وزارة الصحة
Ministry of Health

DSC
مركز سلامة الدواء
Drug Safety Center

Guideline on Licensing of Pharmaceutical Establishments

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Drug Safety Center

2026

First Edition

Table of Contents

Acronyms	4
Definitions	5-6
CHAPTER ONE	
Introduction	7
Purpose	7
Scope	7
Structure	7
CHAPTER TWO	
General Principles	8-13
Procedure	13
CHAPTER THREE	
Responsibilities	16
CHAPTER FOUR	
Document Date & Issue Adjustment	17
References	17

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Acronyms:

DSC	Drug Safety Center
MOH	Ministry of Health
WHO	World Health Organization
GCC	Gulf Cooperation Council
GMP	Good Manufacturing Practice
GSP	Good Storage Practice
GDP	Good Distribution Practice
GXPs	Good Practices
GLP	Good Laboratory Practice
GCP	Good Clinical Practice
QMS	Quality Management System
OMR	Omani Rial

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11 Definitions:

Pharmaceutical Establishments	Pharmacies, Medical Store, pharmaceutical manufacturing facilities, scientific offices, pharmaceutical consultancy offices, drug analysis laboratories, and any other establishments specified by ministerial decision.
Pharmacy	A licensed facility for preparing or retailing medicines and medical supplies, either publicly or privately.
Medical Store	A licensed facility for storing, selling, and distributing medicines wholesale to licensed pharmaceutical establishments or authorized private health institutions.
Pharmaceutical Manufacturing Facility	A licensed facility for manufacturing, preparing, compounding, packaging, or repacking medicines for wholesale to licensed pharmaceutical establishments.
Scientific Office	A licensed entity that provides technical or marketing information about medicines through approved scientific means.
Pharmaceutical Consultancy Office	A licensed entity that offers consultancy, research, or studies related to the pharmacy profession and represents pharmaceutical establishments with relevant authorities for awareness and scientific activities.
Drug Analysis Laboratory	A licensed facility for testing medicines to ensure they meet the required specifications.
Preliminary Approval	An initial approval granted after fulfilling the required technical and structural conditions.
Initial Inspection	A scheduled inspection of the establishment intended to be licensed as a pharmaceutical establishment, aimed at assessing the suitability of the establishment's location, its external surroundings, and its internal preparedness in a manner appropriate for the pharmaceutical services proposed for licensing

Final Inspection	A scheduled inspection of the establishment intended to be licensed as a pharmaceutical establishment, to verify its compliance with the conditions stipulated in the Executive Regulations prior to granting the license

12

13

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CHAPTER ONE

Introduction

This guideline provides applicants with clear instructions on the regulatory requirements and procedures for obtaining a license to open and operate a pharmaceutical establishment in the Sultanate of Oman. It is intended to support a consistent, transparent, and legally compliant licensing process under the authority of the Drug Safety Center (DSC)

Legal Basis

- Law Regulating the Practice of the Pharmacy Profession and Pharmaceutical Establishments issued by Royal Decree No. 35/2015, including Article (10) is applicable
- Executive Regulation issued by Ministerial Decision No. 113/2020, including Chapter Three is applicable

Purpose

The purpose of this guideline is to provide a Comprehensive practical reference for applicants and relevant stakeholders by outlining the technical, health, administrative, and procedural requirements necessary to obtain a pharmaceutical establishment license.

Scope

This guideline applies to licensing applications for pharmaceutical establishments in the Sultanate of Oman, including community pharmacies, in house pharmacies, medical stores, pharmaceutical manufacturing facilities, scientific offices, pharmaceutical consultancy offices, drug analysis laboratories, and pharmaceutical studies centers.

