



**Provisions and
Responsibilities between the
Lessor and the Lessee
Conditions of Storage for
Others (Lessor)**



Provisions and Responsibilities between the Lessor and the Lessee Conditions of Storage for Others (Lessor)

Version 2.2

Saudi Food & Drug Authority

Operations Sector

- **For inquiries**

Est-License.drug@sfda.gov.sa

- **For comments and suggestions**

Est-License.drug@sfda.gov.sa



Please visit SFDA's website



For more information

Saudi Food & Drug Authority Vision and Mission



Vision

To be a leading international science-based regulator to protect and promote public health.



Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed.



Document Control:

Version	Date	Publisher	Remarks
1	April 18, 2019	Executive Management of Registration and Licensing	Update
2	June 20, 2019	Executive Directorate of Registration and Licensing	Update
2.1	April 06, 2021	Executive Directorate of Regulatory Affairs	Update This version does not include an update in the content of the (guide or procedure
2.2	April 04, 2022	Executive Management of Registration and Licensing	Update



Table of Contents:

Definitions	04
1. Provisions and Responsibilities between the Lessor and the Lessee	06
Second: Lessee Responsibilitytrial centers	09
Third: Responsibilities of the warehouse (Lessor)	10
Fourth: Penalties.	13
2. Special Conditions of Storage for Others	14



Definitions:

The following words and phrases, wherever they appear herein, shall have the meanings mentioned opposite to each thereof, unless the context requires otherwise:

- **SFDA:** Saudi Food & Drug Authority
- **Contract:** Agreement concluded between the warehouse's Lessor and the Lessee for the purpose of good storage.
- **Products:** Pharmaceutical, herbal, health, veterinary and cosmetic products.
- **Lessor:** A pharmaceutical establishment licensed to store pharmaceutical, herbal, health, veterinary and cosmetics for others.
- **The parties:** The Lessor and the Lessee.
- **Means of Transportation:** As stated in the Code of Good Storage and Distribution Practice published on SFDA's website (reference pages 10-13).
- **Cosmetic Products:** Any product intended to be used on the outer parts of the human body (hair, nails and the outer parts of the genital) for the purposes of cleaning or perfuming, improving or keeping in good condition.
- **Pharmaceutical Product:** Any product manufactured in a pharmaceutical dosage form and contain one or more substances used externally or internally in the treatment or prevention of human diseases.
- **Veterinary Product:** Any product manufactured in a pharmaceutical form that contains one or more substances that are used externally or internally in the treatment or protection from diseases in animals.
- **Code of Good Storage and Distribution Practice:** A code aims to introduce the procedures necessary to fulfill responsibilities related to various aspects of distribution, storage and transportation operations and to avoid the introduction of counterfeit or fake products into the market throughout the distribution chain.

01

Provisions and Responsibilities between the Lessor and the Lessee

First: Terms and conditions to be taken into account in the contract between both parties:

1. The lessee shall obtain the necessary licenses from SFDA that allowing good storage of products with others before using the area allocated. The Lessor shall obtain the necessary licenses from SFDA that allow the good storage of its products with others.
2. The contract between the two parties shall include the identification of the person responsible for transporting the products to and from the warehouse by the methods determined by SFDA. The Good Storage and Distribution Practice shall be adhered to. (Reference pages 10-13).
3. The Lessor shall verify the availability of the appropriate means of transportation (with the Lessee) through the contract concluded between the two parties or determine the responsibility for the transportation.
4. The area allocated to Lessees shall be specified in the contracts and separated in a clear way outwardly or electronically, with the area allocated to Lessees determined based on the activity, where the area allocated for storing human medicines shall not be less than (20 m²) and cosmetic products shall not be less than (10 m²). In the event that less areas are rented, legal proceedings shall be taken against both parties.

