Amend the Registration Data of a Medical Company or a Manufacturer Licensed to Market

About the Service

This service enables medical companies and manufacturers to submit their applications to amend their registration data.

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
- The competent technical committees will examine the file and refer it to the competent ministerial committee
- Letters are to be addressed to the concerned companies stating the committee's decisions
- The customer will follow up with the Pharmacological Analysis Section of at the Drug Control Department
- The company should complete the requirements and submit them via electronic service
- The relevant technical and ministerial committees will re-deliberate the registration of products that have been deferred in advance as soon as companies complete the requirements
- The certificates of minor changes will be issued after fulfilling all conditions and requirements approved by MOHAP

Required Documents

- A legalized letter issued by the company on its original letterhead, signed and stamped by the responsible person in the company, authorizing a person or a local establishment to submit the registration file on its behalf, to the Drug Control Department. Attested true by UAE Embassy. This person / the local establishment will be responsible to receive the registration certificate from the Drug Control Department
- Legalized Current GMP Certificate Issued By The Competent Authority In Country Of origin. (Attested True By The UAE Embassy In country of origin).
- Legalized Valid Manufacturing License Issued By The Competent Authority In Country Of Origin. (Attested True By the UAE Embassy In country of origin).
- List of medicines manufactured at the manufacturing site.
- Site Master File
- Certified copies of certificates of registration/ certificates of good manufacturing practice of the manufacturing site in other countries.
- A Declaration Letter Issued By The Company On Its Original Letterhead, Signed And Stamped By The Responsible Person In The Company , Showing The Details Of Minor Change With Existing Details & Proposed Minor Changes.
- Current Registration Certificate Issued By MOHAP UAE.

Conditions & Requirements

1. The applicant must be a medical warehouse licensed by MOHAP and must hold a valid license.
2. The Company must provide the valid approval of the competent authorities in the country of origin regarding such submitted changes.

FAQ’s

Service completion duration

- 10 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 offices

Resources

- Help Manual
- Login User Manual
- Portal Manual
- Site Registration - External User Manual
- Infographic_Issue of a Certificate to Amend the Registration Data of a Medical Company or a Manufacturer Licensed to Market

Department name

Drug

Sector name

Health Regulation

Main service

Medical, Pharmaceutical and Drug Licencing and Registration

Service Code

110-04-009-000

Service Classfication

Transactional

Sub Service Type

Variation

Service Type

Government to Business

Related Services

- This service is not linked with other services

Service Bundle

This service is not linked with any service packages

Number of Users

14

Number of Transactions

78

Notes

This service accepts documents authenticated with the UAE PASS Digital Seal.

Sustainable Goals

Good Health And Well-Being