Registration of a Conventional Pharmaceutical Product

About the Service

This service enables clients to submit applications to register conventional, biological or other human pharmaceutical products for importation and trading within the UAE.

Service Process

- Login to the MoHAP website or smart app using the UAE PASS
- Submit the request online, meet all conditions and pay the required fees
- Study the registration file and discuss the pricing of product with the concerned technical committee and then submit report to the concerned ministerial committee
- Follow up shall be done online to complete the Stability, Bioequivalence (if required) & Pharmacovigilance section and Analysis through Quality Control Lab
- Meet all the requirements and submit the file on the agreed date
- The registration of products that have been previously delayed on completion of requirements shall be discussed by the relevant technical and ministerial committees
- Price approval letter will be issued after committee approval and price decree after sign by HE The Minister
- 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
- 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)

Conditions & Requirements

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

FAQ’s

Service completion duration

- 45 working days

Service fees

Service channels

Service locations

- Mohab Website
- MOHAP Smart Application

Support

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

Payment channels

- E- Payment

Target audience

- Medical warehouses
- Local pharmaceutical manufacturers
- Marketing officers

Resources

- Infographic - Registration of a Conventional Pharmaceutical Product - PDF 392KB
- Login User Manual
- Registration of a Conventional Pharmaceutical Produc E-CTD Requirements
- Reference Country List - PDF 21KB

Department name

Drug

Sector name

Health Regulation

Main service

Medical, Pharmaceutical and Drug Licencing and Registration

Service Code

110-04-007-000

Service Classfication

Transactional

Sub Service Type

Variation

Service Type

Government to Business

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 with any service packages

Number of Users

46

Number of Transactions

673

Notes

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

Sustainable Goals

Good Health And Well-Being