





SERVICE DESCRIPTION

This service enables clients to submit their applications to register the locations of manufacturers of human medical products within the UAE.

SERVICE CHANNELS

Website

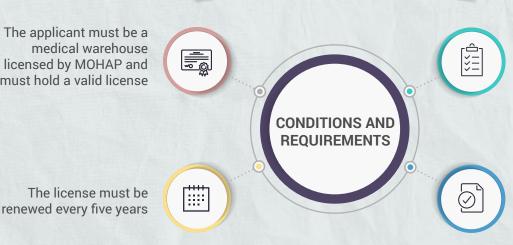


01 Application: AED100

02 Registration of a medical products manufacturer: AED10,000

CONDITIONS AND REQUIREMENTS

The applicant must be a medical warehouse licensed by MOHAP and must hold a valid license



The application must be completed (Part I) in full, signed and stamped by

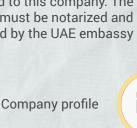
the person in charge of the company

Renewals are subject to the same fees and procedures as new applications

The manufacturer must hold marketing rights (legal manufacturer) and must be registered in the Ministry of Health and Prevention

The company license issued by the authority in the country of origin, indicating all activities licensed to this company. The license must be notarized and certified by the UAE embassy





List of associated

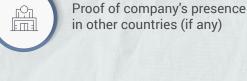
manufacturers (if any)



official letterhead, stamped and signed by the official person in the company and certified by the UAE embassy in the country of origin, must be provided authorizing a representative or a local facility to take responsibility for delivering the registration files to the Department of Medicine List of products handled in the country of origin

An original letter of authorization,

issued by the company on its



The applicant must either submit the documents required for registration via the electronic application services channel or submit the required documents directly to the Department of Medicine in the Ministry of Health and Prevention

REQUIRED DOCUMENTS

Documents required to register the manufacturing site for products (conventional, herbal and public sale):

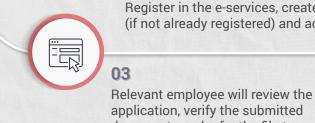
- 1 An original letter issued by the company on its official paper, stamped and signed by the company official, and attested by the UAE embassy in the country of origin, designating responsibility to a person or a local facility to deliver the registration files to the Pharmaceutical Department
- 02 Certificate of good manufacturing practice issued by the authorities in the country of origin and attested by the UAE embassy
- 03 Valid manufacturing license issued by the authorities in the country of origin and attested by the **UAE** embassy
- 04 List of medicines manufactured at the manufacturing site
- **05** Copy of the factory documents file
- Of Copies of the manufacturer's registration certificates/good manufacturing practice certificates attested by other countries

Documents required to register the manufacturing site for medical devices and products: 01 An original letter issued by the company on its official paper, stamped and signed by the company

- official, and notarized by a public notary, designating responsibility to a person or a local facility to deliver the registration files to the Pharmaceutical Department 02 Valid ISO13485 certificate issued by the country of origin and notarized by a public notary
- 03 Valid work license/manufacturing license issued by the competent authority in the country of origin and attested by the UAE embassy in the country of origin
- **04** List of medicines manufactured and/or collected at the manufacturing site **05** Detailed company profile

SERVICE STEPS

Register in the e-services, create a user name and password



(if not already registered) and access the electronic system



documents and refer the file to the technical committee to register such human drugs

Apply to register the manufacturing site and

02

ensure that all documents are available to meet the requirements and pay the fees 05



the conditions and requirements of the Higher Committee for the registration of human drugs

The technical committee will study the application, attach the recommendations with a conditional approval (the final

approval will be issued only after

completion of all requirements), and

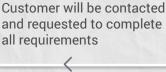
discuss the application and

issue a final decision (conditional approval, the final decision will be issued only after completion of all requirements)

The Higher Committee will

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submit it to the Higher Committee for the registration of human drugs Registration certificate of the manufacturing site will be issued and approved after the company has met





SERVICE LOCATIONS