

Licensing of a Pharmaceutical Facility

About the Service

This service allows customers to apply for a license to establish a pharmaceutical facility to sell pharmaceutical products and medical supplies, to register, import and distribute pharmaceutical products and medical supplies, to represent companies, pharmaceutical factories and international medical supplies registered in the country, to export and re-export pharmaceutical products and medical supplies, or to manufacture pharmaceutical products and medical supplies.

Service Process

- Login to the MOHAP website or smart app using the UAE PASS to apply for the service.
- Apply to obtain a pre-licensing approval for a pharmaceutical facility.
- An approval will be issued for the local citizen owner.
- Submit the request for initial inspection and pay the inspection fee.
- Once the initial inspection is approved, an initial approval request must be submitted by the applicant.
- Proceeded with finalizing the license requirements from relevant government departments, such as Civil Defense.
- Apply for staff licensing (pharmacists).
- Apply for final inspection and pay the fee.
- Once the final inspection is approved, submit the final approval request with the remaining documents.
- If the application is approved, the license fee will be paid.
- The license is issued electronically and sent via email. It can also be downloaded via the website.

Required Documents

- Documents required for pharmacies, warehouses, marketing offices, warehouses for re-export: Initial approval (owner profile check & primary inspection):Registration in Tatmeen:License initial approval:Final inspection and final approval of the license:
- Additional documents for marketing offices: Documents required for initial approval:Documents required for final approval:1. Initial approval of the manufacturing facility2. Manufacturing facility construction and preparation3. Final licensing of the manufacturing facility and good manufacturing practice certificate issuance

Conditions & Requirements

- 1. For pharmacies, warehouses, and scientific offices, the owner must be a UAE national as per the Companies Law. The client must not own more than two pharmacies in the UAE.
- 2. The following technical and health conditions must be met in pharmaceutical facilities:n case of applying for a pharmacy license, the applicant should follow Ministerial Circular No. (932) Regarding the Health and Technical Conditions that Must be Met in Private Pharmacies. Click the link to view the circular:https://mohap.gov.ae/app_content/legislations/php-law-ar-55/mobile/index.htmlIn case of applying for a medical warehouse license, the applicant should follow Circular No. (90) of 2021 of Federal Law No. (8) of 2019 on Medical Products the Profession of Pharmacy and Pharmaceutical Facilities.

FAQ's

Service completion duration

• Categories: Pharmacies, warehouses, marketing offices, warehouses for re-export: 3 working days Manufacturing facilities of pharmaceuticals and medical device: Handling the first licensing step (primary approval): Within 5 working days from the application receiving dateAssigning inspection team to audit the compliance with good manufacturing practice (GMP): 10 days from the date of receiving the requestIssuance of the certificate of compliance with current good manufacturing practice (c-GMP): 5 working days from the date of generation of the visit report. It is recommended to issue a GMP certificate. Issuing MOHAP facility license upon completing the required fees\documents: 3 working days from the date of receiving the last requirement

Service fees

Service channels

Service locations

• MOHAP Website: www.mohap.gov.ae

MOHAP Smart App

Support

Email: <u>info@mohap.gov.ae</u>Call Center: 80011111

Payment channels

• E- Payment

Target audience

- Pharmacies
- Warehouses
- Manufacturers of medicines and medical devices
- Marketing Offices
- Warehouses for re-export

Department name

Licensing and Accreditation

Sector name

Health Regulation

Main service

Medical Establishment Licencing and Registration

Service Code

Service Classfication

Transactional

Sub Service Type

Variation

Service Type

Government to Business

Related Services

- Pharmacies, warehouses, marketing offices, warehouses for re-export:
- Manufacturing facilities of pharmaceuticals and medical device:

Service Bundle

This service is not linked to any bundles

Number of Users

213

Number of Transactions

619

Notes

Manufacturing facilities of pharmaceuticals and medical device:

This service is linked to various services from other government agencies, including:

- Ministry of Interior Obtaining the Approval for the Introductory Statement of the Subjected Facility's Owner(s)
- Departments of Economic Development Registration of Trade Name
- Ministry of Health and Prevention Licensing of Medical Professionals and Pharmacists
- Departments of Economic Development Issuance of Trade License
- Civil Defense Issuance of Civil Defense Certificate
- MOCCAE- Issuing the Environmental Compliance Certificate

Sustainable Goals

Good Health And Well-Being