Guideline on Procedures For Renewing Technical licenses of Operations for Medical Products and Medical Devices Factories Year 2026

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1. Introduction:

In light of the development of working methods and methodologies at the Egyptian Drug Authority, in accordance with the latest scientific and international references, particularly given that the Authority has obtained WHO accreditation at Maturity Level 3, and the Authority aims to achieve Maturity Level 4—one of whose requirements is establishing a validity period for manufacturing licenses—this guide sets out the procedures and controls to be followed by the General Administration of factories Licensing, which is responsible for issuing renewals of Technical licenses of Operations for Medical Products and Medical Devices Factories, after verifying compliance with Good Manufacturing Practice (GMP) requirements for factory licensing (Medical products including human and veterinary Medicals, biological and herbal products, active Medical ingredients, radioMedicals, cosmetics, medical devices, and laboratory reagents).

2. Scope :

The General Administration of factories Licensing, where application begins from receipt of a request for renewal of Technical licenses of Operations for Medical Products and Medical Devices Factories, up to the receipt of the Technical license of Operation with the license validity period included.

3.Definitions :

- **Medical Products:** Any product or preparation containing any substance or combination of substances used for the treatment, prevention, or diagnosis of disease in humans or animals, or described as having another medical effect, or intended to restore, correct, or modify physiological functions by exerting a pharmacological, immunological, or metabolic action on public health, in accordance with applicable references and standards, as well as any preparations or substances that may be introduced in light of scientific developments and/or international standards and references.

- **Biological Products:** Preparations containing one or more active substances produced or extracted from a biological source, including, for example: human vaccines, sera, blood and plasma products and derivatives, as well as products manufactured using biotechnology and the like, as well as any preparations or substances that may be introduced in light of scientific developments or international standards and references.

- **Raw Materials:** Active or inactive substances used in the manufacture of medical products and medical devices, excluding materials used in packaging and labeling.

- **Cosmetics:** Preparations intended for use on the external parts of the human body or the

lining of the oral cavity for the purposes of cleaning, perfuming, protecting, keeping in good condition, or changing and improving appearance, or any other preparations that exist or are introduced and classified as cosmetics in accordance with international references, such as products containing one or more substances intended for use on the external parts of the human body (skin, hair, nails, lips, face, and external parts of the genital organs) or teeth and the lining of the oral cavity for the purposes of cleaning, perfuming, protecting, keeping in good condition, changing and improving appearance, or changing and improving breath odor. The guidelines of the European Cosmetics Association (COLIPA) and the European Cosmetic Regulation (EEC 1223/2009) and its amendments concerning cosmetics shall serve as the reference for evaluating these products.

- **Medical Devices:** An instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
    - Diagnosis, prevention, monitoring, treatment, or alleviation of disease.
    - Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury.
    - Investigation, replacement, modification, or support of the anatomy or of a physiological process.
    - Supporting or sustaining life.
    - Control of conception.
    - Disinfection of medical devices.
    - Providing information for medical purposes by in vitro examination of specimens derived from the human body.
    - Provided that the intended primary purpose is not achieved through pharmacological, immunological, or metabolic means in or on the human body, but may be assisted in its intended function by such means.
- **Good Manufacturing Practices (G.M.P.):** The steps to be followed to ensure a final product conforming to the required specifications.
- **RadioMedicals/Nuclides:** Inorganic compounds, organic compounds, peptides, proteins, monoclonal antibodies, fragments, and oligonucleotides labeled with radionuclides, having a half-life ranging from a few seconds to several days.
- **Factory Layout :** A schematic drawing showing all production and non-production areas within the factory, also illustrating the flow path of personnel (workers), the path of raw

materials and finished products, pressure differentials between different production areas, and the air classification of various areas.

- **Production Machinery:** Equipment used in the various stages of manufacturing medical products and medical devices.
- **Renewal of the Technical licenses of Operations for Medical Products and Medical Devices Factories:** The issuance of the Technical licenses of Operations for Medical Products and Medical Devices Factories by the General Administration of factories Licensing after the expiration of the technical license of operation validity period, which is set at seven years from the date of issuance of the last issued technical license of operation to the factory.

