UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

Registration of A Manufacturer of Medical Products

This service allows the registration of the manufacturing sites of medical products (human) in UAE.

Main service

Medical, Pharmaceutical and Drug Licencing and Registration

Service code

110-04-016-000

Service classification

- Government to business

Service type

Transactional

Service process

1. Login to the MoHAP website or smart app using the UAE PASS
2. Submit the request online and complete the payment to meet all conditions
3. The concerned officer will receive the file, ensure the availability of all documents, and refer the file to the Technical Committee for the registration of human medicines
4. The registration of the manufacturing site will be deliberated by the concerned technical committee and the recommendations shall be submitted with conditional approval (postpone approval until completion of requirements) and applications will be referred to the

Service completion duration

2 to 4 weeks

Payment channels

E-payment

Target audience

Pharmaceutical drug stores
Local manufacturers

Service locations

MOHAP Website

Support

smartservicessupport@mohap.gov.ae
drugreg.inquiries@mohap.gov.ae

Service fees

Application: AED 100
Registration of a medical products manufacturer: AED 10,000

SDGs Goals

Higher Committee for Human Medicines Registration

5 The registration of the manufacturing site will be deliberated by the Higher Committee for final decision (conditional approval, postpone approval until completion of requirements)

6 Communication shall be made with the company and completion of all requirements be requested

7 The registration certificate of the manufacturing site will be issued after the company fulfills the conditions and requirements of the Higher Committee for Human Medicines Registration

8 The issual of the registration certificate of the manufacturing site will be approved

Required documents

1. Required Documents For Registering A (Conventional/GSL/Herbal) Manufacturer:
   - A legalized letter issued by the company on its original letterhead, signed and stamped by the responsible person in the company, authorizing a person or a local establishment to submit the registration file on its behalf, to the Drug Control Department. Attested true by UAE Embassy. This person / the local establishment will be responsible to receive the registration certificate from the Drug Department.
   - Legalized Current GMP Certificate Issued By The Competent Authority In Country Of origin. (Attested True By The UAE Embassy In country of origin).
   - Legalized Valid Manufacturing License Issued By The Competent Authority In Country Of Origin. (Attested True By the UAE Embassy In country of origin).
   - List of medicines manufactured at the manufacturing site.
   - Site Master File.
   - Certified copies of certificates of registration/ certificates of good manufacturing practice of the manufacturing site in other countries.
2. Required Documents For Registering A medical device manufacturing site:
   - A Notarized letter issued by the company on its original letterhead, signed and stamped by the responsible person in the company, authorizing a person or a local establishment to submit the registration files on their behalf, to the Drug Department of ministry of health and prevention.

- Valid legalized ISO 13485 certificate issued by the competent authority in country of origin.
- Require Legalized valid Business licenses / Manufacturing License issued by the competent authority in country of origin (Attested true by the UAE Embassy In country of origin).
- List of the products manufactured and/or assembled by the site.
- Detailed Company profile.

Conditions and requirements

- The applicant must be a medical warehouse licensed by MOHAP and must have a valid license.
- Renewal of registration must be done every 5 years.
- Renewal of registration will be in the same fees and procedures.
- Manufacturing Site Should have a Marketing Authorization Holder (Legal Manufacturer) & it should be registered on Ministry Of Health & Prevention.
- Required documents for MAH registration:
  - The application form (part 1) duly filled, signed and stamped by the responsible person in the company.
  - A legalized letter issued by the company on its original letterhead, signed and stamped by the responsible person in the company, authorizing a person or a local establishment to submit the registration file on its behalf, to the Drug Control Department. Attested true by UAE Embassy. This person / the local establishment will be responsible to receive the registration certificate from the Drug Department.
  - Legalized company license issued by the competent authority in its country origin, showing all its licensed activities there. (attested true by UAE Embassy).
  - Company Profile.
  - List of associated manufacturing facilities, if any.
  - List of all products dealing with, in the country of origin.
  - Evidence of the company's presence in other countries, if available.
- For registration of marketing authorization holder (MAH) in UAE MOHAP, applicant can submit the documents with the site registration application OR by submitting the required documents through the courier to drug department of ministry of health & prevention.

Resources

- Infographic - Registration of A Manufacturer of Medical Products - 376KB.pdf
- Help Manual-293.pdf
- Login User Manual-309.pdf

- Portal Manual-145.pdf
- Site Registration - External User Manual.pdf