Regulatory Guidelines of Decree No. 505 of 2021 issued by the Chairman of the Egyptian Drug Authority regarding the licensing requirements for registering companies in the Register of Toll Manufacturers 2023

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Guideline Contents

Chapter One

Requirements for Registering Companies in the Register of Toll Manufacturers, and Requirements for Updating the Registration

First: Requirements for Registering Companies in the Register of Toll manufacturers

(1) The licensee must be authorized to manage and sign on behalf of the company, and must be a member of the Federation of Medical Professions Syndicates (even if not a partner in the company).

(2) The company's main headquarters must be separate and located only within cities and centers.

The licensee is also permitted to combine Toll Manufacturing activities, and import activity (importers' register) for the same company in one administrative office.

(3) The company must have a full-time pharmacist manager registered with the Pharmacists Syndicate. Companies operating solely in the activity of registering and manufacturing veterinary medicines are permitted to have a veterinarian as their technical manager. A full-time pharmacist manager must be appointed if the activity of registering and manufacturing human medicines is added, and the company is obligated to notify the Central Administration of operation of any changes in the technical manager's data.

(4) The company must be a member of the Pharmaceuticals Division of the General Federation of Egyptian Chambers of Commerce and submit a certificate of membership from the pharmaceutical division in the Federation of Chambers of Commerce

(5) The company is obligated to create its own electronic company profile with the Digital Transformation Unit of the Authority after registering in the Register of Toll Manufacturing Companies.

(6) The company must identify the pharmaceutical factories licensed by the Egyptian Drug Authority with which it will manufacture, and submit the relevant contracts. The company is not bound by a specific timeframe to submit any manufacturing contracts concluded after the date of the Regulatory Guide, Second Edition (24/02/2022), provided that the contract is valid.

(7) Companies registered in the Register of Toll Manufacturers before the implementation of the Registration Rules for Toll Manufacturing issued on 31/12/2018, and whose registration has been in effect for ten calendar years, must submit a request to update the validity period of their registration in the aforementioned register by 01/01/2024. The license holder will retain their status without modification.

(8) For companies registered in the Register of Toll Manufacturing Companies before the implementation of the rules for registration in the Register of Toll Manufacturing Companies (issued on 31-12-2018) and whose registration has not yet reached ten calendar years, an application must be submitted to update the validity period of its registration in the aforementioned register within the tenth year from the date of its registration. The company will be notified that it has been granted a grace period of 6 months from the date of notification to rectify its situation. The company may be granted an additional 6 month period provided that it submits a reasoned request to the competent department in the Central Operations Administration and pays the prescribed service fee. The company's registration will be cancelled after taking the necessary steps, following the failure to complete the validity update procedures.

(9) Companies applying for a new registration for toll Manufacturing must complete the submition of the required documents within one calendar year from the date of application to the Department. If this period expires, the application and its attachments will be archived, and the company must submit a new application and pay a new service fee.
(10) Companies applying to update their registration or appoint a new manager within the specified deadlines must submit the required documents within 6 months from the date of application to the Department. If the 6 months pass without the required documents being submitted, the registration will be cancelled pursuant to the rules and procedures.

- A company's registration in the Register of Toll Manufacturing Companies will be cancelled if the provisions of clauses (7, 8, and 10) are violated.
- A period of 6 months from the date of issuance of the Regulatory Guide - Third Edition is granted to all companies that applied to update their registration or appoint a manager before the issuance of the third edition. This period allows them to submit the required documents for the updated registration to avoid having their application archived and the resulting cancellation of their registration pursuant to the rules and procedures

Second: Requirements for Updating Registeration Data (Making any Change or Amendment to the Registration Data) or Updating the Registration validity Period for Companies in the Register of Toll Manufacturers

(1) Registration data is updated when any change or amendment is made to the company's registration data, such as adding (deleting) a single contract or contract addendum, renewing a single contract, or adding a product registration notification.
(2) The registration validity period is updated once every ten calendar years, starting from the date of registration in the register. The company must submit a request to update the registration validity period within the last three months of the specified registration period, provided that all items except item 1 in First: Requirements for Registering Companies in the Register of Toll Manufacturers are met.
(3) Updating the registration period in the Register of Toll Manufacturers requires a minimum of one registered product notification or the production of one trial batch within the product registration procedures. Proof of the company's commitment to producing the trial batch (import approval for the raw material) is also allowed.

Third: Requirements for the storage of Registered Products

(1) The company must provide a dedicated storage facility that meets all applicable technical and health requirements. The minimum area of this facility is 100 square meters. This facility may not be used for products other than those of the company and the companies listed in item (2) below.

(2) Toll Manufacturing companies that have their own warehouses are permitted to enter into storage contracts with other toll Manufacturing companies that do not have their own warehouses. The number of contracts may not exceed two companies, with three companies per 100 square meters. If the area increases, the number of companies may increase accordingly.

(3) Toll Manufacturing companies may enter into contracts with warehouses licensed by the Egyptian Drug Authority, provided that the warehouse meets the requirements for good storage practices. The number of companies contracted with a licensed warehouse may not exceed three per 100 square meters, and this number increases as the area increases accordingly.

