SERVICE NAME / REGISTRATION OF A MANUFACTURER OF MEDICAL PRODUCTS

DEPARTMENT NAME
Drug Department

SECTOR NAME
Public Health and Licensing Sector

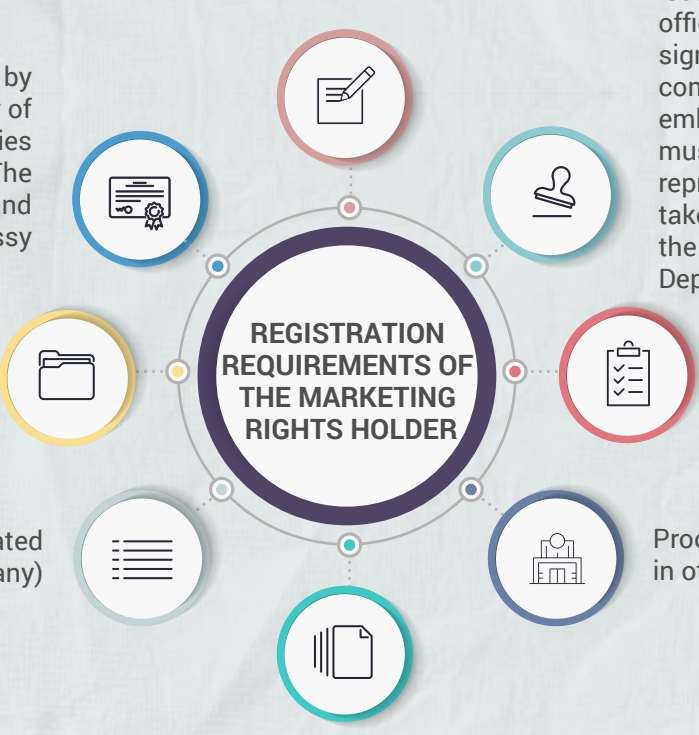
SERVICE DESCRIPTION
This service enables clients to submit their applications to register the locations of manufacturers of human medical products within the UAE.

