Classification of a product

This service allows the classification of products of all types and forms based on Presentation / Composition / Use and Design. Requirements may vary based on the nature of the product, risk class and regulatory status.



Main service

Medical, Pharmaceutical and Drug Licencing and Registration



Service code

110-04-008-000



Service classification

Government to business



Service type

Transactional

(Service completion duration

10 working days



Payment channels

E-payment



റ്റൂ Target audience

Medical warehouses Pharmaceutical manufacturers Local facilities Individuals



Mohap Website MOHAP Smart Application



⊗ Support

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

Service process

- Login to the MoHAP website or smart app using the UAE PASS
- Fill the product details
- Attach the required documents
- Make payment & submit the application



Service fees

Classification of product Fees: AED 500



SDGs Goals





Required documents

- 1. Emirates ID or the applicant's passport or trade license or drug store license (depends on the user type) (mandatory)
- 2. Certificate from the regulatory authority of the country-of-origin, related to the submitted product (copy of the CPP/free sale certificate/CFG/CE/ISO) along with English or Arabic translation (mandatory) [CPP: Certificate of pharmaceutical product; CFG: Certificate to foreign government; CE: European conformity; ISO: International organization for standardization with submitted product name]
- 3. A photo of the product (mandatory)
- 4. Leaflet/product information in English/Arabic (mandatory)
- 5. Product catalogue for medical devices
- 6. Inner pack label with clear and readable product name and information (artwork)
- 7. Outer pack label with clear and readable product name and information (artwork)
- 8. Composition Certificate (Active/ Inactive ingredient list with each ingredients quantity)/ MSDS (applicable for product that have Medicinal/Chemical Ingredients in it) MSDS:
 Material Safety Data Sheet.
- Registration and Marketing Status in other Countries (Copy of the Certificates along with English or Arabic Translation from Reference Countries approved by UAE MOHAP (Reference Country List Attached Above) / CE Certificate from EU approved Notified Body for the submitted Product) [CE: European Conformity. EU: European Union.]
- 10. Product Sample in their Final Original Pack (Upon Request)
- 11. MOHAP Quality Control Lab Analysis Report (Upon Request)
- 12. Letter of Authorisation from Marketing Authorization Holder (Upon Request)



Conditions and requirements

- The purpose of the Classification letter is to inform you about the laws governing your products within UAE.
- The classification letter identifies the product classification if the product needs or does not need registration by MOHAP. If it is determined that it needs registration by MOHAP, it must be registered in MOHAP according to the class identified in the classification letter.
- Classification is available for all types of Companies and for Individuals.
- For more information regarding the conditions and requirements, please check the resources.

Resources

- Infographic Classification of a product 372KB.pdf
- User Manual-751.pdf
- Login User Manual-421.pdf
- Portal Manual.pdf
- Help Manual.pdf
- Classification of a Product- Guidelines-277.pdf