Structure

This is the first version of this guideline and is organized into four chapters. CHAPTER ONE covers the Introduction, Purpose, Scope, and Structure. CHAPTER TWO outlines the detailed procedures and methods. CHAPTER THREE defines responsibilities in relation to this guideline. CHAPTER FOUR includes the document history and version control and references

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CHAPTER TWO

2.1 General Principles

- All pharmaceutical establishments must obtain a license from the Drug Safety Center before commencing operations.
- Applications for licensing pharmaceutical establishments must comply with the applicable laws, regulations, and licensing requirements.
- All licensing applications shall be reviewed by the competent Technical Committee in accordance with the applicable regulatory requirements.
- Except for pharmaceutical manufacturing facilities, applicants whose applications are approved shall be granted initial approval valid for six (6) months to complete the licensing procedures.
- Initial approval may be extended for an additional period of six (6) months, subject to justification and approval by the Drug Safety Center.
- Initial approval does not constitute authorization to commence pharmaceutical activities.
- Pharmaceutical establishments must fulfill all applicable licensing requirements and obtain the final license before commencing operations

2.2 General Requirements for Opening a Pharmaceutical Establishment:

2.2.1. Community Pharmacy

- Must be at least 100 meters from the nearest healthcare facility, measured from the center of each main entrance.
- Must be at least 200 meters from the nearest community pharmacy, except those inside commercial complexes.
- Must be located on the ground floor with an external-facing wall. Pharmacies inside commercial complexes must submit an internal schematic layout.
- Floor level must be elevated above ground level, except in commercial complexes.

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- Minimum interior area: 24 m².
- Must not be internally connected to a residence or another shop.

2.2.2. In-House Pharmacy

- Must be located inside a private hospital.
- Minimum interior area: 20 m².

Preliminary Approval Requirements for Pharmacies (After fulfilling the general requirements listed above)

- Appointment of a licensed pharmacist approved by the Center to manage the pharmacy.
- Air conditioning suitable for the pharmacy's area: at least two units capable of maintaining a temperature not exceeding 24°C, with adequate thermometers.
- Safety and emergency equipment (first aid kits, fire extinguishers) as required by the Public Authority for Civil Defense and Ambulance.
- Refrigerator for medicines requiring 2–8°C storage, and a deep freezer (below 0°C) if necessary. Each must have a thermostat, power indicator, temperature display, and daily temperature log.
- Cabinets and glass display cases for medicine storage in line with recognized pharmacopeia standards.
- Locked cabinet for controlled medicines.
- Telephone, computer, and internet access.
- Clean environment with covered waste disposal containers.
- Adequate lighting and ventilation.
- Dedicated areas for dispensing and pharmaceutical counseling.
- Surveillance cameras covering interior and exterior areas.
- At least one-third of the minimum area allocated for medicine storage and display.
- Contract with a licensed waste disposal company for expired or damaged medicines.
- Front façade made of heat-resistant, shatterproof glass; sun-shielding film required if exposed to sunlight (for community pharmacies).
- Front-facing window and external bell for night shifts (for 24-hour pharmacies).
- Pharmacy name displayed on the façade in Arabic, with optional English.

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- Pharmacies with compounding labs must comply with additional Drug Safety Center requirements.
- Contract with Bee'ah (Environmental Services Company) for pharmaceutical waste disposal.

2.2.3. Medical Store – Licensing Requirements

- The building and roof must be constructed of reinforced concrete or another non-combustible material, in compliance with the safety standards of the Public Authority for Civil Defense and Ambulance.
- The interior area must be at least 60 m², with a ceiling height of no less than 3 meters. An internal engineering drawing must be submitted for the warehouse.
- The floor must be solid, easy to clean, and elevated above the level of the main road or adjacent ground.
- Walls and ceilings must be painted with easy-to-clean paint and repainted whenever necessary.

Requirements for Initial Approval of the Medical Store

- Appointment of a pharmacist licensed by the Directorate to manage the store.
- Adequate shelving to store medicines safely, preventing damage or contamination, in line with recognized international pharmacopeia. Boxes of medicines and medical supplies must not be placed directly on the ground.
- Narcotic and psychotropic substances must be stored in accordance with the official Manual for Dealing with Narcotic Substances and Psychotropic Substances in Health and Pharmaceutical Institutions.
- A separate area must be designated for flammable materials, meeting approved safety conditions.
- Air conditioning appropriate to the warehouse size, ensuring internal temperature does not exceed 24°C, with sufficient thermometers.
- Refrigerator for medicines requiring 2–8°C storage, equipped with a thermometer and daily temperature log.

