Guide for Investor to Obtain a Pharmaceutical Manufacturer License

First edition 1440 AH

Disclaimer: The English version is a translation of the original in Arabic for information purposes only. In case of a discrepancy, the Arabic original will prevail.

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Chapter One

Introduction:

Article One of the Implementing Regulation of the pharmaceutical establishments and pharmaceutical products Law issued by Royal Decree No. M/31 on 1/6/1425 AH. pharmaceutical products manufacturers within the establishments that fall under the definition of (pharmaceutical establishment). Among the tasks of the pharmaceutical products manufacturers are exporting registered pharmaceutical products, and importing raw materials used in the manufacture of pharmaceutical products and the manufacture of pharmaceutical products.

Definition of Investor:

An individual or group of individuals (a company) that wants to invest and set up a manufacturer in an industrial or economic city in the field of manufacturing pharmaceutical and herbal products, whether it is Saudi, Gulf or foreign.

Chapter Two

Field and Applicability:

This guide applies to the investor who desire to obtain a license for a pharmaceutical products manufacturer, for the International Standard Industrial Classification Activities (ISIC) of All Economic under SFDA after meeting all documents and requirements of the concerned government bodies, that are as follows:

- Saudi Food and Drug Authority.
- Ministry of Commerce and Investment.
- Ministry of Industry and Mineral Recourses.
- Saudi Authority for Industrial Cities and Technology Zones.
- Economic Cities and Special Zones Authority.
- The Royal Commission for Jubail and Yanbu.
- Ministry of Investment
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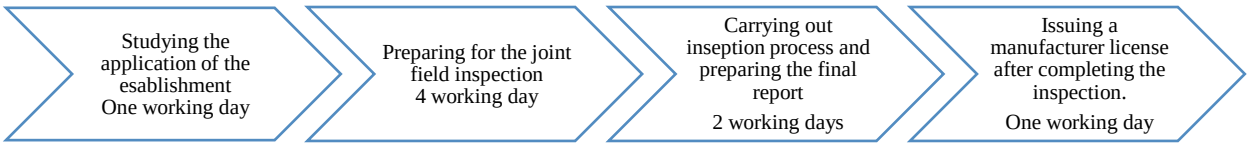
*The activities ISIC to this guide is applied can be viewed on the website of the Authority www.sfda.gov.sa

Chapter Three

Mechanism for Obtaining a (new) License for Pharmaceutical Products Manufacturers

