



## 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.

 <b>Department name</b> Drug	 <b>Sector</b> Health Regulation	 <b>Main Service</b> Medical, Pharmaceutical and Drug Licencing and Registration	 <b>Service Code</b> 110-04-007-000
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 <b>Service Classification</b> Transactional	 <b>Variation / Auxiliary</b> Variation	 <b>Service Type</b> Government to Business
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### 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](http://www.mohap.gov.ae)
 MOHAP Smart App

### Resources

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

### 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.

**Average Service Time**  
45 working days

**Payment channels**  
E-Payment

**Target Audience**  
Medical warehouses, local pharmaceutical manufacturers, marketing officers

**Service Locations**

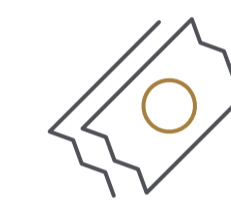
- MOHAP website [www.mohap.gov.ae](http://www.mohap.gov.ae)
- MOHAP Smart App

**Related Services**

- Medical store licencing: Related to licencing department
- Local manufacturer licencing
- 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:**  
[smartservicesupport@mohap.gov.ae](mailto:smartservicesupport@mohap.gov.ae)  
[drugreg.inquiries@mohap.gov.ae](mailto: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



### Notes

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