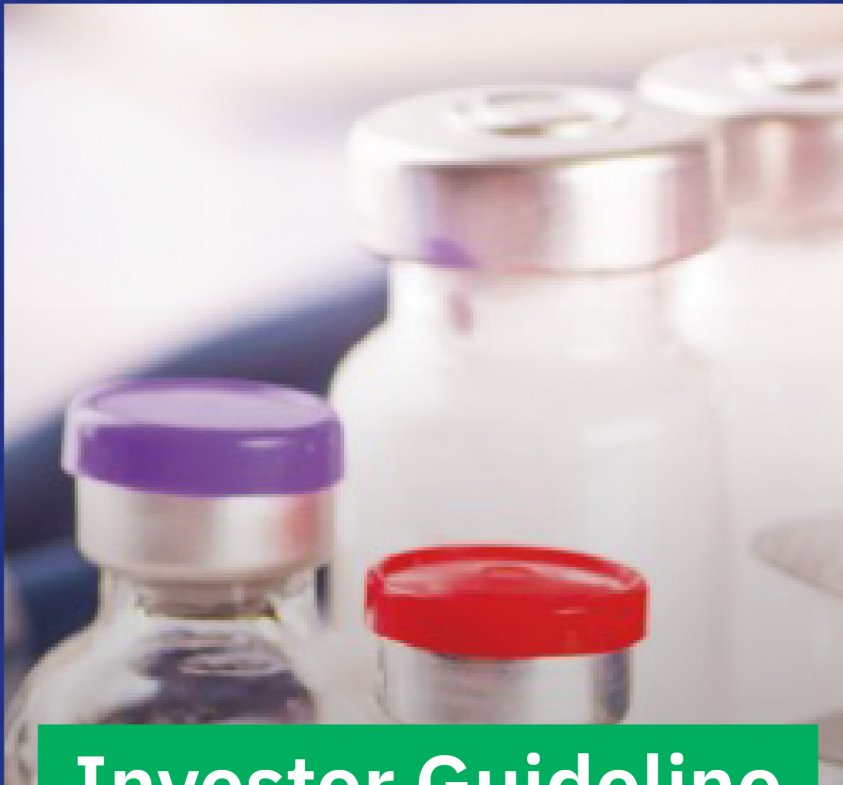




Kingdom of Saudi Arabia  
Saudi Food & Drug Authority



## Investor Guideline

for Pharmaceutical, Herbal  
and Cosmetic Products  
Warehouse License



# Table of Contents

Definition / Field and Applicability .....	02-03
A Guideline for Pharmaceutical, Herbal and Cosmetic Products Warehouse License .....	04
Processes of requesting a License for Pharmaceutical, Herbal and Cosmetic Products Warehouse .....	05
Requirements and Documentations for Issuing a License .....	06
Application Procedures for Issuing a License for Pharmaceutical, Herbal and Cosmetic Products Warehouse .....	07
A Guide to Renew a License .....	08
License Duration and Fees .....	09
Violations and Penalties .....	09
Common Questions .....	11

## 1st Chapter

### Introduction:

The First Article of the implementing regulation of the pharmaceutical establishments and products issued by the Royal Decree no. M/108 on 22/03/1442 included warehouses that trade in Pharmaceutical and herbal products wholesale under the name (Pharmaceutical Establishments). The First Article of the implementing regulation of the pharmaceutical establishments and products issued by the Royal Decree no. M/49 on 18/6/1436 included cosmetic products and The First Article of the implementing regulation of the Veterinary Products Law pertains to veterinary warehouses

### 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 in 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:

<b>Saudi Food &amp; Drug Authority</b>	<b>Ministry of Commerce</b>
<b>Ministry of Investment</b>	<b>Ministry of Municipal and Rural Affairs and Housing</b>



Branch commercial registration specific to the center, in case of multiple branches, or the main .commercial registration



ISIC activities that\* apply for this guideline can be found on SFDA website



### 3rd Chapter

#### A Guideline for Pharmaceutical, Herbal and Cosmetic Products Warehouse License

- Registration in the electronic system of SFDA (GHAD) to issue a practicing activity license.
- A visit to the warehouse by SFDA inspectors.
- Payment of the license fee and downloading the license through establishment account.

