Registration of Pharmaceutical Product for General Sale

About the Service

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.

Service Process

- Login to the MoHAP website or smart app using the UAE PASS
- Submit the request through the electronic service and complete the payment to meet all conditions
- The competent technical committees will deliberate the registration of products and recommendations will be submitted to the competent ministerial committee
- Declarations shall be addressed to the concerned companies stating the committee's decisions via the e- system
- The customer will follow up with the Pharmacological Analysis Section of at the Drug Department
- The company should complete the requirements and submit them online
- 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
- 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
- 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 specificationsThe detailed formulation of the product contains active and inactive substances with their quantities and functions of inactive substancesName of the company entitled to marketing/ manufacturing/ manufacturing sites/ subcontract manufacturers along with their addresses
- One samples 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).

Conditions & Requirements

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

FAQ’s

Service completion duration

- 45 working days

Service fees

Service channels

Service locations

- Mohab Website
- MOHAP smart app

Support

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

Payment channels

- E- Payment

Target audience

- Medical warehouses
- Local pharmaceutical manufacturers
- Marketing officers

Resources

- Infographic - Registration of Pharmaceutical Product for General Sale - PDF 384KB
- Portal Manual_637716056042464487

- Login User Manual_637716056042643318
- Help Manual_637716056041058138

Department name

Drug

Sector name

Health Regulation

Main service

Medical, Pharmaceutical and Drug Licencing and Registration

Service Code

110-04-011-000

Service Classfication

Transactional

Sub Service Type

Variation

Service Type

Government to Business

Related Services

- This service is not linked with other services

Service Bundle

This service is not linked with any service packages

Number of Users

43

Number of Transactions

336

Notes

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

This service accepts documents authenticated with the UAE PASS Digital Seal.

Sustainable Goals

Good Health And Well-Being