Central Administration Of Pharmaceutical Institutions Licensing
General Administration Of Factories Licensing

Regulatory Guideline for the Procedures of Registering Managers of Pharmaceutical and Medical Supplies Factories with the General Administration of Factories Licensing

Code: EDREX:GL.CALI. 005

Version No: 2/0

Issue Date: 12 / 2025

Effective date: 12/ 2025

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1- Introduction

• The General Administration of Factories Licensing is the authority responsible for issuing the Technical License of Operation for the operation of pharmaceutical and medical supplies factories, after ensuring compliance with Good Manufacturing and Storage Practices. It is responsible for establishing the system and technical operating instructions for pharmaceutical and medical supplies factories, including:

- Registration of the Data of a Manager(Factory - Production - Quality Control) under Technical License of Operation for a Pharmaceutical Factory (Human Medicines, Veterinary, Biological, Herbal, Raw Materials, Plasma Derivatives – Disinfectants).
- Registration of the Factory Manager's Data under the Technical License of Operation for a Cosmetics factory.
- Registration of the Data of a Manager (Production -Quality Control)under the Technical License of Operation for a disinfectant production line in a cosmetics or medical supplies factory.
- Registration of the Factory Manager's Data under the Technical License of Operation for a medical supplies factory.
- Registration of the Factory Manager's Data under the Technical License of Operation for a In vitro diagnostics Factory.
- Registration of the Quality Control Manager's Data under the Technical License of Operation for In Vitro diagnostics Factory.
- Proof of departure of a Manager (Factory - Production - Quality Control) for a Pharmaceutical Factory (Human Medicines, Veterinary, Biological, Herbal, Raw Materials, Plasma Derivatives – Disinfectants).
- Departure of the Manager for each of the following:
    - Pharmaceutical Factory
    - Cosmetics factory
      -(Production - Quality Control) for a Disinfectant Production Line in a Cosmetics or Medical Supplies Factory
      - Medical Supplies Factory
      -(Factory - Quality Control) for In vitro diagnostics Factory

2- Scope

The **General Administration of Factories Licensing** , where the application begins:

- From receiving the application for registration of a Manager (Factory - Production - Quality Control) for a Pharmaceutical Factory (Human Medicines, Veterinary, Biological, Herbal, Raw Materials, Plasma Derivatives – Disinfectants) until the issuance and handing over the Technical License of Operation including the names of the managers.

- From receiving the application for the registration of the Factory Manager for a

Cosmetics factory until the issuance and handing over the Technical License of Operation including the name of the manager.

- From receiving the application for the registration of a Manager (Production -Quality Control) for a Disinfectant Production Line in a Cosmetic Products or Medical Supplies Factory until the issuance and handing over the Technical License of Operation including the names of the managers.
- From receiving the application for the registration of the Factory Manager for a Medical Supplies Factory until the issuance and delivery of the Technical License of Operation including the name of the manager.
- From receiving the application for the registration of the Factory Manager for a In vitro diagnostics Factory until the issuance and delivery of the Technical License of Operation including the name of the manager.
- From receiving the application for the registration of the Quality Control Manager for In Vitro diagnostics Factory until the issuance and delivery of the Technical License of Operation including the name of the manager.
- From receiving the Clearance certificate application of a Manager(Factory - Production - Quality Control) for a Pharmaceutical Factory (Human Medicines, Veterinary, Biological, Herbal, Raw Materials, Plasma Derivatives – Disinfectants) until the registration of a new manager and his inclusion in the Technical License of Operation for the factory.
- From receiving the Clearance certificate application of:
- The Manager of the Pharmaceutical Factory
- The Manager of the Cosmetics factory
- Manager (Production - Quality Control) for the Disinfectant Production Line in a Cosmetic Products or Medical Supplies Factory
- The Manager of the Medical Supplies Factory
- Manager (Factory - Quality Control) for the In vitro diagnostics Factory

  All the above applies until the registration of a new manager and its inclusion in the Technical License of Operation for the factory.

