supported by the documents and information that the company is desirous to rely on when its petition is being considered. The petition shall be adjudicated within 60 working days from the date of its submission.

(Article 6)

The Chairperson of the Central Administration of Pharmaceutical Products shall issue the Regulatory Guide within ten working days, provided that the said Guide shall include the executive mechanisms that include all the rules and procedures necessary for the implementation and application of this decree. These mechanisms shall indicate all requirements, approvals, technical studies and attachments necessary for the re-registration as well as cases of exempting products from resubmission and evaluation after they are approved by the competent central administrations within their respective mandates, as per the ratified technical rules that are updated at the time of their approval. The issuer of the Regulatory Guide shall also take into account its updating whenever required by work need and in accordance with the new laws and regulatory rules.

(Article 7)

The grace periods, which are required for fulfilling the requirements, approvals, technical studies and attachments necessary for re-registering the products submitted for this purpose prior to the enforcement of this decree these periods in conformity with the applicable rules and resolutions as follows, shall be determined, provided that importation, manufacturing and circulation shall be permitted during these periods in conformity with the applicable rules and resolutions as follows:

- Re-registration in accordance with the Ministerial Resolution No. (425) of 2015: a period of (4) years from the expiry date of the registration notification, proceeding approval, scientific committee approval, or technical committee approval, whichever is the later.
- Re-registration in accordance with the Ministerial Resolution No. (296) of 2009: a period of (4) years from the date of enforcing this resolution.
- Re-registration in accordance with the decision of the Sub-Committee and Ministerial Resolutions No. (645) of 2012 and No. (370) of 2006: a period of two years from the date of enforcing this resolution.

In the event of exceeding this period, a detailed report shall be presented to the President of the Authority for taking appropriate decision(s) that he deems conducive to the common good with regard to the product. In the event that any of the active ingredients has undergone a change, be in quantity or in quality that conforms to reference products agrees with scientific references or implements scientific committees' recommendations, all the procedures prescribed for registration as a new product shall be taken while keeping its place in the similars box. The circulation of the product shall be permitted after being presented to the Technical Committee for Drug Control until fulfilling the registration procedures with the new composition in accordance with the rules.

It is imperative that the requirement of quality file evaluation shall be applied to all products that will have not submitted the final re-registration file before 1/1/2026.

(Article 8)

The President of the Authority shall have the right to suspend or cancel the re-registration procedures of any human medical product whose circulation may cause harm to public health on the basis of a technical memorandum supported by scientific evidence and market studies for each product individually.

(Article 9)

In the cases of emergency circumstances, any product may be circulated, with the exception of some conditions required for re-registration contained in this decree, on the basis of a detailed technical memorandum supported by scientific evidence and market studies prepared by the Central Administration of Pharmaceutical Products and approved by the president of the Authority.

(Article 10)

This DECREE shall be published in Al-Waqa'i' Al-Misriyya 'Egyptian Chronicles', the Supplement of the Official Gazette' and shall enter into force as of the day following its publication the issuance date of the regulatory guide therein. Any other provision that may contradict this DECREE shall be null and void.

President of
Egyptian Drug Authority
Prof /Tamer Mohamed Essam

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