UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

Registration of a Conventional Pharmaceutical Product

This service enables clients to submit applications to register 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

110-04-007-000

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. Study the registration file and discuss the pricing of product with the concerned technical committee and then submit report to the concerned ministerial committee
4. Follow up shall be done online to complete the Stability, Bioequivalence (if required) & Pharmacovigilance section and

Service completion duration

45 working days

Payment channels

E-payment

Target audience

Medical warehouses
Local pharmaceutical manufacturers
Marketing officers

Service locations

MOHAP Website
MOHAP Smart Application

Support

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

Service fees

Application: 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

SDGs Goals

Analysis through Quality Control Lab

5 Meet all the requirements and submit the file on the agreed date

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

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

8 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

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

Required documents

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

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.

Resources

- Infographic - Registration of a Conventional Pharmaceutical Product - 392KB.pdf
- Login User Manual-353.pdf
- Registration of a Conventional Pharmaceutical Produc E-CTD Requirements.xls