3- Definitions

- **Manager of a Pharmaceutical Factory** (Human Medicines, Veterinary, Biological, Herbal, Raw Materials, Plasma Derivatives, Disinfectants): A pharmacist who is the head of the factory with at least fifteen years of scientific and practical experience in a pharmaceutical manufacturing field .
- **Production Manager of the Pharmaceutical Factory** (Human Medicines, Veterinary, Biological, Herbal, Raw Materials, Plasma Derivatives, Disinfectants): A pharmacist with at least ten years of scientific and technical experience in his field.
- **Quality Control Manager of Pharmaceutical Factory** (Human Medicines, Veterinary, Biological, Herbal, Raw Materials, Plasma Derivatives, Disinfectants): A pharmacist with at

least ten years of scientific and technical experience in his field.

• **Manager of a Cosmetics factory**: The person in charge who heads a Cosmetics factory and possesses relevant scientific and practical experience in the field, provided that he/she:
-Holds a university academic degree;
- Holds postgraduate studies or specialized training certificates in a relevant field or Possesses appropriate practical experience in the field of cosmetics manufacturing in case that postgraduate studies or training certificates are not obtained. The Factory Manager shall be responsible for the employees of the establishment with regard to the implementation of the provisions of the Pharmacy Practice Law, the Egyptian Drug Authority Law, their executive regulations, and all decisions issued in implementation thereof, as well as the applicable regulatory guidelines and rules. The Factory Manager shall also be responsible for ensuring the quality, safety, and suitability for use of the manufactured products.

• **Production Manager of a Disinfectants Production Line at a Cosmetics factory, Medical Supplies Factory , or In vitro diagnostics Factory :** is the person who possesses experience in the field of manufacturing Pharmaceuticals , in accordance with the regulatory decisions governing the licensing of disinfectants manufacturing factorys/production lines and the procedures of their registration.

• **Quality Control Manager of a Disinfectants Production Line at a Cosmetics factory, Medical Supplies Factory, or Laboratory and Dignostic Reagents Factory :** is the person who possesses experience in the field of quality control of Pharmaceuticals , in accordance with the regulatory decisions governing the licensing of disinfectants manufacturing factorys/production lines and the procedures for their registration.

• **Medical Supplies Factory Manager**: is the responsible person who heads a Medical Supplies Factory and possesses a relevant scientific and practical experience in the field by obtaining a university academic qualification and any of the following:

1- Postgraduate studies or training certificates in a relevant field.

2- Appropriate practical experience in the field of medical supplies manufacturing.

And shall be responsible for compliance with all applicable laws of the Arab Republic of Egypt in force, in particular the laws regulating the competencies and functions of the Egyptian Drug Authority, in accordance with its Law of Establishment issued under Law No. **(**151) of the year 2019 and its Executive Regulations. He / She shall also be responsible for the personnel working at the factory with regard to the implementation of the provisions of the Egyptian Drug Authority Law, its Executive Regulations, and the decisions issued in implementation thereof, as well as the applicable regulatory guidelines, regulatory rules, and their relevant amendments

related to medical devices, medical supplies,

And laboratory reagents, as well as the quality rules related to the activities of the factory, and shall be responsible for the safety, quality, and suitability for use of the manufactured medical supplies.

• **In vitro diagnostics Factory Manager**: is the responsible person who heads a In vitro diagnostics manufacturing factory and possesses relevant scientific and practical experience in the field by obtaining a university academic qualification and any of the following:

1- Postgraduate studies or training certificates in the relevant field.
2- Appropriate practical experience in the field of manufacturing laboratory and In Vitro diagnostics

And shall be responsible for compliance with all applicable laws of the Arab Republic of Egypt in force, in particular the laws regulating the competencies and functions of the Egyptian Drug Authority, in accordance with its Law of Establishment issued under Law No. (151) of the year 2019 and its Executive Regulations. He / She shall also be responsible for the personnel working at the factory with regard to the implementation of the provisions of the Egyptian Drug Authority Law, its Executive Regulations, and the decisions issued in implementation thereof, as well as the applicable regulatory guidelines, regulatory rules, and their relevant amendments related to medical devices, medical supplies, and laboratory reagents, as well as the quality rules related to the activities of the factory, and shall be responsible for the safety, quality, and suitability for use of the manufactured medical supplies.