5. The contract shall include the full responsibilities of both parties and in particular the clear identification of each of the following:
 - Receiving and delivering.
 - Unloading and loading.
 - Destruction.
 - Recall
 - Responsibility for transportation to and from the warehouse.
 - Transferring expired products to the designated area.
6. The contract shall include a provision stating that automatic renewal between the two parties shall not be permissible.
7. A new contract shall be signed between the two parties at or before the expiration of the previous contract.
8. The duration of the contract shall not exceed one year from the date of signing.
9. The contract shall include a provision that prevents the lessees from storing products of unknown origin or not registered.
10. The lessee shall not rent the warehouse or part of it to others in any way.
11. SFDA shall not bear any liability in respect of disputes or financial claims that occur between the two parties.
12. The contract shall include an express provision stating the responsibility for storing expired or returned drugs, whether the Lessor or the Lessee. A penalty shall be imposed on the causing establishment. In the event that the Contract period expires and the license is not
13. revoked, SFDA shall have the right to revoke the license issued without referring to the lessee and the lessee shall bear the resulting penalties.
14. The two parties shall adhere to the Pharmaceutical and Herbal Establishments Law, the Veterinary Products Law and the Cosmetic Products Law published on SFDA's website.

Second: Lessee Responsibility:

The Lessee shall:

1. Verify the sources of purchase and supply of the products that are stored in the area allocated to the Lessee in the warehouse, provided that they are from pharmaceutical establishment licensed to trade, or the Lessee shall import them in its capacity as the official agent or authorized distributor. The Lessee shall bear liability and the consequences of not registered or listed products.
2. Document and archive, in paper or electronically, all receiving and delivering of products stored in the area allocated to the Lessee.
3. The Lessee shall comply with the rules, regulations, instructions and requirements issued by SFDA.
4. All agreements between the Lessor and the Lessee shall be adhered to.
5. The Lessee shall fully comply with all procedures related to any recalls for products issued by SFDA.
6. The lessee shall inform the Lessor in the event of expired or recalled products to be isolated in the allocated areas.
7. The lessee shall abide by the area specified in the Lease Contract mentioned in paragraph (4) of the "Terms and Conditions to be taken into account in the Contract between the two parties".
8. In the event that the lessee is responsible for transporting the products to and from the warehouse, the lessee shall adhere to provide the main Lessor with the receiving and delivering data signed with a third party.
9. In the event that the Contract expires and the lessee does not wish to renew the Contract, the lessee shall inform SFDA and submit a request to cancel the license.
10. In the event that the Contract period expires and the license is not cancelled, SFDA shall have the right to revoke the license issued without referring to the lessee and the lessee shall bear the resulting penalties.

10. In the event that the Contract period expires and the license is not cancelled, SFDA shall have the right to revoke the license issued without referring to the lessee and the lessee shall bear the resulting penalties.
11. The Lessee shall register in RSD in case of practicing the activity of human medicines.
12. The Lessee shall inform SFDA of any violations observed on the Lessor or related to the safety and security of products.
13. The import of unregistered products to warehouses that store with others shall be prohibited based on Article (23), Paragraph "H" of the Executive Regulations of Pharmaceutical Products and Facilities Law.

Third: Responsibilities of the warehouse (Lessor):

The warehouse (lessor) shall comply with the following:

1. The Lessor shall ensure that all receiving and delivering of stored products in the warehouse are documented and archived on paper or electronically. The Lessor shall bear liability and the consequences in the event of the presence of products of unknown origin.
2. All expired products shall be transported immediately upon expiry of their validity period to the allocated area.
3. The expired products shall not be kept in the warehouse for more than one year from the date of expiry unless there is a criminal or judicial order that requires the same.
4. The lessee shall be informed in writing or by e-mail of any circulars or recalls issued by SFDA immediately according to the address indicated in the concluded Contract.
5. All requirements and violations related to the quality of storage shall be followed up. The warehouse shall be prepared to suit the storage of the products allocated to it. All technical conditions related to the storage of the products shall be applied.

