UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

Registration of a Medical Equipment

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

Main service

Medical, Pharmaceutical and Drug Licencing and Registration

Service code

110-04-013-000

Service classification

- Government to business

Service type

Transactional

Service process

1. Login to the MoHAP website or smart app using the UAE PASS
2. Submit the request through the electronic service and complete the payment to meet all conditions
3. The competent technical committees will deliberate the registration of products and recommendations shall be submitted to the competent ministerial committee
4. Letters shall be addressed to the concerned companies stating the committee's decisions

Service completion duration

45 working days

Payment channels

E-payment

Target audience

Medical warehouses
Local pharmaceutical manufacturers
Marketing offices

Service locations

MOHAP Website
MOHAP Smart Application

Support

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

Service fees

Application: 100 AED
Registration of a medical device: 5,000 AED

SDGs Goals

3 GOOD HEALTH AND WELL-BEING

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

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

7 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

8 The certificates of registration of products that have been approved for registration will be issued, provided all conditions and requirements are fulfilled. Registration certificates are valid for five years effective the date of committee's approval

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

Required documents

1. Filling out the application form of registration completely and to be signed and stamped by company.
2. A copy of valid registration certificate of the factory.
3. A valid certificate of free sale/ registration issued by the competent authorities in the country of origin certified by the Embassy of the United Arab Emirates.
4. A copy of the product agency contract signed between the company and the agent.
5. Certificate 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.
6. Post-marketing monitoring requirements.
7. Product's information, including: description, formulation, types, sizes, models, accessories, usages, side effects, contradictions, warnings, precautions, usage guidelines, photos of packaging covers, brochures and usage manuals.
8. Provide laboratory requirements and analysis, as well as pricing for certain medical equipment.
9. Providing one samples, certificate of analysis (as per equipment type), external and internal covers and brochures.
10. Acknowledgement of the company that equipment conforms to the specifications as per the Medical Equipment Manual (EC(European Conformity)-Declaration

of Conformity)

11. Safety and efficacy data (for products classified as Class III, IV).
12. Special requirements: Certificate of conformity to equipment manufactured from animal products.

Conditions and requirements

- Marketing Authorization Holder companies must be registered by MOHAP before they could register their products.
- The marketing office or medical warehouse must be licensed by the Ministry of Health and have a valid license.

Resources

- Pricing Rules-128.pdf
- Drug Registration - External User Manual-163.pdf
- Help Manual-265.pdf
- Login User Manual-41.pdf
- Portal Manual-790.pdf
- Infographic - Registration of a Medical Equipment - 420KB.pdf