• **Quality Control Manager at a Laboratory and** In Vitro diagnostics **Factory :** is a person who possesses the required practical, scientific, and technical experience in the relevant fields, in terms of academic qualification, in accordance with the regulatory decisions governing the rules for the registration and circulation of laboratory and In Vitro diagnostics, as follows: Academic qualification: (Science / Pharmacy / Veterinary Medicine / Human Medicine), in addition to five (5) years of experience in the same field.

4- Procedures

4-1 - Procedure for Registering the Data of the Manager (Factory – Production – Quality Control) of a Pharmaceutical Factory (Human Drugs, Veterinary, Biological, Herbal, Raw Materials, Plasma Derivatives-Disinfectants) on the Factory's Technical License of Operation .

1- Documents to be Submitted by the Factory for the Registration of the Manager (Factory – Production – Quality Control):

A- A request on the prescribed form for registering or changing the name of the Manager (Factory – Production – Quality Control), signed and stamped by the Chairman of the Board or by the authorization holder to sign according to the Commercial Register.

B- The original certificate of the pharmacist's Official assignment status, issued by the General Administration of Certificates and Licensing Follow-up, for the Manager (Factory – Production – Quality Control).

C- A Delegation document for the company's representative to deal with the Egyptian Drug Authority, Central Administration of Pharmaceutical Institutions licensing , General Administration of Factories Licensing, to receive and submit all documents related to the company. The Delegation document must be certified for signature authenticity by a bank of a authorization holder to sign.

2- All required documents shall be submitted via the electronic window of the General Administration of Factories Licensing , provided that the original documents are submitted upon receiving the Technical License of Operation

3- The Technical License of Operation shall be issued with the name of the Manager clearly indicated

Note:

1- The Manager of a Plasma Derivatives Manufacturing factory may be a non-pharmacist, provided that he/she is a medical doctor.

2- The Manager of a Plasma Derivatives Manufacturing Factory may be of **foreign nationality, provided that the following documents are submitted**

- **Curriculum Vitae**, including:
  - Original Degree certificates (University – Postgraduate, if any) , authenticated by the Ministry of Foreign Affairs of the issuing country and certified by the relevant Egyptian Embassy/Consulate.
  - Original training and scientific experience certificates, stamped by the issuing authority, authenticated by the relevant Chamber of Commerce, and certified by the relevant Egyptian Embassy/Consulate.

	- Certified copy of the foreign national's work permit, issued by the Licensing Administration for Foreigners at the **Ministry of Manpower Egypt** or by the Foreign Work Licensing Office at the competent Directorates of Manpower under the Ministry of Manpower Egypt.

4-2- Procedure for Registering the Data of the Cosmetics Manufacturing Factory Manager to the Technical License of Operation of the Facility:

1- Documents to be submitted by the factory for the registration of the Cosmetics Manufacturing Factory Manager:

A- A request on the prescribed form for registering/changing the Factory Manager, signed and certified by a bank signature authenticity, by the Chairman of the Board or by the authorization holder to sign according to the Commercial Register, and stamped by the facility's seal.

B- Documents related to the Manager:

- **In case of an Egyptian national Manager:**
  - Curriculum Vitae, including:
    - Degree certificates (University – Postgraduate, if any)
    - Training certificates and practical experience certificate
  - Copy of the National ID Card
  - In the case of a pharmacist Manager, a Manager Registration Certificate shall be submitted, issued by the Certificates and Licensing Follow-up Administration at the Central Administration of Pharmaceutical Institutions licensing , Egyptian Drug Authority.
- **In the case of a foreign national Manager:**
  1- **Curriculum Vitae**, including:
     Original Degree certificates (University – Postgraduate, if any) , authenticated by the Ministry of Foreign Affairs of the issuing country and certified by the relevant Egyptian Embassy/Consulate.
  2- **Original training and scientific experience certificates, stamped by the issuing authority, authenticated by the relevant Chamber of Commerce, and certified by the relevant Egyptian Embassy/Consulate.**

