Renewal of Registration of a Conventional Pharmaceutical Product

This service enables clients to submit applications to renew the registration of conventional, biological or other human pharmaceutical products for import and trading within the UAE.

Department name
Drug

Sector
Health Regulation

Main Service
Medical, Pharmaceutical and Drug Licencing and Registration

Service Code
110-04-007-007

Service Classification
Transactional

Variation / Auxiliary
Auxiliary

Service Type
Government to Business

Service Process

01 To apply for e-services, create an account on MOHAP with a username and password.

02 Submit the request online, meet all conditions and pay the required fees.

03 The registration officer will review the online application and notify the applicant online.

04 The company should complete the requirements requested by the officer.

05 The customer will follow up with the Analysis Section of at the Drug Department (whenever requested).

06 The certificates of registration renewal will be issued provided all conditions and requirements are fulfilled. They will be valid for five years effective from the last expiry date of the last registration certificate.

Required Documents

- Application to renew the registration of pharmaceutical product signed and stamped [Part A from the MAH and part B from the manufacturing site]
- Certificate of registration of the original product issued by the Ministry of Health & Prevention (whenever requested)
- A recent copy of the certificate of pharmaceutical product [CPP] issued by the concerned authorities in the country of origin attested by the United Arab Emirates Embassy
- Valid copy of the registration certificate of the manufacturer issued by the Ministry of Health & Prevention
- A copy of all certificates of minor changes issued by the Ministry of Health & Prevention
- External packaging data, inner packaging, internal leaflet
- Samples of the pharmaceutical product submitted for renewal within the UAE with the certificate of analysis
- Documents related to the active substances (DMF) or approvals from the concerned authorities, letter from the source (factory) clarifying active ingredient
- Pharmacovigilance system of the company or medical product and risk management plan
- Price certificate (whenever requested)

Requirements & Conditions

- Marketing Authorization Holder companies must be registered by MOHAP before they could register their products.
- The applicant must be a medical warehouse licensed by the Ministry of Health and have a valid license.

Service Channels

MoHAP Website: www.mohap.gov.ae

MoHAP Smart App

Resources

- User Manual

FAQs

None

Average Service Time
The service is available 24 hours daily through the website

Payment channels
E-Payment

Target Audience
Medical warehouses, local pharmaceutical manufacturers

Service Locations
- MoHAP website www.mohap.gov.ae
- MoHAP Smart App

Related Services
This service is not linked to other services

Service Bundle
This service is not linked to any other bundle

Contact Details
Email:
smartservicessupport@mohap.gov.ae
drugreg.inquiries@mohap.gov.ae

Service Fees

Application fees:
AED 100

Registration of a conventional biological pharmaceutical product:
AED 3,500

Sustainable Development Goals

Notes

Marketing Authorization Holder companies must be registered by MOHAP before they could register their products.