Investor Guide to Obtain
Scientific Office Licensing

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.

(1440H First) Edition

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Chapter 1

Introduction:

Article 1 of implementing regulation of establishments Law and pharmaceutical products issued by Royal Decree No. M/31, date 1/6/1425H placed scientific offices within the establishments which fall under definition (Pharmaceutical Establishment). One of the scientific offices tasks is to provide scientific, technical, and marketing information of pharmaceutical products in the Kingdom of Saudi Arabia.

Investor Definition:

Person or group of people (Company) who want to invest and establish scientific offices in one of the Kingdom of Saudi Arabia countries in medicines field whether he/she is a Saudi/Gulf/foreigner.

Chapter 2

Field and Application Scope:

This guide is applied on the investor who wants to obtain scientific office licensing of pharmaceutical products of the classified activities according to (ISIC) Guide, which Saudi Food and Drug Authority is responsible of after the fulfilment of all the special requirements and documents of the concerned government agencies as follows:

- Saudi Food and Drug Authority.

- Ministry of Commerce.

- Ministry of Investment

*** You can check ISIC activities that this Guide is applied via Saudi Food and Drug Authority website.**

www.sfda.gov.sa

Chapter 3

Procedures to Obtain (New) Licensing for Scientific Office:

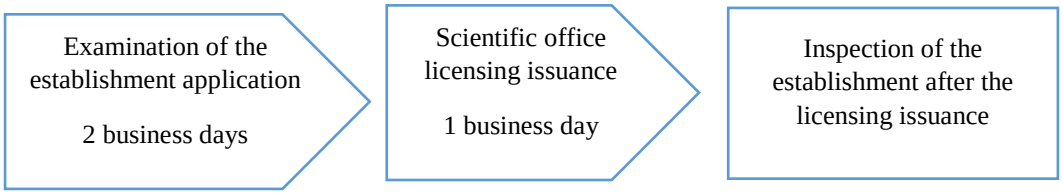
1. **Go to Saudi Food and Drug Authority website to obtain application for scientific office licensing.**

2. Licensing fee issuance.

3. Obtaining the licensing by Saudi Food and Drug Authority

4. Visiting the establishment by Saudi Food and Drug Authority inspectors.

- **Expected duration to obtain a licensing.**



* The direct licensing of low risk activities is done where the establishment application is being examined, and the licensing is being immediately issued after the fee payment, provided that the inspection shall be done later after the licensing issuance "the establishment can practice the activity after obtaining the licensing.

Course Procedures of Application for Obtaining (New) Scientific Offices Licensing

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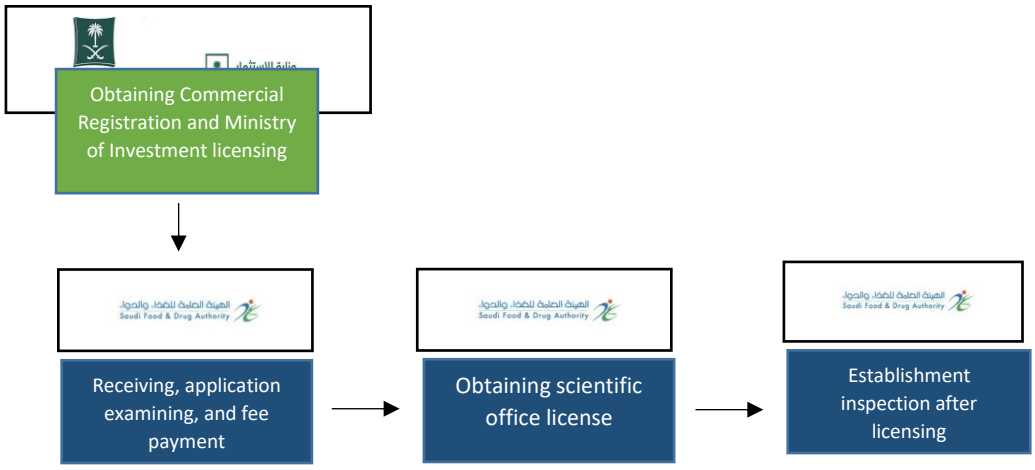

Chapter 4

Documents and Conditions to Obtain Licensing

Conditions:

1. The scientific office shall contain mechanical offices to do the assigned tasks.

2. The scientific office shall contain preparation and necessary references to do the assigned tasks.

3. There shall be specified and appropriate place to store the free samples of the registered products according to the technical principals of storage.

4. The office manager shall be Saudi and free pharmacist who is licensed to do the job.

Documents:

1. Application for scientific office licensing.

2. National identification copy of the scientific office manager.

3. Professional registration copy of the scientific office manager.

4. National identification copy of the official who is in charge of following the application by Saudi Food and Drug Authority.