3 - **Certified copy of the foreign national's work permit, issued by the Licensing Administration for Foreigners at the Ministry of Manpower Egypt or by the Foreign Work Licensing Office at the competent Directorates of Manpower under the Ministry of Manpower, in accordance with the provisions of the Investment Law No. (72) of 2017, and the decision issued by the Ministry of Manpower.**

All documents shall be submitted in Arabic or accompanied by a certified translation from the original language into Arabic, pursuant to the provisions of Article (2) of the Egyptian Constitution issued on 18/01/2014 and Article (1) of Law No. (115) of 1958 regarding the mandatory use of the Arabic language in correspondence and signage within the territory of the Arab Republic of Egypt.

C - Declaration by the responsible Manager on the prescribed form , to be completed in the presence of an inspector from the General Administration for Factories Licensing.
D - A Delegation document for the company's representative to deal with the Egyptian Drug Authority, Central Administration of Pharmaceutical Institutions licensing , General Administration of Factories Licensing, and to receive and submit all documents related to the company. The Delegation document must be certified by a signature authenticity by a bank of a authorization holder to sign.
2- The legal representative of the facility shall submit a request for the issuance of the Technical Operating License, including the newly appointed Manager, accompanied by all the required documents via the electronic portal of the General Administration for Factories Licensing, provided that the original documents are submitted upon receiving of the Technical License of Operation
3- The new Technical License of Operation shall be issued with the Manager's name clearly indicated.

4-3 Procedure for Registering the Data of a Manager (Production - Quality Control) for a Disinfectants Production Line at a Cosmetics Manufacturing Factory or Medical Supplies Factory on the Technical License of Operation of the Facility .

In the case of licensing a disinfectants production line at a Pharmaceutical factory (human medicines, veterinary, biological, herbal, raw materials, plasma derivatives)	It is sufficient to register the Managers of the Pharmaceutical factory.
In the case of licensing a disinfectants production line at a cosmetics manufacturing factory, medical supplies factory, or In vitro diagnostics factory	• It is mandatory to register the Production and Quality Control Managers of the disinfectants line in accordance with the regulatory decisions governing the industry and quality control of Pharmaceutical .

1-<u>Documents to be submitted by the facility for registering the (Production Manager – Quality Control Manager):</u>

A- A request on the prescribed form for registering/changing the Factory Manager , certified by a signature authenticity by a bank & signed by the Chairman of the Board or by the authorization holder to sign according to the Commercial Register, and stamped with the facility's seal.

B- Curriculum Vitae of the responsible Manager to be registered, attached with the Manager's practical experience certificates, including the experience periods mentioned in the regulatory decisions, and a copy of the National ID.

-In case of a pharmacist Manager, a Manager Registration Certificate shall be submitted, issued by the Certificates and Licensing Follow-up administration at the Central Administration of Pharmaceutical Institutions licensing , Egyptian Drug Authority.

C - Declaration by the responsible Manager on the prescribed form , to be completed in the presence of an inspector from the General Administration for Factories Licensing.
D - A Delegation document for the company's representative to deal with the Egyptian Drug Authority, Central Administration of Pharmaceutical Institutions licensing , General Administration for Factories Licensing, to receive and submit all documents related to the factory. The Delegation document must be certified by a signature authenticity of a bank of the authorization holder

2- The factory shall submit a request for the issuance of the Technical License of Operation, including the newly appointed Manager, accompanied by all the required documents via the electronic portal of the General Administration for Factories Licensing, provided that the original documents are submitted upon receiving the Technical License of Operation
3- The new Technical License of Operation shall be issued with the Manager's name clearly.

4-4 Procedure for Registering the Data of a Medical Supplies Manufacturing Factory Manager on the Technical License of Operationof the Facility:

1- Documents to be submitted by the factory for the registration of the Medical Supplies Manufacturing Factory Manager:

A-A request on the prescribed form for registering/changing the Factory Manager, certified by a signature authenticity of a bank & signed by the Chairman of the Board or by the authorization holder according to the Commercial Register, and

stamped with the facility's seal.

