

Investor Guideline for Issuing a License for Pharmaceutical, Herbal and Cosmetic Products Warehouse

First Version (2018)

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.

Table of Contents

Pages	Title	Chapter
2	Definition / Field and Applicability	2-1
3	A Guideline for Issuing a License for Pharmaceutical, Herbal and Cosmetic Products Warehouse	3
4	Processes of requesting a License for Pharmaceutical, Herbal and Cosmetic Products Warehouse	3
5-6	Requirements and Documentations for Issuing a License	4
7	Application Procedures for Issuing a License for Pharmaceutical, Herbal and Cosmetic Products Warehouse	5
8	Guide to Renew a License	6
9	License Duration and Fees	7
10	Violations and Penalties	8
11	Common Questions	9

1st Chapter

Introduction:

The First Article of the implementing regulation of the Pharmaceutical establishments and products issued by the Royal Decree no. M/108 in 22/03/1442 included warehouses that trade in Pharmaceutical and herbal products wholesale under the name (Pharmaceutical Establishments).

Investor Definition:

An individual or a group of people (company) that desire to invest and license a warehouse of Pharmaceutical, herbal, and cosmetic products, whether the investor is a Saudi, Gulf individual, or a foreigner.

2nd Chapter

Field and Applicability:

The guideline applies to investors who desire to have a licensed pharmaceutical, herbal and cosmetic for activities which falls under the SFDA (ISIC), after meeting all the documentations and special requirements for the following government entities:

- Saudi Food & Drug Authority.
- Ministry of Commerce.
- Ministry of Investment.
- Ministry of Municipal and Rural Affairs and Housing.
- Civil Defense.

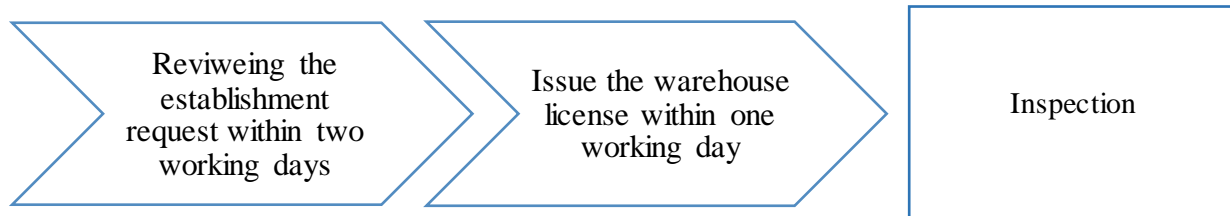
*ISIC activities that apply for this guideline can be found on SFDA website www.sfda.gov.sa

3rd Chapter

A Guideline for Issuing a License for Pharmaceutical, Herbal and Cosmetic Products Warehouse