(4) The company may contract with or license two warehouses, provided they are added to the toll card. An increase to this number is permitted upon a request submitted to the Central Administration of Operations to determine the company's need based on its production volume and scope of activity.

(5) The storage contract must be added to the Toll manufacturing register upon production of the first batch.

Chapter Two

Regarding Products of Toll Manufacturing Companies, and Inspection

First: Products of Toll Manufacturing Companies

The number of products registered and under registration for each company shall be twenty active ingredients for human products and twenty active ingredients for veterinary products, with no limit on the number for herbal medicines. Products registered or submitted for registration for export or tender purposes shall not be counted in this number.

Second: Inspection of Toll Manufacturing Companies

(1) The company shall maintain at its headquarters a permanent or secure electronic record (capable of tracking amendments), which includes data on its products, batch numbers and sizes, and their manufacturing location throughout the registration period of those products.

(2) The transfer of raw materials is prohibited in the event of a change of manufacturing location or the addition of a new manufacturing location, except with the approval of the Central Administration of Operations of the Egyptian Drug Authority.

(3) The Egyptian Drug Authority is the supervisory authority over Toll Manufacturing Companies to verify the implementation of the provisions of this Decree. It has the authority to conduct technical inspections of companies and their warehouses, as well as their records and books, to verify the application of the provisions contained in the laws and Decrees, in accordance with the rules stipulated in the Pharmacy Practice Law, the Law Establishing the Egyptian Drug Authority, and the Decrees implementing them

The contracted manufacturer bears responsibility for the product during its production stages, and the product's owner bears responsibility for its registered products throughout all stages of their distribution in the market.

(4) When applying to manufacture a trial batch, Toll Manufacturing companies are obligated to submit a statement signed by the chairman of the board of directors of the manufacturing plant approving the storage of the trial batch in the plant's warehouses until its destruction, that is in the case of the absence of a licensed warehouse belonging to the company or a storage contract with a warehouse licensed by the Egyptian Drug Authority on the toll card.

(5) If the company produces production batches without a licensed warehouse added to the toll card of the toll Manufacturing company, the entire batch will be seized until the situation is rectified and the warehouse is added

Chapter Three

Cases of Registration Suspension and Cancellation

First: Definitions

1- Suspension of Company Registration:

No dealings with the relevant departments of the Egyptian Drug Authority during the suspension period, except products currently in circulation and valid. In the event of company registration suspension, dealings with the company will cease, and no files or requirements related to the company will be accepted by the General Administration of Importers' Register Licenses and Toll Manufacturers, as well as by the Pharmaceutical Systems and Information Department at the Central Department of Pharmaceutical Policies and Market Support, until the situation is rectified and the suspension is lifted.

2- Cancellation of Company Registration:

The company's registration will be cancelled while retaining valid product registration notifications. The products ownership will be transferred to one of the companies operating in the market pursuant to the applicable rules. If the company rectifies its situation, it may reapply for registration while retaining valid product registration notifications.

Second: Cases of Suspension of Registration for Companies in the Register of Toll Manufacturers

The company's registration in the Register of Toll Manufacturing Companies will be suspended for a period of six months:

A- If the company does not submit the documents for registering its pharmacy manager or the documents for registering the pharmacy manager of its warehouse within three months of the termination of the previous pharmacy manager's service, by means of a sealed and signed clearance letter from the company addressed to the Egyptian Drug Authority, or if the previous pharmacy manager submits their clearance letter by means of a company receipt acknowledgment via registered mail with return receipt, confirming the termination of their service.

B- When any update to registration data occurs (amendments or changes regarding product registration notifications) without submitting the application to the General Administration of Importers' Register Licenses and Toll Manufacturers within 3 months of the date of the amendment.

Note: If companies wish to lift the suspension, the service fee must be paid along with the submission of the corrective plan and a request to lift the suspension before the end of the period.

The suspension ends upon full implementation of the corrective plan for the violation

Third: Cases of Cancellation of Registration for Companies in the Register of Toll Manufacturers:

(1) Change or amendment to its commercial register and failure to notify the Central Administration of Operations, within eighteen months from the date of the change or amendment, as applicable, regarding the following information:

* Company Name.
* License Holder.
* Company Activity.
* Company Address.

(2) If the company obtains a license for its own pharmaceutical factory from the Egyptian Drug Authority.

(3) If the period stipulated in the case of failure to appoint a pharmaceutical manager for the company or its warehouse has elapsed, the company's registration will be cancelled after taking the necessary measures, including a suspension for a period of six months, followed by a second warning for another suspension period of six months, to rectify the situation.

(4) If the company fails to submit a minimum of one registered product, or products under registration with trial batches, or proof of the company's commitment in producing the trial batch (import approval for the raw material), when updating its registration validity period in the Register of Toll Manufacturers before the notified period for updating the registration expires.

(5) A new grace period, not exceeding one calendar year, may be granted from the date of expiry of the first grace period, based on a reasoned request submitted by the company to the competent department in the Central Administration of Operations.