UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

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 importation and trading within the UAE.

Main service

Medical, Pharmaceutical and Drug Licencing and Registration

Service code

110-04-007-007

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, meet all conditions and pay the required fees
3. The registration officer will review the online application and notify the applicant online
4. The company should complete the requirements requested by the

Service completion duration

5 working days

Payment channels

E-payment

Target audience

Medical warehouses
Local pharmaceutical manufacturers

Service locations

MOHAP Website

Support

smartservicessupport@mohap.gov.ae
drugreg.inquiries@mohap.gov.ae

Service fees

Application: AED 100
Registration of a conventional biological pharmaceutical product: AED 3,500

SDGs Goals

officer

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

6 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

1. Application to renew the registration of pharmaceutical product a signed and stamped [Part A from the MAH and part B from the manufacturing site].
2. Certificate of registration of the original product issued by the Ministry of Health & Prevention.(whenever requested).
3. 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.
4. Valid copy of the registration certificate of the manufacturer issued by the Ministry of Health & Prevention.
5. A copy of all certificates of minor changes issued by the Ministry of Health & Prevention.
6. External packaging data, inner packaging, internal leaflet.
7. Samples of the pharmaceutical product submitted for renewal within the UAE with the certificate of analysis.
8. Documents related to the active substances (DMF) or approvals from the concerned authorities, letter from the source (factory) clarifying active ingredient.
9. Pharmacovigilance system of the company or medical product and risk management plan.
10. Price certificate (whenever requested).

Conditions and requirements

- 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

1. MOHAP website: www.mohap.gov.ae
2. MOHAP smart app

Resources

- Login User Manual-865.pdf
- Infographic - Renewal of Registration of a Conventional Pharmaceutical Product.pdf