B- Documents related to the Manager:

- In the case of an Egyptian national Manager:

  - Curriculum Vitae, including:

  - Degree certificates (University – Postgraduate, if any)
  - Training certificates and practical experience certificates
  - Copy of the National ID Card
  - In the case of a pharmacist Manager, a Manager Registration Certificate shall be submitted, issued by the Certificates and Licensing Follow-up Administration at the Central Administration of Pharmaceutical Institutions licensing , Egyptian Drug Authority.

- In the case of a foreign national Manager:

1- Curriculum Vitae, including:

1-Original Degree certificates (University – Postgraduate, if any) , authenticated by the Ministry of Foreign Affairs of the issuing country and certified by the relevant Egyptian Embassy/Consulate.

2- Original training and scientific experience certificates, stamped by the issuing authority, authenticated by the relevant Chamber of Commerce, and certified by the relevant Egyptian Embassy/Consulate.

3 - Certified copy of the foreign national's work permit, issued by the Licensing Administration for Foreigners at the Ministry of Manpower Egypt or by the Foreign Work Licensing Office at the competent Directorates of Manpower under the Ministry of Manpower, in accordance with the provisions of the Investment Law No. (72) of 2017, and the decision issued by the Ministry of Manpower.

<All documents shall be submitted in Arabic or accompanied by a certified translation from the original language into Arabic, pursuant to the provisions of Article (2) of the Egyptian Constitution issued on 18/01/2014 and Article (1) of Law No. (115) of 1958 regarding the mandatory use of the Arabic language in correspondence and signage within the territory of the Arab Republic of Egypt.

C - Declaration by the responsible Manager on the prescribed form , to be completed in the presence of an inspector from the General Administration for Factories Licensing.

D - A Delegation document for the company's representative to deal with the Egyptian Drug Authority, Central Administration of Pharmaceutical Institutions licensing , General Administration for Factories Licensing, to receive and submit all documents related to the factory. The Delegation document must be certified for signature authenticity by a bank of an authorization holder

2- The factory shall submit a request for the issuance of the Technical License of Operation, including the newly appointed Manager, accompanied by all the required documents via the electronic portal of the General Administration for Factories Licensing, provided that the original documents are submitted upon receiving of the Technical License of Operation
3- The new Technical License of Operation shall be issued with the Manager's name clearly

4-5 Procedure for registering the data of the manager of In vitro diagnostics factory on the factory's Technical License of Operation

1- Documents required to be submitted by the factory to register the factory manager:

A- An application on the prescribed form for registering / changing the factory manager, duly signed with a bank-certified signature by the Chairman of the Board of Directors or by the authorization holder to sign according to the commercial register, and stamped with the factory seal.

B- Documents related to the Manager:

- **In the case of an Egyptian national Manager:**
  - Curriculum Vitae, including:
    - Degree certificates (University – Postgraduate, if any)
    - Training certificates and practical experience certificates
  - Copy of the National ID Card
  - In the case of a pharmacist Manager, a Manager Registration Certificate shall be submitted, issued by the Certificates and Licensing Follow-up Administration at the Central Administration of Pharmaceutical Institutions licensing , Egyptian Drug Authority.
- **In the case of a foreign national Manager:**
  1- **Curriculum Vitae**, including:
     Original Degree certificates (University – Postgraduate, if any) , authenticated by the Ministry of Foreign Affairs of the issuing country and certified by the relevant Egyptian Embassy/Consulate.
  2- Original training and scientific experience certificates, stamped by the issuing authority, authenticated by the relevant Chamber of Commerce, and certified by the relevant Egyptian Embassy/Consulate.

  3 - Certified copy of the foreign national's work permit, issued by the Licensing Administration for Foreigners at the Ministry of Manpower Egyptor by the Foreign Work Licensing Office at the competent Directorates of Manpower under the Ministry of Manpower, in accordance with the provisions of the Investment Law No. (72) of 2017, and the decision issued by the Ministry of Manpower.