6. The Lessor shall have the right to assume responsibility for transporting products, provided that appropriate means of transportation shall be available which meet the necessary conditions and requirements issued by SFDA.
7. SFDA's approval shall be obtained upon contracting with a third party for the good transport of pharmaceutical, herbal, health, veterinary and cosmetics products as per the requirements of the Code of Good Storage and Distribution Practice, provided that this shall be mentioned in the Contract concluded with the Lessee.
8. In case of revocation or termination of the Contract, the lessor shall address SFDA thereof. The Lessor shall bear the legal responsibility for any pharmaceutical, herbal, health, veterinary and cosmetics products in the warehouse without a new contract for the Lessee. The pharmaceutical and cosmetic products shall not be disposed of by the Lessee until SFDA is notified of the expiry, termination or non-renewal of the Contract.
9. The warehouse licensed to store for others shall not be allowed to store narcotic drugs and psychotropic substances unless it is licensed to do so in accordance with laws and regulations pertaining to these substances.
10. The Lessor shall be responsible for legal and actual responsibility in applying the circulars issued by SFDA regarding allowing SFDA's employees to withdraw samples from the products in the warehouse.
11. The Lessor shall inform SFDA about the Lessee's activity in storage during the Contract period or not upon inquiring.
All recalled product data shall be documented and stored in the allocated area.

- 12.** All recalled product data shall be documented and stored in the allocated area.
- 13.** It shall be ensured that there is an actual proportion between the total area of the warehouse licensed to store for others with the number of Lessees in the warehouse. The Lessor shall allow SFDA to access the leased area and ensure that there is an actual proportion between the leased area and the actual inventory in the warehouse.
- 14.** An accurate and comprehensive electronic system shall be provided to follow up the receipt and disbursement of products with full readiness for electronic linkage with SFDA.
- 15.** The technical requirements contained in the Code of Good Storage and Distribution Practice shall be fully complied with, in particular the following:
 - Non-licensed workers in the warehouse shall not enter the areas allocated for storage.
 - There shall be a part of the warehouse that is fully isolated and used as a recalled medicine area (RECALL).
 - An isolated part of the warehouse shall be allocated for expired medicines.
 - The Lessor shall suspend SFDA's license for the Lessee in their areas.
- 16.** The Lessor shall inform SFDA periodically (every four months) of the updated lists of all Lessees in the warehouse.

The Lessee shall abide by the area specified in the Lease Contract mentioned in paragraph (4) of the "Terms and Conditions to be taken into account in the Contract between the parties".
- 17.** The Lessee shall abide by the area specified in the Lease Contract mentioned in paragraph (4) of the "Terms and Conditions to be taken into account in the Contract between the parties".

18. The Lessor shall comply with the laws, regulations, instructions and requirements issued by SFDA and adhere to the agreements made between the lessor and the lessee.
19. The Lessor shall inform SFDA of any violations observed on the Lessee or related to the safety and security of products.
20. The Lessor shall register in RSD in case of practicing the activity of human medicines.

Fourth: Penalties.

Failure to comply with the above exposes the Lessor and Lessee to the penalties stipulated in the Law of Pharmaceutical and Herbal Establishments and Products and its Executive Regulations, the Cosmetic Products Law and its the Executive Regulations, and the Veterinary Products Law and its Executive Regulations.



02

Special Conditions of Storage for Others

1. The Contract concluded between the Lessor of licensed warehouse and the Lessee wishing to store shall clarify all the responsibilities of each of them, in particular receiving and delivering, destruction, recalling, location, area, transportation, and storage.
2. All receiving and delivering of pharmaceutical, herbal, health, veterinary and cosmetic products stored in the warehouse at both parties shall be documented, archived and comply with the regulations issued by SFDA in this regard.
3. The licensee to store for others shall transport all expired medicines upon expiry of their validity period to the allocated area. Expired products may not be kept in the warehouse for more than one year from the date of their expiry unless there is a criminal or judicial order that requires it.
4. In the event of revocation or termination of the Contract, the warehouse licensed to store for others shall address SFDA thereof, and shall legally bear having any medicines for a Lessee who does not have a valid Contract.
5. In the event of revocation or termination of the Contract or the transfer of a location, the Lessee shall address SFDA and revoke the license. The Lessee shall legally be responsible for having any medications and not having a valid contract.

