



Renewal of the Registration of a Manufacturer of Medical Products

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



Main service

Medical, Pharmaceutical and Drug Licencing and Registration



Service code

110-04-016-016



Service completion duration

2 to 4 weeks



Payment channels

E-payment



Target audience

Medical Warehouse
Local Pharmaceutical factories



Service locations

[MOHAP Website](#)
MOHAP Smart Application



Support

smartservicesupport@mohap.gov.ae
drugreg.inquiries@mohap.gov.ae



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 it 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 will be submitted with conditional approval (postpone approval until



Service fees

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



SDGs Goals



completion of requirements), and referred to the 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 request the completion of all requirements
- 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 Approval shall be given for the registration certificate of the manufacturing site



Required documents

1. 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.
2. 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 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

Resources

Infographic - Renewal of the Registration of a Manufacturer of

- [Medical Products - 377KB.pdf](#)
- [Required documents for each type of manufacturer-997.pdf](#)

Site Registration - External User

- [Manual_637716326133683924.pdf](#)
- [Portal Manual_637716326139465417.pdf](#)
- [Login User Manual_637716326134465290.pdf](#)
- [Help Manual_637716326134152646.pdf](#)