Registration of Pharmaceutical Product for General Sale

This service enables the customers to submit applications to register simple pharmaceutical products with limited medicinal usage, which cannot be considered medicines and are intended for general sale. These include products such as dietary supplements,medical cosmetics and medical disinfectants.

Department name
Drug

Sector
Health Regulation

Main Service
Medical, Pharmaceutical and Drug Licencing and Registration

Service Code
110-04-011-000

Service Classification
Transactional

Variation / Auxiliary
Variation

Service Type
Government to Business

Average Service Time
45 working days

Payment channels
E-Payment

Target Audience
Medical warehouses, local pharmaceutical manufacturers, marketing officers

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 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 through the electronic service and complete the payment to meet all conditions.

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

04 Declarations shall be addressed to the concerned companies stating the committee's decisions via the e-system.

05 The customer will follow up with the Pharmacological 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 Issuing certificates of registration of products that have been approved for registration following fulfilling all conditions and requirements. Registration certificates are valid for five years effective the date of committee approval.

09 Issuing pharmaceutical certificates (for locally manufactured pharmaceutical products) valid for one year effective the date of issuance.

Required Documents

- Certificate of pharmaceutical product in accordance with the WHO (World Health Organization) system or a certificate of free sale of the product issued by the competent authorities in the country of origin and certified by the Embassy of the United Arab Emirates. It should contain the following information:
  - Product Brand Name: If the brand name required to be registered in UAE is different from the name in the country of origin, this shall be made clear in the certificate, besides stating the reason for that and making both names clear with an emphasis on their conformity in terms of formulation and other specifications
  - The detailed formulation of the product contains active and inactive substances with their quantities and functions of inactive substances
  - Name of the company entitled to marketing/ manufacturing/ manufacturing sites/ subcontract manufacturers along with their addresses
- One sample of the product
- A valid registration certificate of the manufacturing company issued by MOHAP-UAE with intended production line
- Halal certificate issued by certified authorities and organizations
- A statement issued by the company confirming that the product to be registered is free of hormones, heavy metals, antibiotics, steroids, pig derivatives and any other natural or chemical substances that have a harmful impact on human beings biologically and behaviorally
- If the product contains animal derived substances, the animal type and the part extracted from it should be mentioned with the percentage of alcohol used "if any and why it is used"
- A copy of the certified contract signed between the marketing company and local agent indicating the products for which the agent will be responsible
- A certified certificate from the competent authorities of the country of origin stating that the materials used in manufacturing the product is free from mad cow disease and its causes (if the product contains substances classified as potential substances for transmitting the disease) (Bovine Spongiform Encephalopathy (BSE)/ Transmissible Spongiform Encephalopathies (TSE) free certificate)
- A copy of the outer and inner cover and the leaflet printed on letterhead paper stamped by the company and signed by the authorized person
- Detailed composition certificate (active & inactive ingredients with their quantities)
- Summary of product characteristics (SPC)

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

- Portal manual_637716056042464487
- Login user manual_637716056042643318
- Help manual_6377160560 41058138
- Pricing rules

Service Fees

Application fees:
AED 100

Registration of a pharmaceutical product for general sale:
AED 5000

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

1. What are the fees for the registration of a pharmaceutical product for general sale?
- Application: AED 100
- Registration of a pharmaceutical product for general sale: AED 5,000

2. What is the average length of time for the registration of a pharmaceutical product for general sale?
45 working days

3. What is the target group for a pharmaceutical product registration service with general sales?
Drug warehouses, local pharmaceutical manufacturers, marketing officers

4. What are the conditions and requirements for obtaining a pharmaceutical product registration service with general sales?
- Marketing authorization holder companies and product manufacturing sites must be registered in MOHAP prior to the registration of their products.
- The applicant must be a medical warehouse licensed by the Ministry of Health and Prevention and must hold a valid license.