

## SERVICE NAME / REGISTRATION OF A MANUFACTURER OF MEDICAL PRODUCTS



**DEPARTMENT NAME**  
Drug Department



**SECTOR NAME**  
Public Health and Licensing Sector

### 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



### SERVICE FEES

**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 license must be renewed every five years



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



### CONDITIONS AND REQUIREMENTS

The application must be completed (Part I) in full, signed and stamped by the person in charge of the company



An original letter of authorization, issued by the company on its 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



Proof of company's presence in other countries (if any)



Proof of company's presence in other countries (if any)



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



Company profile



List of associated manufacturers (if any)



### REGISTRATION REQUIREMENTS OF THE MARKETING RIGHTS HOLDER

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):

- 01** 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
- 06** 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

**01**

Register in the e-services, create a user name and password (if not already registered) and access the electronic system



**03**

Relevant employee will review the application, verify the submitted documents and refer the file to the technical committee to register such human drugs

**02**

Apply to register the manufacturing site and ensure that all documents are available to meet the requirements and pay the fees



**04**

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 submit it to the Higher Committee for the registration of human drugs



**05**

The Higher Committee will discuss the application and issue a final decision (conditional approval, the final decision will be issued only after completion of all requirements)



**07**

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



**06**

Customer will be contacted and requested to complete all requirements



**SERVICE LOCATIONS**  
Website