6. The lease contract shall indicate the party responsible for transporting medicines by the methods determined by SFDA in accordance with the Code of Principles of Practice for Good Distribution and Storage. The lessor shall verify the availability of the appropriate means of transport through the contract concluded between the two parties.
7. The warehouse licensed to store for others has the right to assume the responsibility of transporting the products provided that appropriate means of transport are available and the approval of SFDA is obtained.
8. The warehouse licensed to store for others shall contract with a third party for the appropriate transport of pharmaceuticals and cosmetics in accordance with the requirements of the Code of Principles of Good Distribution and Storage Practice, provided that this shall be mentioned in the contract concluded with the lessee.
9. The warehouse licensed to store for others shall bear all the requirements and violations related to the quality of storage. The warehouse shall be prepared to suit the storage of pharmaceutical, herbal and veterinary products and cosmetic products. All technical conditions related to the warehouse shall be applied.
10. The warehouse shall legally and actually apply SFDA's circulars regarding the providing medicines and samples to SFDA.
11. The Lessee shall legally and actually bear the procedures for recalling pharmaceuticals, herbal, veterinary and cosmetic products issued by SFDA. The warehouse licensed to store for others shall document all the data of the recalled products and store them in the allocated area.
12. A warehouse licensed to store for others may practice the activity of importing, exporting and wholesale trade in pharmaceuticals, herbal products and products, provided that an appropriate area shall be available.

- 13.** The area of the warehouse licensed to store for others shall be commensurate with the number of Lessees, so the area shall be (20 m²) for pharmaceuticals and (10 m²) for cosmetic products.
- 14.** The warehouse shall meet the following technical conditions:
- Adhere to the Code of Good Storage and Distribution Practice.
 - The areas allocated to Lessees shall be specified in contracts and clearly separated.
 - Non-workers in the warehouse shall not enter the areas allocated for storage.
 - Allocate a portion of the warehouse isolated as a recalled drug area.
 - An isolated part of the warehouse shall be allocated for expired medicines.
- 15.** The warehouse shall not be allowed to store pharmaceutical, herbal and veterinary products and cosmetic products for others unless the following conditions are met:
- A valid license shall be obtained from SFDA for the warehouse leased for storage activity to others.
 - A commercial register for the Lessee in the same administrative area of the warehouse.
 - Signing a contract between the two parties certified by the Chamber of Commerce.
 - These products shall be sourced by licensed pharmaceutical establishments.
 - The contract signed between the two parties shall stipulate the Lessee is not allowed to store pharmaceutical, herbal and cosmetic products of unknown origin or unregistered pharmaceutical, herbal and veterinary products.

- The warehouse licensed to store shall verify the sources of purchase, whether from the first or second party, and shall keep a copy of the purchase invoices showing the regular sequence of products stored.
- 16.** The warehouse licensed to store for others shall keep records of receiving and delivering and copies of purchase invoices for a period of one year in the warehouse in paper and for a period of not less than five years in electronic form.
 - 17.** The warehouse licensed to store for others shall inform Lessees in writing or by e-mail of any circulars or recalls issued by SFDA immediately.
 - 18.** The warehouse licensed storage for others shall bear the existence of sufficient area before accepting the license application for the Lessee. SFDA shall have the right, in the event of non-compliance, to suspend the license application and impose penalties on the Lessor.
 - 19.** warehouse licensed store for others shall not be allowed to store narcotic drugs and psychotropic substances unless licensed to do so and with the approval of SFDA.
 - 20.** Failure to comply with the above-mentioned may expose the establishment or Lessee to the penalties stipulated in the Pharmaceutical and Establishments Law and its Executive Regulations, the Cosmetic Law and its Executive Regulations, and the Veterinary Law and its Executive Regulations.
 - 21.** The import of unregistered products to warehouses that are stored with others shall be prohibited based on Article (23), Paragraph "H" of the Executive Regulations of Pharmaceutical Products and Facilities Law.

22. Both the Lessor and the Lessee shall bear the failure to register in the RSD system in the event of practicing the activity of human medicines. The Contract shall clarify the responsibility for registration in RSD.
23. SFDA's acceptance of the contracts attached in the electronic applications shall not mean its approval of the Contract, but both parties in the event of non-compliance with the responsibilities shall bear the statutory penalties therein.





Kingdom of Saudi Arabia
Saudi Food & Drug Authority

A row of seven small, white social media icons: X (Twitter), Telegram, Instagram, YouTube, Facebook, a copyright symbol, and a download icon. To the right of these icons is the text 'Saudi_FDA' and below it, the website address 'www.sfda.gov.sa'.

Saudi_FDA
www.sfda.gov.sa