5. Legal Agency or approved authorization copy of the chamber of commerce of the official who is in charge of following the application by Saudi Food and Drug Authority.

6. Attach a copy of the reference no. to pay the fees of the inspection (Inspection management of establishments) of (5000) Riyals in (Sadad System) Invoiced no. of Saudi Food and Drug Authority is 109.

7. Attach a copy of the reference no. to pay licensing fees (Licensing management of establishments) of (1000 Riyals) in (Sadad System) Invoiced no. of Saudi Food and Drug Authority is 109.

Chapter 5

- **How to apply for activity practicing licensing via the electronic system of Saudi Food and Drug Authority.**
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1. Go to the electronic website of Saudi Food and Drug Authority www.sfda.gov.sa

2. Choose drug/forms.

3. Choose (Scientific office) of "Classification" list.

4. Fill the form in details and attach the required documents list.

5. Pay the service fees.

Chapter 6

How to Renew Activity Practicing Licensing

1- The establishment shall apply a new application of the licensing before 6 months of the expiration date of the applicable licensing.

2- The renewal application is applied after filling the specified forms.

3- Issuance of the activity practicing licensing fees.

4- Obtaining the activity practicing licensing by Saudi Food and Drug Authority.

5- Visiting the establishments by Saudi Food and Drug Authority inspectors to ensure that the scientific office applies the technical requirements and ensure of the technical regulations and standards correspondence.

Chapter 7

Licensing and Fees Duration

Licensing Duration

5 years.

Fees

Saudi Food and Drug Authority meets the fees of (1000 Riyals) for the provided services in the field of registration and licensing of the scientific offices.

Chapter 8

Sanctions and Violations

The committees of the Private Health Institutions Law issued by Royal Decree No. M/40, date 3/11/1423 H has specified the provisions violations of this Law.

1. Warning.

2. 100,000 Riyals fine.

3. Closing of the establishment for a period not more than 60 days.

4. Cancellation of the licensing.

5. The fine and the suspension sanctions can be combined, and the sanctions committee of the relevant bodies can examine the cases and determine the penalties according to the violation case.

*** You can see the implementing regulation of establishments and pharmaceutical products Law No. M/31, date 1/6/1425 H by using the link below:**

http://www.sfda.gov.sa/ar/drug/drug_reg/DocLib/ExecutiverolesforInstitutionsandPharmaceuticalProductslaw.pdf

Chapter 9

Common Questions

Q/ Why is registration in the registration and licensing of the pharmaceutical establishments Law is considered important?

Registration in the registration and licensing of the pharmaceutical establishments Law is considered important for several reasons:

1. Issuance of activity practicing licensing of the pharmaceutical establishment.

2. Establish database of all the pharmaceutical establishments and their products in the Kingdom of Saudi Arabia.

3. Enhance the communication ways between Saudi Food and Drug Authority and the local pharmaceutical establishments.

4. Enabling pharmaceutical establishments to update their data regularly in addition to facilitating the communication procedure with Saudi Food and Drug Authority as a regulatory body on these establishments.

Q/ Who is in charge of registration in the registration system in the establishments?

Tbe registration procedure of the pharmaceutical establishment shall be done by an official and authorized person by the establishment and has sufficient technical information to continue the technical and administrative registration steps.

Q/ When is the application of activity practicing license by Saudi Food and Drug Authority?

The application of activity practicing licensing is done via the electronic system.

Q/ When is the scientific office has the right to practice the activity?

The scientific office has the right to practice the activity when having the licensing by Saudi Food and Drug Authority, it is prohibited to practice the activity before that, and the person who commits a provision shall be punished with the determined penalties according to the establishments and pharmaceutical products Law and its implementing regulation.

Q/ How long is the duration of activity practicing licensing issued by Saudi Food and Drug Authority to practice medicinal activity?

5 years.

Q/ When the investor shall make a new application of renewing the activity practicing licensing?

The establishment shall apply licensing renewal before 6 months of the expatriation date of the applicable licensing.

Q/ If the investor has more than one pharmaceutical establishment (Scientific office), are they going to be registered as one establishment in the registration and licensing system by Saudi Food and Drug Authority?

The investor shall register each establishment separately.

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

Yes, it is required to update the data when necessary such as commercial register or contact information.

Q/ What are the contact information that I can call when I need help?

When the applicants need help, they can call the dedicated line 19999 or send an e-mail to Est-license.drug@sfda.gov.sa

Contact information	
19999	**Dedicated line**
Est-License.drug@sfda.gov.sa	**E-mail**