Licensing of a Pharmaceutical Facility

This service enables 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 suppliers registered in the country, to export and re-export pharmaceutical products and medical supplies, or to manufacture pharmaceutical products and medical supplies.

Department name
Licensing and Accreditation

Sector
Health Regulation

Main Service
Medical Establishment Licencing & Registration

Service Code
110-03-020-000

Service Classification
Transactional

Variation / Auxiliary
Variation

Service Type
Government to Business

Service Process

01 Login to the MOHAP website or smart app using the UAE PASS to apply for the service.
02 Apply to obtain a pre-licensing approval for a pharmaceutical facility.
03 An approval will be issued for the local citizen owner.
04 Submit the request for initial inspection and pay the inspection fee.
05 Once the initial inspection is approved, an initial approval request must be submitted by the applicant.
06 Proceeded with finalizing the license requirements from relevant government departments, such as Civil Defense.
07 Apply for staff licensing (pharmacists).
08 Apply for final inspection and pay the fee.
09 Once the final inspection is approved, submit the final approval request with the remaining documents.
10 If the application is approved, the license fee will be paid.
11 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):
- A copy of owner's passport
- A copy of owner's family book
- A copy of valid ID card
- A recent color photograph
- An introductory statement filled out exclusively by the owner and the responsible pharmacist (the statement is available at any Customer Happiness Center)
- The site's architectural drawing approved by an engineering consultant office

Registration in Tatmeen:
- Location photos

License initial approval:
- Affection plan attested by the municipality
- A copy of the establishment lease agreement
- A copy of the trade name

Final inspection and final approval of the license:
- A copy of trade license issued by the Department of Economic Development
- A copy of license of the pharmacist responsible for pharmaceutical facility
- A copy of a certificate of conformity with preventive safety requirements issued by the civil defense
- A list of partners

Additional documents for marketing offices

Documents required for initial approval:
- A copy of the marketing office's memorandum and articles of association
- A document representing the marketing authorization holder registered with the ministry (the licensed applicant must be a representative of a medical product company registered with MOHAP)
- A copy of the project's feasibility study
- The partnership contract, which includes the owners' right to the capital in accordance with the UAE Companies' Law
- Initial inspection report of the marketing office

Documents required for final approval:
- Approval regarding the pharmacist responsible for the marketing office
- Final inspection report

1. Initial approval of the manufacturing facility
- A copy of the memorandum and articles of association
- A copy of the project's feasibility study
- The partnership contract, which includes the owners' right to the capital in accordance with the UAE Companies' Law
- A copy of the partners' passports
- A copy of the family book (for UAE national partner(s))
- A copy of the national ID card of each partner
- Photos for each partner

This step also includes security approval of each partner separately, and this will be done by filling an 'introductory statement' and attaching a copy of the passport, the family book, the ID card and photos.

Note: The requirements are submitted to the Ministry of Health and Prevention and the initial approval is issued by the Pharmaceutical Licensing Committee after completing security clearances and document submission. The approval granted is valid for 6 months and can be extended upon request.

2. Manufacturing facility construction and preparation
After obtaining the initial approval in step (1), the manufacturing facility must submit detailed engineering drawings of the facility – including the drawings that demonstrate material flow, personnel flow and other technical requirements for good manufacturing practices (GMP) – and obtain approval of drawings from the technical committee concerned within the drug department prior to construction.

After obtaining the technical committee's approval on the drawings, this step also includes submission of the following documents:
- A copy of the Ministry of Industry's approval of the manufacturing facility's project
- A copy of the approval of the planning department or the municipality
- A copy of the approval of the water and electricity department
- A copy of the approval of the municipality regarding sanitation
- A copy of the relevant authorities' approvals regarding environmental pollution
- Copies of detailed engineering drawings of the manufacturing facility (approved by the technical committee)
- A copy of the technical agreement with international expertise houses
- List of pharmaceutical forms or medical means and production lines to be established
- A list of equipment and devices for each production, packaging and sterilization line used in the project
- Explanation of the necessary equipment for the quality control laboratory

After submitting the above-mentioned required documents, the manufacturing facility is ready for inspection (GMP certification inspection) through coordination with the drug department to set an appointment for inspection.

