Registration of a Manufacturer of Medical Products

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

Department name
Drug

Sector
Health Regulation

Main Service
Medical, Pharmaceutical and Drug Licencing and Registration

Service Code
110-04-016-000

Service Classification
Transactional

Variation / Auxiliary
Variation

Service Type
Government to Business

Average Service Time
2 to 4 weeks

Payment channels
E-Payment

Target Audience
Pharmaceutical drug stores and local manufacturers

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

Related Services
This service is not linked to any other services

Service Bundle
This service is not linked to any bundles

Contact Details
Email:
smartservicessupport@mohap.gov.ae
drugreg.inquiries@mohap.gov.ae

Service Process

01 To apply for e-services, create an account on MOHAP website or smart app with a username and password.

02 Submit the request online and complete the payment to meet all conditions.

03 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.

04 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 Higher Committee for Human Medicines Registration.

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

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

07 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.

08 The issual of the registration certificate of the manufacturing site will be approved.

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 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 by the UAE Embassy in country of origin)
  - Legalized valid manufacturing license issued by the competent authority in country of origin (attested 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
- **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 by the UAE Embassy in country of origin)
  - List of the products manufactured and/or assembled by the site
  - Detailed company profile

Requirements & Conditions

- 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 incur the same fees and follow the same procedures.
- Manufacturing site should have a marketing authorization holder (legal manufacturer) & it should be registered with 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 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, the 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 and Prevention.

Service Channels

MOHAP Website: www.mohap.gov.ae

MOHAP Smart App

Resources

- User Manual
- Login User Manual
- Portal Manual
- Site Registration - External User Manual
- Reference Country List

FAQs

None.

Service Fees

Application fees:
AED 100

Registration of a medical products manufacturer:
AED 10,000

Sustainable Development Goals

3 GOOD HEALTH AND WELL-BEING

Notes

None