<All documents shall be submitted in Arabic or accompanied by a certified translation from the original language into Arabic, pursuant to the provisions of Article (2) of the Egyptian Constitution issued on 18/01/2014 and Article (1) of Law No. (115) of 1958 regarding the mandatory use of the Arabic language in correspondence and signage within the territory of the Arab Republic of Egypt.

C - Declaration by the responsible Manager on the prescribed form , to be completed in the presence of an inspector from the General Administration for Factories Licensing.
D - A Delegation document for the company's representative to deal with the Egyptian Drug Authority, Central Administration of Pharmaceutical Institutions licensing , General Administration for Factories Licensing, and to receive and submit all documents related to the company. The Delegation document must be certified for signature authenticity by a bank of a authorization holder to sign.
2- The factory shall submit a request for the issuance of the Technical Operating License, including the newly appointed Manager, accompanied by all the required documents via the electronic portal of the General Administration for Factories Licensing, provided that the original documents are submitted upon receipt of the Technical License of Operation
3- The new Technical License of Operations hall be issued with the Manager's name clearly indicated.

4-6 Procedure for registering the data of the Quality Control Manager of a In vitro diagnostics factory on the factory's Technical Operating License:

1- Documents required to be submitted by the factory to register the Quality Control Manager:

A- An application on the prescribed form for registering / changing the Quality Control Manager of In vitro diagnostics factory, provided that the application is d signed with a bank-certified signature by the Chairman of the Board of Directors or by the authorization holder t according to the commercial register, and stamped with the factory seal.

B- Documents related to the Quality Control Manager:

- **In the case of an Egyptian national Manager:**
  1-Curriculum Vitae (CV) including:

  2- University degree (Science / Pharmacy / Veterinary Medicine / Human Medicine) and certificates of professional experience (provided that a less than five years of experience in the same field is present), in accordance with the regulatory decisions regarding the rules for organizing the registration and circulation of laboratory and diagnosticss).
  -3Copies of the National ID card.

- **In the case of a foreign national Manager:**

1- **Curriculum Vitae**, including:

Original Degree certificates (University – Postgraduate, if any) , authenticated by the Ministry of Foreign Affairs of the issuing country certified by the relevant Egyptian Embassy/Consulate.

2- **Original training and scientific experience certificates, stamped by the issuing authority, authenticated by the relevant Chamber of Commerce, and certified by the relevant Egyptian Embassy/Consulate.**

3 - **Certified copy of the foreign national's work permit, issued by the Licensing Administration for Foreigners at the Ministry of Manpower Egypt or by the Foreign Work Licensing Office at the competent Directorates of Manpower under the Ministry of Manpower, in accordance with the provisions of the Investment Law No. (72) of 2017, and the decision issued by the Ministry of Manpower.**

<All documents shall be submitted in Arabic or accompanied by a certified translation from the original language into Arabic, pursuant to the provisions of Article (2) of the Egyptian Constitution issued on 18/01/2014 and Article (1) of Law No. (115) of 1958 regarding the mandatory use of the Arabic language in correspondence and signage within the territory of the Arab Republic of Egypt.

C - A Delegation document for the company's representative to deal with the Egyptian Drug Authority, Central Administration of Pharmaceutical Institutions licensing , General Administration of Factories Licensing to receive and submit all documents related to the company. The Delegation document must be certified by a signature authenticity of a bank of an authorization holder .

2- The factory shall submit a request for the issuance of the Technical License of Operation, including the newly appointed Quality Control Manager , accompanied by all the required documents via the electronic portal of the General Administration for Factories Licensing, provided that the original documents are submitted upon receiving the Technical License of Operation

3- The new Technical License of Operation shall be issued with the Quality Control Manager's name clearly indicated.

4-7 Procedure for the Clearance of a Manager (Factory - Production - Quality Control) for a Pharmaceutical Factory (Human Medicines, Veterinary, Biological, Herbal, Raw Materials, Plasma Derivatives – Disinfectants).