4. Main Topic:

Steps for Renewing the Technical licenses of Operations for Medical Products and Medical Devices Factories

1. The legal representative of the factory or their agent submits a request for renewal of the Technical licenses of Operations to the General Administration of factories Licensing not less than 6 months before the license expiry, using the designated form, along with the following documents:
    - A valid copy of the national ID card (original for review). (In case of change of the authorized person in the manufacturing license)
    - A valid criminal record certificate addressed to the Egyptian Drug Authority. (In case of change of the authorized person in the manufacturing license)
    - Two paper copies and one electronic copy of the factory's Layout, reflecting the actual layout, approved by the factory's engineering department.
    - A copy of the most recent commercial register issued to the company owning the factory (original for review).
    - A copy of the most recent tax card issued to the company owning the factory — Taxpayer Data Certificate (original for review).
    - A paper copy of a statement of tanks and machinery in the factory, approved by the factory manager, and

an additional electronic copy on the designated form.

- An undertaking that there are no modifications to the data of the manufacturing license to be renewed.

2. The General Administration of factories Licensing examines the documents submitted by the factory.

3. The General Administration of factories Licensing contacts the General Administration of factories Inspection at the Central Administration for Inspection of Medical Institutions to obtain a copy of the factory's GMP certificate, which must be valid during the month of the technical license of operation renewal. This certificate must be fulfilled within a maximum of 5 working days.

4. The General Administration of factories Licensing notifies the factory of the examination result or any additional required documents, within five working days following receipt of the factory's GMP certificate.

5. Once all documents are fulfilled, the renewed technical license of operation is issued by the General Administration of factories Licensing.

Note regarding previously licensed Medical products and medical devices factories:
Factories for oharmaceutical products and medical devices that were previously licensed by the Egyptian Drug Authority must regularize their status within a maximum of two years from the date of issuance of this regulatory guide, in order to apply to the General Administration of factories Licensing for the issuance of the technical license of operation with a specified validity period.

5. References:

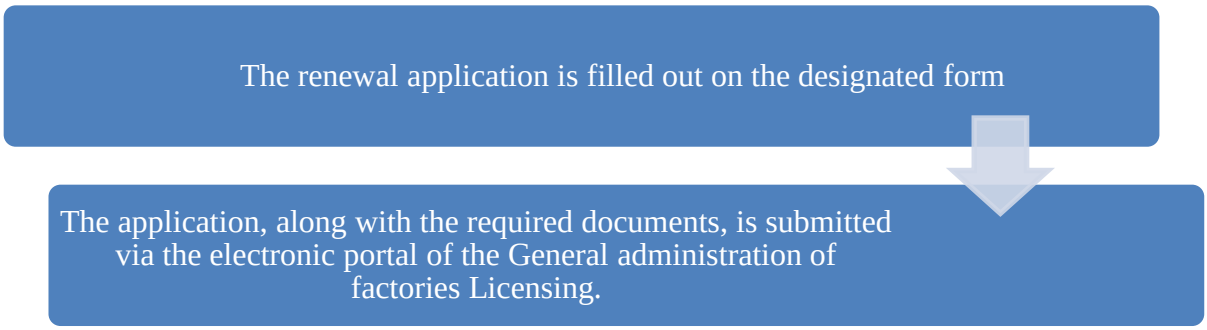
- Law No. 127 of 1955 on the Practice of the Pharmacy Profession.
- The Egyptian Drug Authority Law issued by Law No. 151 of 2019.
- Law on Procedures for Facilitating the Granting of Licenses for Industrial Establishments issued by Law No. 15 of 2017.
- The Regulatory Guide on Procedures for Registration of Managers of Medical Products and Medical Devices Factories.
- Licensing Requirements for Cosmetics Factories in accordance with ISO 22716.
- Licensing Requirements for Medical Devices Factories.

- Licensing Requirements for Medical Factories in accordance with World Health Organization requirements.
- Licensing Requirements for Disinfectant Factories.

6. Annexes :

Steps for renewing the Technical Licenses Of Operations for Medical Products and medical Devices factories:

1- The factory submits an application to renew the technical license of operation to the General Administration of Factories Licensing at least 6 months before the technical license of operation expires



2-General Administration Of Factories Licensing Procedures