Renewal of the Registration of a Manufacturer of Medical Products

About the Service

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

Service Process

- Login to the MoHAP website or smart app using the UAE PASS
- Submit the request online and complete the payment to meet all conditions
- 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
- 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
- The registration of the manufacturing site will be deliberated by the Higher Committee for final decision (conditional approval, postpone approval until completion of requirements)
- Communication shall be made with the company and request the completion of all requirements
- 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
- 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

Conditions & Requirements

1. The applicant must be a medical warehouse licensed by MOHAP and must have a valid license
2. Renewal of registration must be done every 5 years
3. Renewal of registration will be in the same fees and procedures

FAQ’s

Service completion duration

- 2 to 4 weeks

Service fees

Service channels

Service locations

- MOHAP Website
- MOHAP Smart Application

Support

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

Payment channels

- E- Payment

Target audience

- Medical Warehouse
- Local Pharmaceutical factories

Resources

- Infographic - Renewal of the Registration of a Manufacturer of Medical Products - PDF 377KB
- Required documents for each type of manufacturer
- Site Registration - External User Manual_637716326133683924
- Portal Manual_637716326139465417
- Login User Manual_637716326134465290
- Help Manual_637716326134152646
- Reference Country List - PDF 21KB

Department name

Drug

Sector name

Health Regulation

Main service

Medical, Pharmaceutical and Drug Licencing and Registration

Service Code

110-04-016-016

Service Classfication

Transactional

Sub Service Type

Auxiliary

Service Type

Government to Business

Number of Users

44

Number of Transactions

269

Sustainable Goals

Good Health And Well-Being