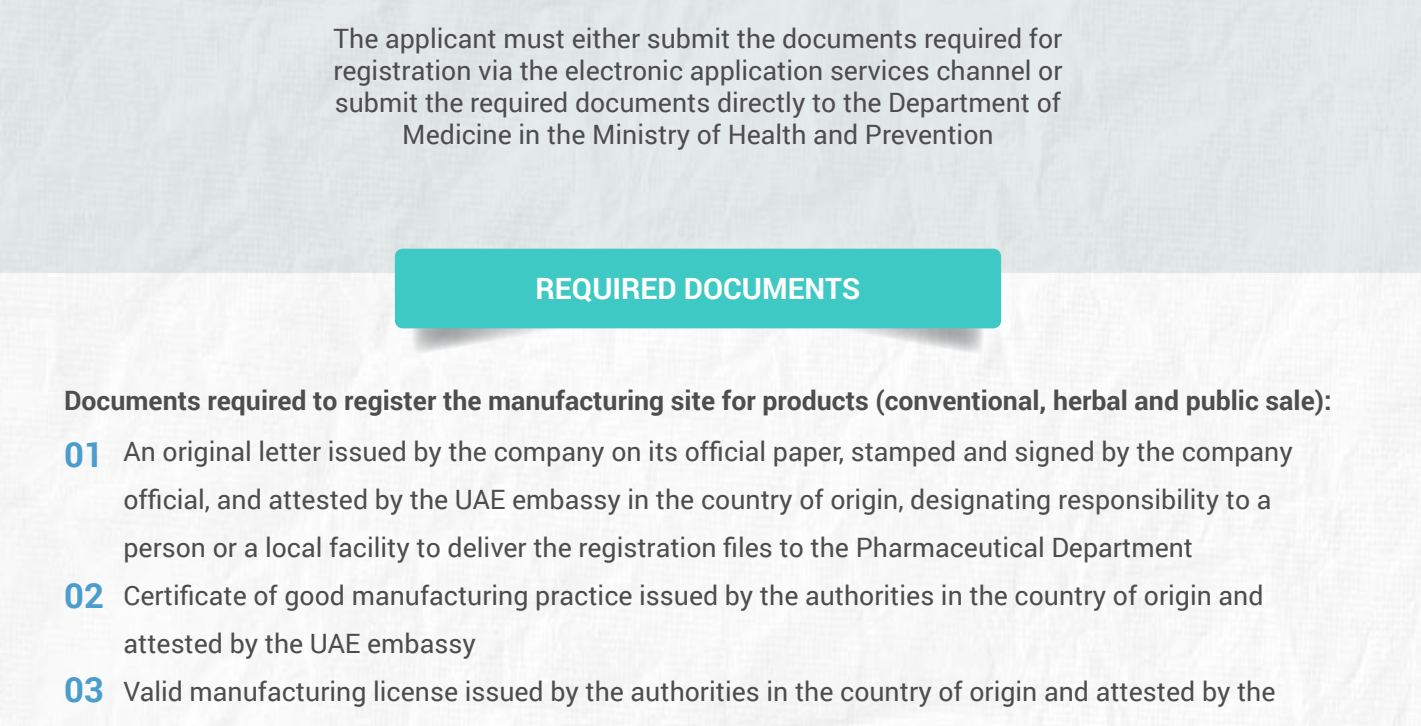
SERVICE CHANNELS
Website

SERVICE FEES
01 **Application:** AED100

02 **Registration of a medical products manufacturer:** AED10,000

CONDITIONS AND REQUIREMENTS





The applicant must 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

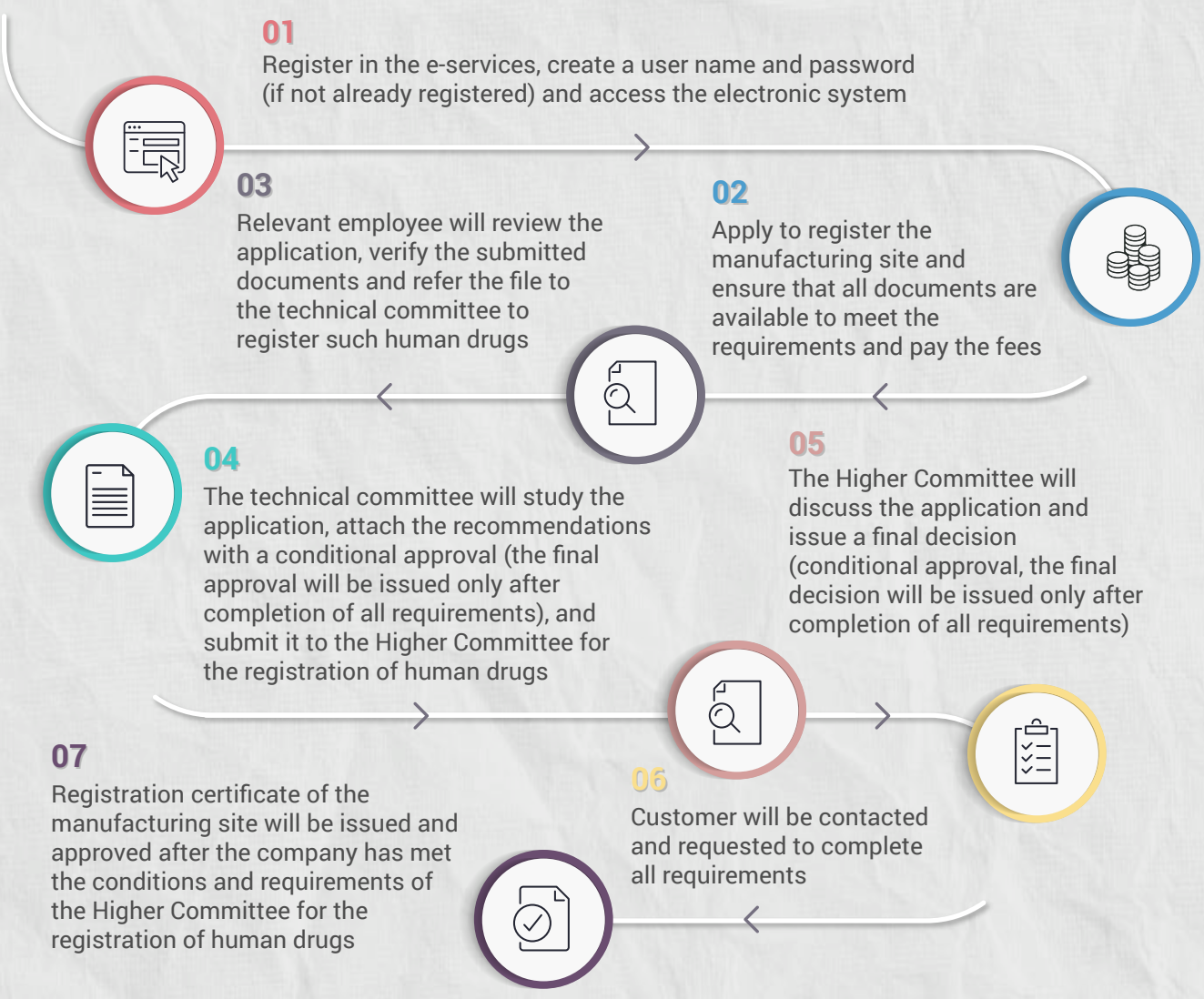
02 Valid ISO13485 certificate issued by the country of origin and notarized by a public notary

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



SERVICE LOCATIONS
Website