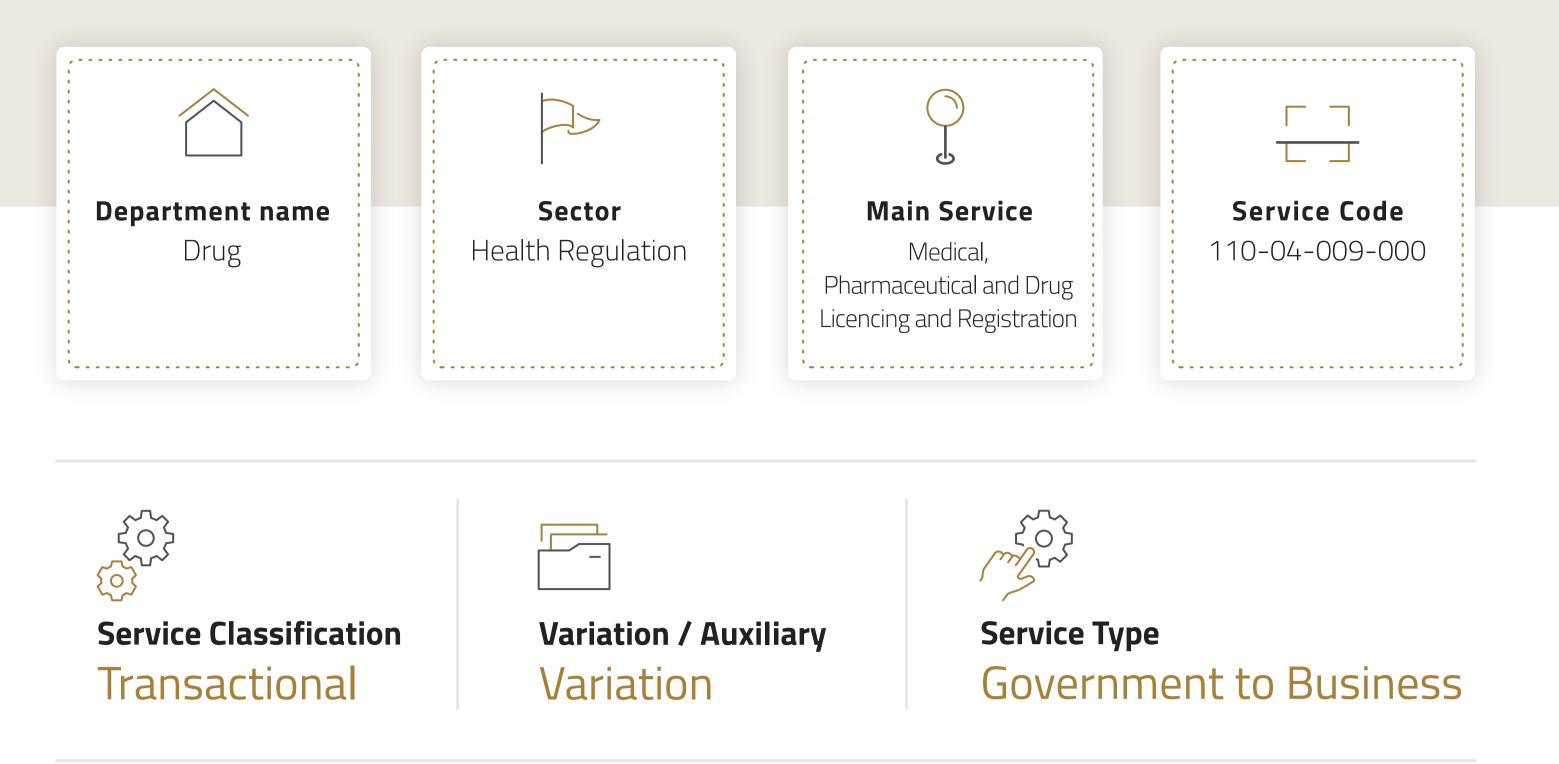
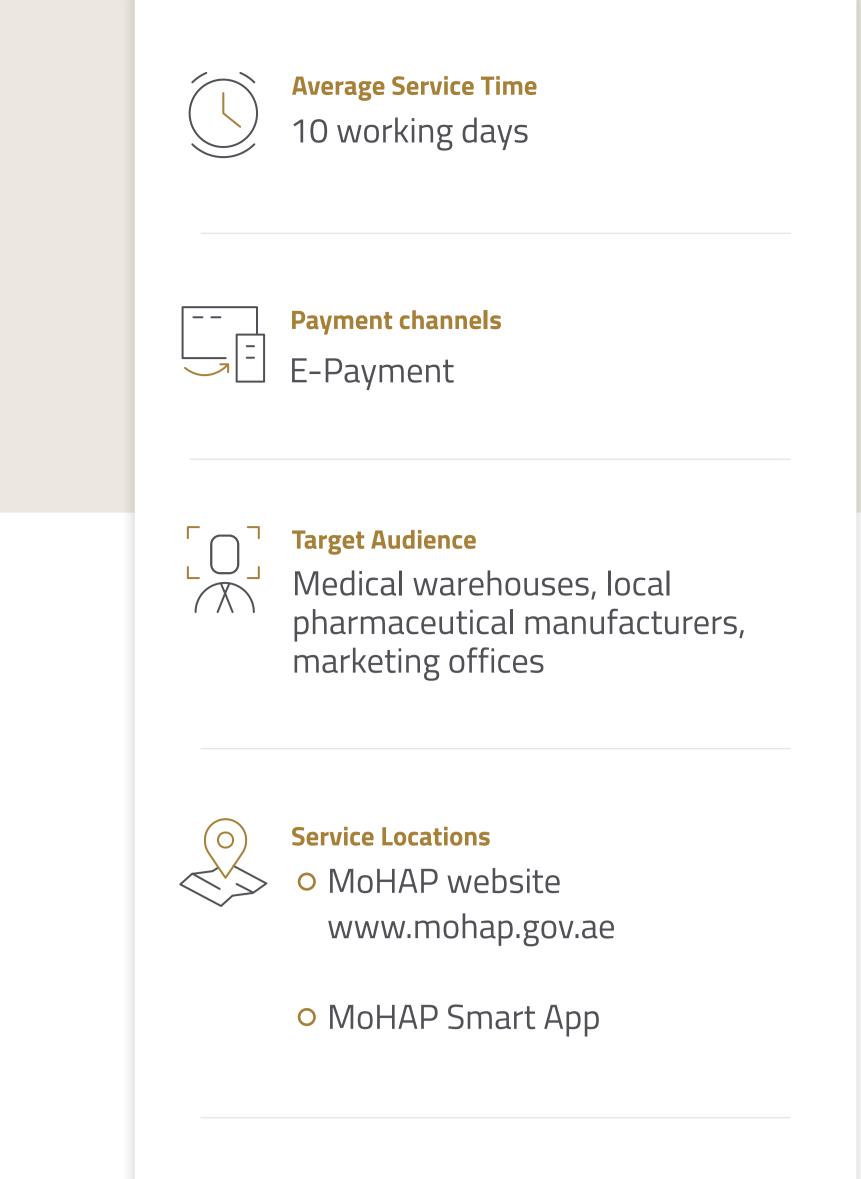




# Issue of a Certificate to Amend the Registration **Data of a Medical Company or a Manufacturer Licensed to Market**

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









#### **Service Process**



To apply for e-services, create an account on MOHAP website or smart app with a username and password.

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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 fulfiling all conditions and requirements approved by MOHAP.



**Service Bundle** This service is not linked to any other bundle



**Contact Details Email:** 

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



## **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

# Sustainable **Development Goals**



- 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

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# **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 Ο regarding such submitted changes.

### **Service Channels**

### Notes





#### Resources

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

# 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