#### Estimated Time for Issuing a License:

For pharmaceutical and  
herbal product warehouses,  
Reviewing the  
establishment request  
within **two working days**



Preparation and  
readiness inspection  
**working days 4**



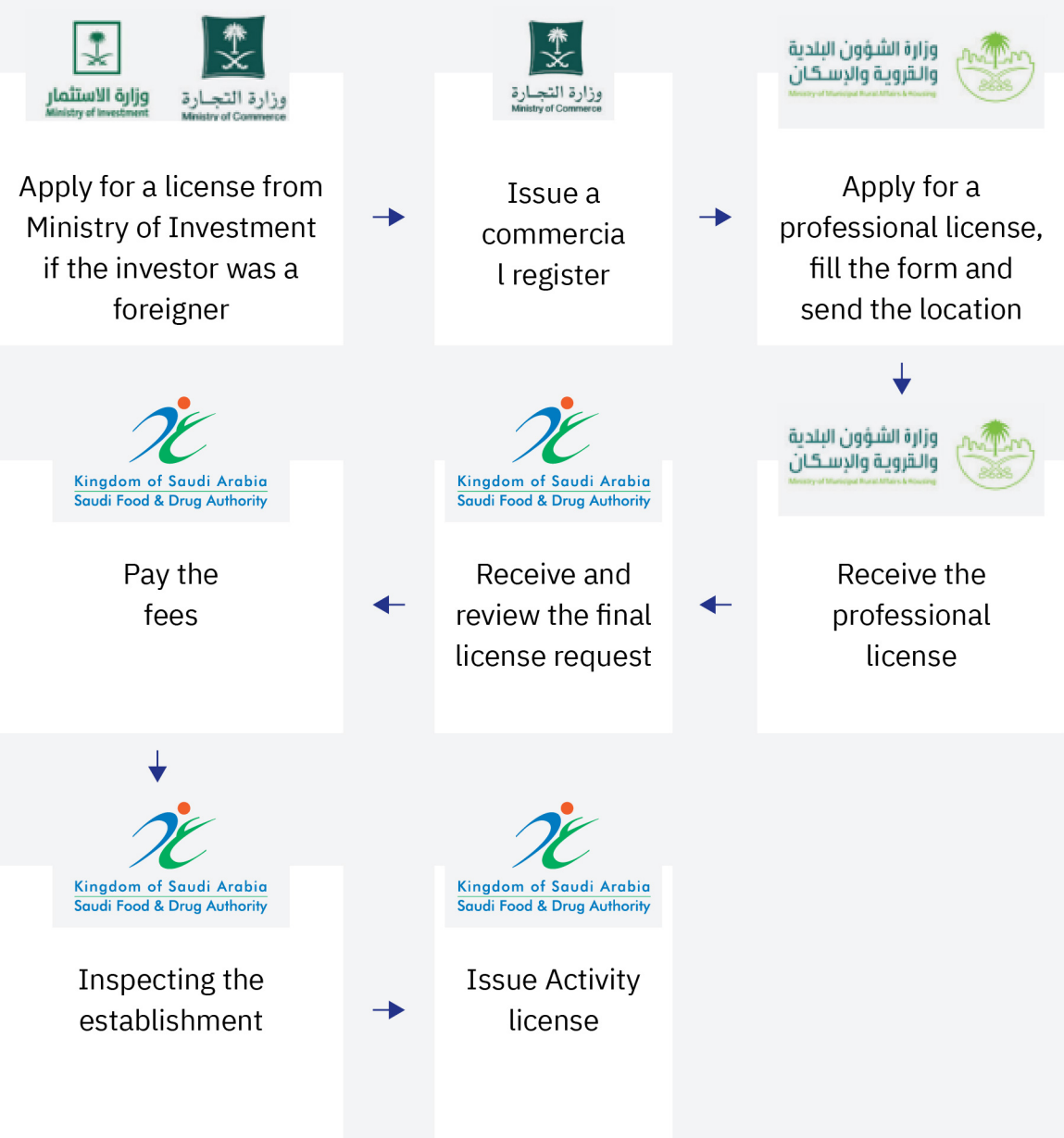
Issuing the factory license  
after completing the  
inspection  
**working day 1**

For cosmetic  
warehouses, Reviewing  
the establishment  
request within  
**two working days**



Issuing a  
warehouse license  
**working days 4**

Processes of requesting a License for Pharmaceutical, Herbal and  
Cosmetic Products Warehouse Located in Warehouse areas:



## 4th Chapter

### Requirements and Documentations for Issuing a License

#### 01 Requirements

- Appointing a full-time Saudi Pharmacist or Pharmacy Technician licensed to practice the profession, if the warehouse handles pharmaceutical products.
- Appointing a full-time Saudi Technical Manager, if the warehouse handles cosmetic products.
- Appointing a full-time Saudi Pharmacist, Pharmacy Technician, or Veterinarian licensed to practice the profession, if the warehouse handles veterinary products only.
- If the warehouse handles narcotics and psychotropic substances, a full-time Saudi Pharmacist licensed to practice the profession must be appointed as the Warehouse Manager and shall be held responsible for these substances. If the Warehouse Manager is a pharmacist, there is no objection to appointing a full-time Saudi Pharmacy Technician licensed to practice the profession to be responsible for narcotics and psychotropic substances.
- The warehouse shall be within warehouse area.
- Adherence to Good Distribution Practices (GDP) for warehouses.
- Pay the licensing fee

## 02 Documentations

- A copy of the following documentations shall be submitted:
  - National ID/ Residence Permit (Iqama)
  - Health Specialty Card If the manager is a pharmacist or Pharmacy Technician
  - 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.
  - Copy of the Municipal License.