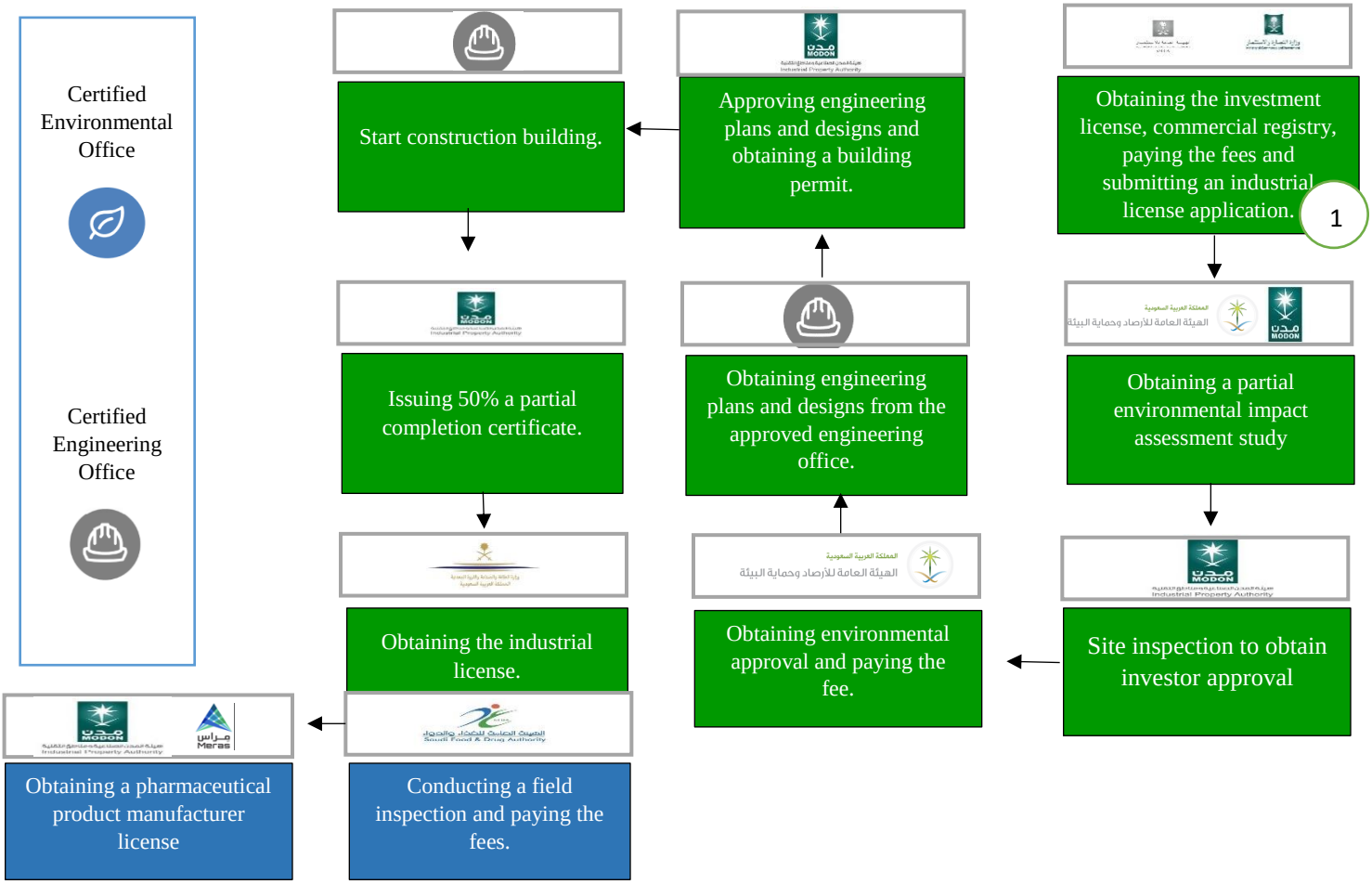
1. Registration in the electronic system of SFDA for the purpose of obtaining a license to practice the activity.
2. Issuing the financial compensation for the license if the inspection department of SFDA is approved.
3. A visit to the establishment by inspectors of SFDA.
4. Obtaining a license from SFDA, and the establishment shall not practice the activity until obtaining a GMP certificate.
5. The establishment shall submit an application to issue a GMP certificate and a product registration certificate.
6. Conduct a field inspection.
7. Obtaining GMP certification and product registration certificate.

- **<u>Estimated Period to Obtain a Pharmaceutical Product Manufacturer License</u>**



A direct license will be issued for low-risk activities after examining the establishment application and issue the license shortly after paying the financial compensation. The site inspection will take place after issuing the license, the establishment can practice the activity in activities afterward.

Process of Applying for a License (New) for Pharmaceutical Products Manufacturers Located in The Industrial Areas.



Chapter Four

Conditions and Documents for Obtaining a License

✓ **Conditions:**

1. The technical director shall have the following :

- A full-time Saudi pharmacist.
- Registered with the Saudi Commission for Health Specialties.
- Experience of not less than 3 years.

2. The following shall be available in the quality control officer before production begins:

- A pharmacist.
- Licensed to practice the profession.
- Registered with the Saudi Commission for Health Specialties.
- At least 3 years of experience in the same field.

3. If manufacturing narcotic drugs or psychotropic substances, a licensed Saudi pharmacist or pharmacist technician shall be appointed to be responsible for their monitoring.

Obtaining a document free of criminal evidence for the person in charge of the custody of narcotic drugs and psychotropic substances.

4. Paying the financial compensation for the license (10,000 riyals) through the SADAD system (invoice number of SFDA after obtaining the invoice from the Law of issuing invoices financial compensation for drug sector services.

Implementation of GMP requirements for pharmaceutical products.

Documents:

1. A copy of the following documents for the technical director of the manufacturer:

- A copy of the academic qualification certificate attested by the embassy (for non-Saudis).
- A copy of the national identity / residency.
- A certified copy of the technical director certificate.
- A certified copy of experience certificates.
- A copy of the professional registration card.

