UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

Registration of a Conventional Pharmaceutical Product

This service enables clients to submit applications to register conventional, biological or other human pharmaceutical products to be imported and traded within the UAE.

Department name
Drug

Sector
Health Regulation

Main Service
Medical, Pharmaceutical and Drug Licencing and Registration

Service Code
110-04-007-000

Service Classification
Transactional

Variation / Auxiliary
Variation

Service Type
Government to Business

Service Process

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

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

03 Study the registration file and discuss the pricing of product with the concerned technical committee and then submit report to the concerned ministerial committee.

04 Follow up shall be done online to complete the Stability, Bioequivalence (if required) & Pharmacovigilance section and Analysis through Quality Control Lab.

05 Meet all the requirements and submit the file on the agreed date.

06 The registration of products that have been previously delayed on completion of requirements shall be discussed by the relevant technical and ministerial committees.

07 Price approval letter will be issued after committee approval and price decree after sign by HE The Minister.

08 The certificates of registration of products that have been approved for registration will be issued, which is valid for five years from the date of committee approval.

09 Pharmaceutical certification (for local pharmaceutical products) is valid for one year from the date of issuance.

Required Documents

- The required documents are to be submitted in accordance with the requirements of the standard technical file eCTD (Electronic Common Technical Document)

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

- Login user manual
- Registration of a Conventional Pharmaceutical Product E-CTD Requirements
- Reference Country List

Average Service Time
45 working days

Payment channels
E-Payment

Target Audience
Medical warehouses, local pharmaceutical manufacturers, marketing officers

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

Related Services
- Medical store licensing: Related to licensing department
- Local manufacturer licensing
- Registration of a conventional pharmaceutical product is a pre-requisite for import service

Service Bundle
This service is not linked to any bundles

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

Service Fees

Application fees:
AED 100

Registration of a conventional pharmaceutical product:
AED 7,000

Analysis or re-analysis of a medical product:
AED 3,500

Pricing certificate after committee approval:
AED 500

For PV plan evaluation:
AED 1000

Sustainable Development Goals

3 GOOD HEALTH AND WELL-BEING

Notes

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

FAQs

1. What is the fees for obtaining a registration service for a conventional pharmaceutical product?
- Application: AED 100.
- Registration of a conventional or biological medicine product etc.: AED 7,000.
- Analysis or re-analysis of a medical product: AED 3,500.
- Pricing certificate after committee approval: AED 500.
- For PV plan evaluation – AED 1000.

2. What is the average length of time for the registration of a conventional pharmaceutical product?
45 working days

3. What is the average length of time for the registration of a conventional pharmaceutical product?
- Drug warehouses
- Local pharmaceutical manufacturers
- Marketing officers

4. What channels are available to apply for a conventional pharmaceutical product registration service?
The applications can be submitted through MOHAP website and smart application.