UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

Renewal of Registration of Medical Equipment

This service allows the renewal of registration of medical equipment with the purpose of importing and trading them in the UAE.

Department Name
Drug

Sector
Health Regulation

Main Service
Medical, Pharmaceutical and Drug Licencing and Registration

Service Code
110-04-013-013

Service Classification
Transactional

Variation / Auxiliary
Auxiliary

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 and complete the payment to meet all conditions.

03 The competent technical committees will deliberate the registration of products and recommendations shall be submitted to the competent ministerial committee.

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

05 The customer shall follow up with the Analysis Section of at the Drug Department.

06 The company should complete the requirements and submit them online.

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 registration of products that have been approved for registration will be issued, provided all the conditions and requirements are met. Registration certificates are valid for five years effective the date of last expiry date of the previous certificate.

09 The pharmaceutical certificates (for locally manufactured pharmaceutical products) will be issued and be valid for one year effective the date of issuance.

Required Documents

- The application form of renewing the registration of medical equipment and reagents
- The original registration certificate of the product issued previously by the Drug Control Department
- A valid manufacturing certificate of the factory issued by MOHAP
- Certificate of free sale/ registration issued by the competent authorities in the country of origin
- A copy of all minor changes certificates issued by the Drug Control Department and certificates of quality conformity/ marketing authorization, such as EC (European Conformity), 510 K (Premarket Notification), PMA (Parts Manufacturer Approval) as per the classification of the equipment, i.e. Class I, II, III, IV
- Post-marketing monitoring requirements
- Providing 3 samples (as per equipment type), certificate of analysis (as per equipment type), external and internal covers and brochures
- Acknowledgment of the company that equipment conforms to the specifications as per the Medical Equipment Manual (EC (European Conformity)-Declaration of Conformity)

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

MOHAP Smart App

Resources

- Medical warehouses, and local pharmaceutical manufacturers
- Pricing rules

Average Service Time
15 working days

Payment channels
E-Payment

Target Audience
Medical warehouses, and local pharmaceutical manufacturers

Service Locations
- MOHAP Website
  www.mohap.gov.ae
- MOHAP Smart App

Related Services
This service is not linked to any other services

Service Bundle
This service is not linked to any bundles

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

Service Fees

Application: AED 100

Renewal of the registration of a medical device: AED 2500

Sustainable Development Goals

3 GOOD HEALTH AND WELL-BEING

Notes

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

FAQs

None.