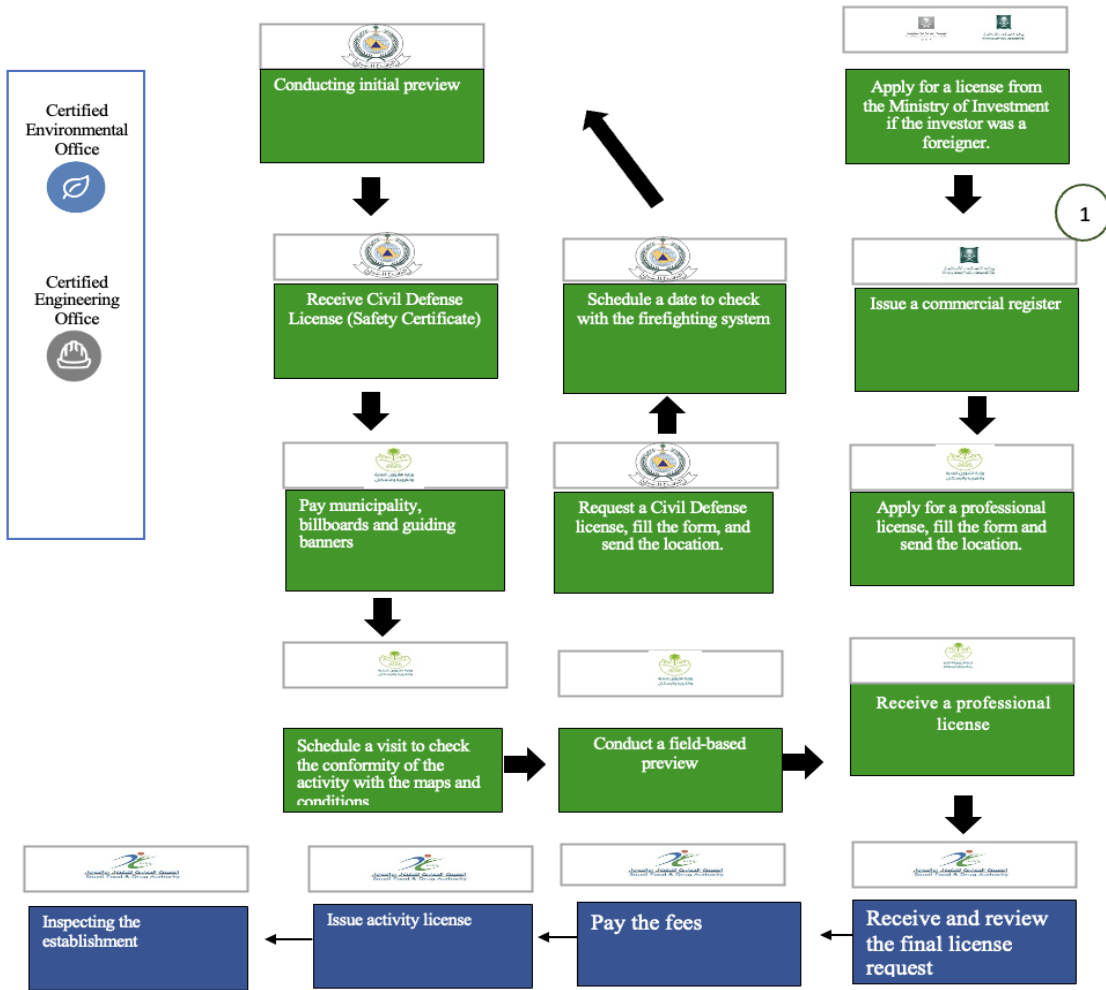
1. Registration in the electronic system of SFDA (ELS) to issue a practicing activity license.
2. Issue the license fees.
3. A visit to the body by SFDA inspectors.
4. Obtaining the license by SFDA.
5. Inspection visits by SFDA inspectors

- **Estimated Time for Issuing a License:**



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

Processes of requesting a License for Pharmaceutical, Herbal and Cosmetic Products Warehouse



4th Chapter

Requirements and Documentations for Issuing a License

Requirements:

- 1- Warehouse director of pharmaceutical products warehouse shall obtain the following:
 - Fulltime and Saudi pharmacist or pharmacy technician.
 - Registered in the Saudi Commission for Health Specialties
- 2- Warehouse shall be within warehouse area.
- 3- Letter that demonstrates absence of criminal record (an exception shall be made for cosmetic warehouses and companies)
- 4- Adherence to warehouse good distribution Practices (GDP)

Documentations:

- 1- A copy of the following documentations shall be submitted:
 - National ID/ Residence Permit (Iqama)
 - Professional registration
 - Covenant from the warehouse director authorized by the Chamber of commerce.
 - Covenant from the official custody of narcotic drugs and psychotropic substances (if available) authorized by the chamber of commerce.
 - Letter that demonstrates absence of criminal record of the official custody of narcotic drugs and psychotropic substances (if available)

5th Chapter

Application Procedures for Issuing a Practicing License through SFDA Electronic System:

- 1- Enter SFDA electronic system
- 2- Select Electronic System (ELS) www.sfda.gov.sa
- 3- Select (Pharmaceutical, Herbal and Cosmetic Products Warehouse)
- 4- Fill the form in detail and attach the required documentations.
- 5- Pay the fees in exchange to the service.