## Conditions and Documents for Issuing a License for Renting Space Within a Warehouse:

### 01 Conditions

- Contracting with a licensed warehouse that provides storage services for third parties, provided it is authorized to handle the activities intended to be carried out, and complying with the terms and conditions for storing goods for third parties.
- Adhering to the regulations and responsibilities between the lessor and lessee as published on the SFDA's website at the following link:



## 5th Chapter

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

- Registering on the Saudi Food and Drug Authority's (SFDA) electronic system (Ghad): <https://ghad.sfda.gov.sa>
- Creating an account using the same commercial registration number as the warehouse where the activity will be conducted.
- Selecting the type of field (pharmaceutical or cosmetic) and then selecting the type of establishment (warehouse) or "renter of space within a warehouse."
- The application will be reviewed by the SFDA, followed by a visit to the establishment by SFDA inspectors to ensure the warehouse meets all technical requirements.
- Payment of the license fee and electronic printing of the license.

## 6th Chapter:

### Guide to Renew a License

- Establishment shall request a license renewal three months before expiry date of the current license.
- Register on the unified electronic system (Ghad): <https://ghad.sfda.gov.sa>
- An inspection visit will be conducted to the establishment by Saudi Food and Drug Authority (SFDA) inspectors to verify compliance with all technical requirements.
- Payment of the license renewal fee and electronic printing of the renewed license.

## 7th Chapter

### License Duration:

Five Years

License duration for renting space within a warehouse = 1 year

### Fees:

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

SFDA shall have 800 SAR for the services provided in registering, licensing and inspecting warehouses of drugs, pharmaceutical and cosmetic products rented spaces within a warehouse.

## 8th Chapter

### Violations and Penalties

Committees have defined according to the Cosmetics Law No. M/108 issued on 26/1/1442 the violations of this law as follows:

- A fine not exceeding five million Saudi Riyals.
- Warning.
- Fine of 100,000 SAR
- Closing the establishment for no more than 60 days
- Revoking the license.
- Penalties of fines and suspension can be combined. The Penalty Committee, consisting of representatives from relevant entities, has the authority to review cases and impose penalties according to the violation's severity.





Implementing regulation of  
Pharmaceutical Establishments Law  
No. M/108 issued on 26/1/1442 can  
be found in the link below:



**Committees have defined according to the Cosmetics Law No. M/49 issued on 18/06/1436 the violations of this law as follows:**

- Fine of Five Million Saudi Riyals.
- Closing the manufacture of the warehouse until irregularities are corrected.
- Delicense the manufacture or the warehouse.
- Imprisonment not exceeding five years
- Penalties may be doubled in cases of repeated violations.



Implementing regulation  
of Cosmetics Law No. M/49  
issued on 18/06/1436 can  
be found in the link below:

**\*The Implementing  
regulation of the Veterinary  
Products Law can be found  
on the SFDA's website.**



## 9th Chapter

### Common Questions

#### **Q/ 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.

#### **Q/ 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.

#### **Q/ 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%.

#### **Q/ 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

**Q/ How long is the period of the warehouse license issued by the SFDA in pharmacological activities?**

5 Years

**Q/ When shall the investor apply for license renewal?**

The establishment shall apply for a license renewal before 3 months of the expiry date of the current license.

**Q/If the investor has multiple pharmaceutically 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)

**Q/ 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.

**Q/When renting space within a warehouse, is it mandatory to select a warehouse with the same type of activity?**

Yes, the activities of both the lessor and the lessee must align.

**Q/Which commercial registration number should be used to open an account in the electronic system?**

An account on the electronic system must be opened using the same commercial registration number as the warehouse where the intended activity will be conducted. If there are multiple warehouses with different commercial registration numbers, a separate account must be created for each establishment.

**Q/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@sfd.gov.sa](mailto:est-license.drug@sfd.gov.sa)

# Contact Details

Unified Number  
19999



Email



[est-license.drug@sFDA.gov.sa](mailto:est-license.drug@sFDA.gov.sa)