3. Final licensing of the manufacturing facility and good manufacturing practice certificate issuance
After obtaining approval for the construction and preparation stage in step (2), the manufacturing facility must appoint technicians and issue licenses for technicians working in the following jobs: production manager / quality assurance manager / quality control manager.

Note: Pharmacists' license may be replaced by a biomedical engineer license if the manufacturing facility is limited to medical equipment production only.

To obtain the final approval, the following documents must be submitted:
- Site master file
- Technical manager appointment letter and notarized employment contract + MOHAP license
- Production manager appointment letter and notarized employment contract + MOHAP license
- Quality control manager appointment letter and notarized employment contract + MOHAP license
- A copy of the licenses of the staff working in the facility
- List of employees in each department and their responsibilities

After submitting all documents, the manufacturing facility becomes eligible for the final inspection. After final inspection by the inspection team and submission of documents, the final license is issued to the facility.

Requirements & Conditions

- For pharmacies, warehouses and scientific offices, the owner must be a UAE national as per the UAE Companies' Law. The customer must not own more than two pharmacies in the UAE.

The following technical and health conditions must be met in pharmaceutical facilities:
- In 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.html
- In 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.

Service Channels

MOHAP Website: www.mohap.gov.ae
MOHAP Smart App

Resources

- Pharmaceutical_licensing_English_end_user_manual_ver_1
- Circular No. (90) of 2021 of Federal Law No. (8) of 2019 on Medical Products the Profession of Pharmacy and Pharmaceutical Facilities

Average Service Time
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 workingdays from the application receiving date

Assigning inspection team to audit the compliance with good manufacturing practice (GMP): 10 days from the date of receiving the request

Issuance 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

Payment channels
E- Payment

Target Audience
Pharmacies, Warehouses, Manufacturing facilities of pharmaceuticals and medical device, Marketing offices, Warehouses for re-export

Service Locations
- MOHAP website www.mohap.gov.ae
- MOHAP Smart App

Related Services
Pharmacies, warehouses, marketing offices, warehouses for re-export :

1. Ministry of Interior: Obtaining the security approval of the owner
2. Departments of Economic Development: Reserving the trade name
3. Ministry of Health and Prevention: Licensing medical professions/pharmacists
4. Departments of Economic Development: Issuance of a trade license
5. Civil Defense: Issuance of a civil defense certificate

Manufacturing facilities of pharmaceuticals and medical device:

Good manufacturing certificate

Service Bundle
This service is not linked to any bundles

Contact Details
Email
info@mohap.gov.ae
Call Center
80011111

Service Fees

- Application fee: AED 100

Fees for initial inspection, according to the type of facility:
- Warehouses, pharmacies and marketing offices: AED 1,000 per inspection

Final inspection fees, according to the type of facility:
- Warehouses, pharmacies and marketing offices: AED 1,000 per inspection

Final license fees, according to the type of facility:
- Pharmacies and warehouses: AED 7500
- Marketing offices: AED 10,000
- Warehouses for export: AED 10,000

Manufacturing facilities of pharmaceuticals and medical device:
- Application fee: AED 100
- Final inspection fee: AED 3000 per inspection
- Approval fee for architectural plans and drawings: AED 2000
- Fees for final licensing of manufacturing facilities of pharmaceuticals and medical device: AED 50000

Sustainable Development Goals

3 GOOD HEALTH AND WELL-BEING

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)

Economic Development Departments - Registration of Trade Name

Ministry of Health and Prevention - Licensing of Medical Professionals and Pharmacists

Economic Development Departments - Issuance of Trade License

Civil Defense - Issuance of Civil Defense Certificate

MOCCAE- Issuing the Environmental Compliance Certificate

FAQs

1. Is it possible for a non-citizen to own a pharmaceutical establishment?
Yes, provided that the local authority to which the facility belongs issues an approval letter regarding the percentage of foreign ownership.

2. Who should be licenced at the manufacturing facility?
To obtain the final approval for the license, the facility should appoint a licensed experienced pharmacist in the following roles:
- Technical manager
- Quality manager
- Production manager