Renewal of Registration of a **Pharmaceutical Product for General Sale**

This service enables applications for the renewal of registrations of 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.



Main service

Medical, Pharmaceutical and Drug Licencing and Registration



Service code

110-04-011-011



15 Working days

Payment channels

E-payment

rga Target audience

Medical warehouses Local pharmaceutical manufacturers

Service locations

MOHAP Website

Support

smartservicessupport@mohap.gov.ae <u>drugreg.inquiries@mohap.gov.ae</u>



Service classification

Government to business



Service type

Transactional

Service process

Login to the MoHAP website or smart app using the UAE PASS

Submit the request online, complete the payment and meet all conditions

The registration renewal file will be examined and companies will receive a letter stating the specific requirements

Service fees

Application: AED 100 Renewal of the registration of pharmaceutical product for general sale: AED 2,500



SDGs Goals





- The customer shall follow up with the Analysis Section of at the Drug Department
- The company should complete the requirements and submit them online
- The certificates of registration of products that have been approved for registration will be issued, provide all the conditions and requirements are met. Registration certificates are valid for five years effective from the last expiry date of the last registration certificate
- 7 The pharmaceutical certificates (for locally manufactured pharmaceutical products) will be issued, valid for one year effective the date of issuance



Required documents

- 1. Filling out the application form for renewal of registration of pharmaceutical products with general sale completely and to be signed and stamped by company.
- 2. A copy of a valid certificate of a pharmaceutical/ free sale product.
- 3. A valid manufacturing certificate of the factory issued by MOHAP.
- 4. The original registration certificate issued by MOHAP.
- 5. The original registration certificate of the product issued previously by the Drug Department.
- 6. A new copy of the product registration certificate issued by the competent authorities in the country of origin certified by the Embassy of the United Arab Emirates.
- 7. A valid registration certificate of manufacturing location issued by the Drug Control Department.
- 8. A copy of all minor changes certificates issued by the Drug Department.
- 9. The outer cover, the inner poster and the internal leaflet.
- 10. Original 2 samples of the product used in UAE.



Conditions and requirements

 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.

Resources

Infographic - Registration of Pharmaceutical Product for General

- Sale 384KB.pdf
- Drug Registration External User Manual-558.pdf
- Help Manual-604.pdf
- Login User Manual-832.pdf
- Portal Manual-564.pdf
- Pricing Rules-742.pdf