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

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

Department name
Drug

Sector
Health Regulation

Main Service
Medical, Pharmaceutical and Drug Licencing and Registration

Service Code
110-04-009-000

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 The competent technical committees will examine the file and refer it to the competent ministerial committee.

04 Letters are to be addressed to the concerned companies stating the committee's decisions.

05 The customer will follow up with the Pharmacological Analysis Section of at the Drug Control Department.

06 The company should complete the requirements and submit them via electronic service.

07 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.

08 The certificates of minor changes will be issued after fulfiling 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 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 by the UAE Embassy in country of origin)
- Legalized valid manufacturing license issued by the competent authority in country of origin. (Attested 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

Requirements & Conditions

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

Service Channels

MoHAP Website: www.mohap.gov.ae

MoHAP Smart App

Resources

- Help Manual
- Login User Manual
- Portal Manual
- Site Registration - External User Manual

Average Service Time
10 working days

Payment channels
E-Payment

Target Audience
Medical warehouses, local pharmaceutical manufacturers, marketing offices

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

Related Services
This service is not linked to other services

Service Bundle
This service is not linked to any other bundle

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

Service Fees

AED 2000

Sustainable Development Goals

Notes

-

FAQs

1. What are the fees for the issuance of an amendment certificate concerning any registration date of a medical company or a manufacturer holding the marketing rights?

Amendment certificate concerning any registration date of a medical company or a manufacturer holding the marketing rights: AED 2,000

2. What is the average length of time for the issuance of an amendment certificate concerning any registration date of a medical company or a manufacturer holding the marketing rights?

10 working days

3. What channels are available to apply for the issuance of an amendment certificate concerning any registration date of a medical company or a manufacturer holding the marketing rights?

MOHAP website and smart application