# Renewal of the Registration of a Manufacturer of Medical Products

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

**Department name**
Drug

**Sector**
Health Regulation

**Main Service**
Medical, Pharmaceutical and Drug Licencing and Registration

**Service Code**
110-04-016-016

**Service Classification**
Transactional

**Variation / Auxiliary**
Auxiliary

**Service Type**
Government to Business

## 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 it 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 will be submitted with conditional approval (postpone approval until completion of requirements), and 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 request the completion of all requirements.

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 Approval shall be given for the registration certificate of the manufacturing site.

## Required Documents

- **Documents for registering a (conventional medicines/biological medicines/GSL products/natural source medicines) 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 the country of origin. (Attested true by the UAE Embassy in the country of origin)
- Legalized valid manufacturing license issued by the competent authority in the country of origin. (Attested true by the UAE Embassy in the 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.
- **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 the Ministry of Health and Prevention
- Valid legalized ISO 13485 certificate issued by the competent authority in country of origin
- Required legalized valid business licenses/manufacturing license issued by the competent authority in the country of origin (attested true by the UAE Embassy in the 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.

## Service Channels

MOHAP Website: www.mohap.gov.ae

MOHAP Smart App

## Resources

- Required documents for each type of manufacturer
- Site Registration - External User Manual
- Portal Manual
- Login User Manual
- Help Manual
- Reference Country List

**Average Service Time**
2 to 4 weeks

**Payment channels**
E-Payment

**Target Audience**
Medical warehouse, and local pharmaceutical factories

**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 Fees

**Application fees:**
AED 100

**Registration of medical products manufacturer:**
AED 10,000

## Sustainable Development Goals

3 GOOD HEALTH AND WELL-BEING

## Notes

None

## FAQs

**1. What is the fee for renewing the registration of a medical products' manufacturer service?**
- Application fees: AED 100
- Renew Registration of a medical products' manufacturer: AED 10,000

**2. What is the average time for renewing the registration of a medical products' manufacturer service?**
2 - 4 weeks

**3. What is the target group for the registration of a medical products' manufacturer service?**
Drug warehouses, local pharmaceutical manufacturers

**4. What channels are available to apply for the registration of a medical products' manufacturer service?**
MOHAP Website and Smart Application