DRAFT

- Freezer with suitable shelving for medicines requiring very low temperatures, equipped with an automatic temperature recorder that retains data for at least one year.
- Adequate lighting and ventilation.
- One or more entrances for loading/unloading, plus emergency exits.
- Separate areas for receiving, dispatch, storage, and handling of damaged, expired, or returned medicines.
- A management desk separates from the storage area.
- Pest control measures and closed receptacles for waste.
- Security and safety measures in compliance with the Public Authority for Civil Defense and Ambulance.
- Contract with a specialized company for disposal of expired or damaged medicines.
- Surveillance cameras covering both internal and external areas of the warehouse.
- Records documenting drug batch quantities, numbers, and distribution. Controlled substance records must be numbered and stamped with the official seal of the Center.
- Telephone, computer, and internet access.
- Suitable refrigerated transport for medicine distribution, with temperature monitoring.
- Store name displayed on the façade in Arabic, with optional English.
- Commitment to Good Practices and Quality Management Systems (GSP/GDP and QMS).

2.2.4. Pharmaceutical Manufacturing Facility – Licensing Requirements

- Fulfillment of all conditions stipulated in the licensing manual for factories producing human medicines, herbal medicines, medical devices, and supplies, as issued by the Center.
- Strict adherence to Good Pharmaceutical Manufacturing Practice (GMP) principles in accordance with the (GCC-GMP) and the World Health Organization (WHO-GMP) guidelines.
- Compliance with Good Practices (GXPs), including Good Storage Practice (GSP), Good Distribution Practice (GDP), and other relevant regulatory standards.
- Commitment to continuous implementation of quality management systems to ensure product safety, efficacy, and consistency.

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2.2.5. Scientific Office – Licensing Requirements

- Must not be part of any pharmaceutical institution other than a pharmaceutical manufacturer.
- Must be equipped with air conditioning, proper lighting, ventilation, and a refrigerator for storing medicine samples requiring refrigeration.
- A designated area must be provided for storing medicine samples that do not require refrigeration, in accordance with stipulated conditions.
- Must have the necessary equipment and scientific references to carry out its functions.
- Must be equipped with security and safety measures in compliance with the requirements of the General Authority for Civil Defense and Ambulance.
- Commitment to the implementation of quality management systems ensures compliance with regulatory standards

2.2.6. Pharmaceutical Consultancy Office – Licensing Requirements

- Must not be part of any other pharmaceutical establishment.
- Must be equipped with appropriate air conditioning, lighting, and ventilation.
- Must have the necessary equipment and scientific references to perform its functions.
- Must be equipped with security and safety measures in compliance with the General Authority for Civil Defense and Ambulance.
- The office manager must be a full-time Omani pharmacist.

2.2.7. Drug Analysis Laboratory – Licensing Requirements

- Floors and walls must be non-flammable, non-chemically reactive, and easy to clean.
- Sections must be separated to prevent and reduce contamination.
- Secure storage must be provided for controlled substances.
- Adherence to Good Laboratory Practice (GLP) principles in accordance with the WHO-GLP.
- Sensitive devices must be placed in independent rooms to avoid interference.
- Must be equipped with security and safety measures in compliance with the General Authority for Civil Defense and Ambulance.
- Contract with a specialized company for disposal of expired or damaged medicines.

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- Compliance with GXPs and continuous quality management.

2.2.8. Pharmaceutical Studies Center – Licensing Requirements

- Location and space must be suitable for operations.
- Center area must be divided into:
  - A separate, secure place for chemicals.
  - Storage for biological and drug samples, with appropriate preservation methods.
  - Record-keeping area documenting sample arrival dates, quality, quantity, and analysis results. Records must be retained for at least five (5) years, with a data retrieval system available.
  - Examination room for physicians, equipped with first aid supplies.
  - Sampling room.
  - Space for instruments required for analysis, aligned with study requirements.
  - Reception desk and administrative office.
- Must meet international standards for Good Clinical Practice (GCP) and Good Laboratory Practice (GLP).
- Must provide accommodation for volunteers during study periods.