6th Chapter: Guide to Renew a License

- 1- Establishment shall request a license renewal six months before expiry date of the current license.
- 2- License renewal request shall be applied through the electronic system for establishment licensing (ELS)
- 3- Pay license fees.
- 4- Obtain a practicing license by the Saudi Food and Drug Authority.
- 5- Inspection visits by SFDA inspectors to ensure technical requirements are applied in the warehouse.

7th Chapter

License Duration and Fees

Duration:

Five years

Fees:

SFDA shall have 3000 SAR for the services provided in registering, licensing and inspecting warehouses of drugs, pharmaceutical and cosmetic products.

8th Chapter

Violations and Penalties

Committees have defined according to the Private Health Establishments Law issued by a royal decree No. M/40 issued on 06/01/2003, the violations of this law as follows:

- 1- Warning.
- 2- Fine of 100.000 SAR.
- 3- Closing the establishment for no more than 60 days
- 4- Violations committee including relevant authorities can close the establishment and ask for a fine, study cases, adopt sanctions according to the violation.

Implementing regulation of Pharmaceutical Establishments Law No. M/108 issued on 22/03/1442 can be found in the link below:

https://www.sfda.gov.sa/ar/drug/drug_reg/DocLib/ExecutiverolesforInstitutionsandPharmaceuticalProductsLaw.pdf

Committees have defined according to the Cosmetics Law No. M/49 issued on 07/04/2015 the violations of this law as follows:

- 1- Fine of Five Million Saudi Riyals.
- 2- Closing the manufacture of the warehouse until irregularities are corrected.
- 3- Delicense the manufacture or the warehouse.
- 4- Imprisonment not exceeding five years

Implementing regulation of Cosmetics Law No. M/49 issued on 07/04/2015 can be found in the link below:

<https://www.sfda.gov.sa/sites/default/files/2019-10/20%التفذية%20ولاحته%20%التجميل%20%منتجات%20%نظام.pdf>

9th Chapter

Common Questions

1. *Why is registering Pharmaceutical Establishments in the registration and licensing system considered crucial?*

Registering Pharmaceutical Establishments in the registration and licensing system is considered crucial owing to the following:

- Issuance of the license to conduct the establishment activity.
- Building a database for all Pharmaceutical Establishments in Saudi Arabia.
- Enhancing communications between the SFDA and Pharmaceutical Establishments.
- Enabling Pharmaceutical Establishments to update their data consistently, besides easing the communication process with the SFDA as a regulatory body of these establishments.

2. *Who is registering in the Establishments Registration system?*

An official and an authorized individual by the establishment who has access to adequate technical information to complete the registering technical and administrative process.

License.

3. *When to apply for a license from SFDA to engage in activities?*

Apply for a license through the Electronic System, after obtaining an Industrial License and finalizing the establishment preparations by 100%.

4. *When is the warehouse entitled to practice activities?*

The warehouse can practice activities after obtaining the license from the SFDA, any activities before issuing the license are prohibited and penalties shall be applied upon violators according to Pharmaceutical Establishments Law and its implementing regulations.

5. How long is the period of the warehouse license issued by the SFDA in pharmacological activities?

5 Years.

6. When shall the investor apply for license renewal?

The establishment shall apply for a license renewal before 6 months of the expiry date of the current license.

7. If the investor has multiple pharmaceutical establishments, is it registered as a single establishment in SFDA registration and licensing system?

Each establishment shall be registered by the investor separately (two independent applications)

8. Is it necessary to update the file of the registered establishment?

Yes, information shall be updated if needed such as the commercial register or contact details.

9. What contact details do I reach when I need help?

Applicants may reach out to us if needed by contacting through the unified number 19999 or our email:

Est-license.drug@sfda.gov.sa

Contact Details

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