2. A copy of the following documents for the quality control official:

- A copy of the academic qualification certificate attested by the embassy (for non-Saudis).
- A copy of the national identity / residency.
- A certified copy of experience certificates
- A copy of the professional registration card
- A pharmacist
- Registered with the Saudi Commission for Health Specialties.
- At least 3 years of experience in the same field

3. A copy of the following documents for the person in charge of narcotic drugs and psychotropic substances:

- A copy of the national identity.
- A copy of the professional registration card.

A document free of criminal evidence.

4. Applying GMP of pharmaceutical products. Besides, the manufacturer implementation of these requirements is confirmed by the Inspection Department during the manufacturer visit. Foundations Code can be found on the following website:

Chapter Five

- **How to apply for a pharmaceutical products manufacturer license to practice an activity through the Authority electronic system:**

1. Entering the Authority website. www.sfda.gov.sa
2. Select drug/ forms.
3. Select “Manufacturer of pharmaceutical and herbal products” from the list of “Classifications".
4. Fill out the form in detail and attach the list of required documents.
5. Pay the financial compensation.

Chapter Six

Mechanism for Renewing a License to Practice Activity

1. The establishment shall submit a renewal application for the license 6 months from the expiration date of the valid license.
2. The renewal application shall be submitted after filling out the relevant forms.
3. Issuing the financial compensation for a license to practice the activity if the inspection department at SFDA is approved.
4. A visit to the establishment by SFDA inspectors to ensure that the manufacturer applies the technical conditions and to ensure that the product is in compliance with the Technical Regulations and specifications.
5. Obtaining a license to practice the activity from SFDA.

Chapter Seven

License Duration and Fees

License Duration:

5 years

Fees:

The Authority receives the fee (5000 riyals) for the services it provided in the field of registering, licensing and inspecting drug manufacturers and pharmaceutical products.

Chapter Eight

Violations and Penalties:

The committees formed according to the private health institutions Law that is issued by Royal Decree No. M/40 on 3/11/1423 AH. in violations of the provisions of this Law:

1. Warning
2. Fine 100000 riyals
3. Close the establishment for a period of no more than 60 days
4. License revocation
5. The two penalties can be combined with a fine and suspension, and the Penalties Committee consisting of relevant authorities may study cases and approve penalties according to the requirements of the violation.

The implementing Regulations for the pharmaceutical establishments and products Law No. 79 can be viewed using the following link:

Chapter Nine

Common Questions

Q / Why is registering in the pharmaceutical establishments registration and licensing system important?

Registration in the pharmaceutical establishments registration and licensing system is an important matter for several reasons:

1. Issuing a license to practice activity for a pharmaceutical establishment.
2. Building a database for all pharmaceutical establishments and their products in the Kingdom of Saudi Arabia.
3. Improving communication means between SFDA and local pharmaceutical establishments.
4. Enabling pharmaceutical establishments to update their data continuously, besides facilitating the process of communicating with the Authority as a supervisory body over these establishments.

Q/ Who does register in the electronic establishment licensing system?

The registration process for a pharmaceutical establishment shall be carried out by a responsible and authorized person by the establishment and has sufficient technical information to complete the technical and administrative registration steps.

Q / When to apply for a license to practice activity with the Authority?

A license to practice the activity shall be submitted via the electronic system once the industrial license is extracted and the manufacturer is prepared for 100 %.

Q / When does the manufacturer have the right to practice the activity?

The establishment has the right to practice the activity once it has obtained a license by SFDA and practicing the activity before that is forbidden. The penalties prescribed according to the system of pharmaceutical establishments and products and its Implementing Regulations.

Q / How long is the license to practice activity issued by SFDA for practicing food activity?

5 years.

Q / When shall the investor apply to renewal the license for practicing the activity?

The establishment shall apply for the renewal of the license 6 months before the expiration date of the valid license.

Q / If the investor has more than one pharmaceutical establishment (manufacturer), is it registered as one in SFDA registration and licensing system?

The investor shall register each pharmaceutical establishment separately (two independent applications).

Q / Is it necessary to update the file of the registered establishment?

Yes, the data shall be updated when needed, such as the commercial registration, industrial license, or contact information.

Q / What are the contact addresses that I can call If I need help?

If they need assistance, applicants can call the unified number 19999 and send to an e-mail to Est-license.drug@sfda.gov.sa .

Contact Information	
Unified Number	19999
Email	Est-license.drug@sfda.gov.sa