2.3 Procedure

To apply for a Pharmaceutical Establishment License through the Ministry of Health website follow these steps

1. Visit Ministry of Health website Go to https://www.moh.gov.om to access the portal
2. Select Drug Safety Center Navigate to Business, then choose Drug Safety Center.
3. Start the service Click Start to begin the application process.
4. Log in with PKIU se your National ID Card (PKI) or Mobile PKI to sign in.
5. Review service guide through the following link
6. https://moh.gov.om/media/b4bg0uiy/pharmaestablishmentrequest_english.pdf
7. Attach Commercial Registration Upload the Commercial Registration document with your application

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Fees for Opening a Pharmaceutical Establishment

Type of Pharmaceutical Establishment	Fees
Community Pharmacy	OMR 300
In- House Pharmacy	No fees
Medical Store	OMR 450
Scientific Office	OMR 300
Pharmaceutical Consultancy Office	OMR 300
Drug Analysis Laboratory	OMR 600
Pharmaceutical Studies Center	OMR 600
Pharmaceutical Manufacturing Facility	OMR 1,500

Note: Fees are subject to change in accordance with the applicable regulations and official decisions issued by the competent authorities

Application Status Follow-up

After submitting the application, the status may appear as follows:

- Pending Initial Review
- Pending Inspection Review
- Pending MOH Decision

The applicant may follow up on the application status through their dashboard on the platform.

Site Field Inspections

- The inspection team visits the establishment's site to verify compliance with the required health and technical requirements.
- The inspection report is uploaded through the system.

Issuance of the License

- After fulfilling all requirements and paying the prescribed fees, the application is submitted to the Pharmaceutical Licensing Committee.
- If approved, the Drug Safety Center issues the final license electronically.
- The license can be printed from the applicant's account.

Important Notes

- A license holder for opening a community pharmacy shall not be an owner or partner in more than one pharmacy.
- No activity may be commenced before obtaining the license.

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CHAPTER THREE

Responsibilities

Applicant	• Complete all licensing requirements. • Prepare and submit the required documents. • Follow up on the application status.
Pharmaceutical Licensing Section	• Receive and review licensing applications. • Verify compliance with licensing requirements. • Issue initial approval. • Coordinate site inspections
Inspection Team	• Conduct site inspections. • Verify compliance with regulatory requirements. • Prepare and submit inspection reports.
Pharmaceutical Licensing Committee	• Review applications and inspection findings. • Approve or reject licensing applications in accordance with its authority. • Recommend the issuance of licenses.
Director of the Health Planning and Regulation Department in the Governorate	• Coordinate and conduct site inspections within the governorate. • Review and submit inspection reports.
Director of the Regulatory Compliance Department	Post-Operational Monitoring and Compliance

CHAPTER FOUR

Document History and Version Control

Revised Date	Description	Version
October 2026	**First Edition**	1

References:

Ministry of Health, Oman (2020) *Ministerial Decision No. 113/2020 issuing the Executive Regulation of the Law Regulating the Practice of the Pharmacy Profession and Pharmaceutical Establishments*. Muscat: Official Gazette, Sultanate of Oman. Available at: https://qanoon.om/p/2020/moh20200113/

Ministry of Health, Oman (n.d.-a) *Apply for a pharmacy establishment license*. Available at: https://gov.om/w/apply-for-a-pharmacy-establishment-license

Ministry of Health, Oman (n.d.-b) *Guidelines for licensing manufacturing plant for human medicines, herbal medicines, and medical devices*. Available at: https://www.scribd.com/document/488818863/Guidelines-for-Licensing-Manufacturing-Plant-for-Human-Medicines-Herbal-Medicines-and-Medical-Devices-English

Ministry of Health, Oman (n.d.-c) *Pharmaceutical facility license and medical device establishments*. Available at: https://moh.gov.om/en/services/businesses/drug-safety-center/apply-for-pharmacy-establishment-license-medical-device-establishments-approval/

Sultanate of Oman (2015) *Royal Decree No. 35/2015 promulgating the Law Regulating the Practice of the Pharmacy Profession and Pharmaceutical Establishments*. Muscat: Official Gazette, Sultanate of Oman.

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