Without submission of documentation evidencing the registration of a new manager:

"This procedure shall be carried out through the General Administration of Factories Licensing – General Administration for Factories Inspection".

1- A clearance request must be submitted immediately upon leaving the factory, and no later than 48 hours (either by the manager personally or by the factory's legal representative), through the electronic portal of the General Administration of Factories Licensing or by direct submission at the counter of the General Administration for Factories Licensing

The General Administration of Factories Licensing shall notify the factory to take the following actions:

A- Immediately appoint a manager for the position of the departing manager as follows:

-In case of the Factory Manager leaving the position, the Production Manager registered on the Technical License of Operation shall perform the duties of the factory manager for a maximum of three calendar months; otherwise, the factory owner must administratively close the factory. If the factory is not closed, the Egyptian Drug Authority shall administratively close the factory.

- In case of the Production Manager or Quality Control Manager leaving the position, the Factory Manager registered on the Technical License of Operation shall perform the duties of the manager who left, for a maximum period of three (3) calendar months; otherwise, the Egyptian Drug Authority shall suspend the circulation of the products manufactured within the factory after the expiration of the specified period ,until the registration of the new manager is completed and included in the factory's Technical License of Operation

8-4 Procedure for the Clearance of a cosmetics factory manager – manager (production - quality control) of a disinfectant production line in a cosmetics or Pharmaceutical factory - manager of a Pharmaceutical factory - manager (factory - quality control) of a In vitro diagnostics factory without providing any evidence of registering a new manager :

"This procedure shall be carried out through the General Administration of Factories Licensing – General Administration for Factories Inspection".

2- A clearance request must be submitted immediately upon leaving the factory, no later than 48 hours (whether by the manager personally or by the legal representative of the factory) through the electronic portal of the General Administration for Factories Licensing, or by direct submission at the service counter of the General Administration for Factories Licensing.

The General Administration of Factories Licensing shall notify the factory to take the following actions:

-In case of the Clearance of the Factory Manager, the factory must notify the General Administration of Factories Licensing of the acting manager, and must appoint a new factory manager

- **Within a maximum period of three (3) calendar months** ; otherwise , the Egyptian Drug Authority shall suspend the circulation of the products manufactured within the factory after the expiration of the specified period , until the registration of the new manager is completed and included in the factory's Technical License of Operation
- **A second grace period of three (3) calendar months may be granted**; otherwise, the factory owner must administratively close the factory. If the owner fails to close the factory, the Egyptian Drug Authority will administratively close it.

1. **In case of the Clearance of the Production Manager or Quality Control Manager** for a disinfectant production line in a cosmetics or Pharmaceutical factory, or In Vitro diagnostics , the factory must appoint a new manager and register them with the General Administration of Factories Licensing **within a maximum period of three (3) calendar months**; otherwise , the Egyptian Drug Authority shall suspend the circulation of the products manufactured within the factory after the expiration of the specified period, until the registration of the new manager is completed and included in the factory's Technical License of Operation.

5- References

-Law No. 127 of 1955 concerning the practice of pharmacy.

-Chapter Two: Articles 10 to 29 , Article 54, Article 56 -Chapter Three: Articles 58–62- Chapter Five: Article 75.

-Law No. 15 of 2017 regarding the Facilitation of Licensing Procedures for Industrial institutions, and its Executive Regulations.

-Law No. 151 of 2019 concerning the Establishment of the Egyptian Drug Authority (EDA), and its Executive Regulations.

-Law No. 8 of 2021 regulating blood operations and plasma collection for the manufacture and export of its derivatives, and its Executive Regulations.

-Ministerial Decree No. 265 of 1981 regarding the requirements for pharmaceutical manufacturing facilities.

-Decision of the Chairman of the Egyptian Drug Authority No. 394 of 2021 regarding licenses for factories/production lines of disinfectant products and their registration procedures.

-Decision of the Chairman of the Egyptian Drug Authority No. 2 of 2021 concerning the rules for the registration and circulation of laboratory and diagnosticss.