Issue of Permit to Import Medical Equipment

About the Service

This service allows obtaining a permit to import medical equipment for the local agent who holds a valid medical store license issued by MOHAP.

Service Process

- Login to the MoHAP website or smart app using the UAE PASS
- Submit an initial import permit application before shipping from the country of origin, and then pay the application fee
- If the requirements and conditions are met, the initial import permit application will be approved with sixty days validity, during which the shipment from the country of origin can be prepared.
- In completion of the second stage, the applicant submits a shipment clearance application - upon obtaining the Air Way Bill (Air) / Bill of Lading (Sea) / Truck Way Bill (Consignment Note) (Road) - and pays the due fees.
- In the event that the requirements and conditions are met, the approval is obtained electronically and the permission is printed from the electronic system. The permit is valid for sixty days from the date of its issuance and is conditional on the approval of the Ministry's inspectors for customs clearance then the inspection for the release to loacl market (for medicated medical devices).

Required Documents

- The first stage: Pre-import permit: The submission is made through the electronic system of import to obtain the initial approval for import before starting to ship from the country of origin, and it requires attaching the following documents: The invoice (Commercial Invoice or Invoice) issued by the manufacturer / marketing authorization holder, including the country of origin, production, and expiry dates for each batch. The remaining shelf life of the product must not be less than two-thirds of the total shelf life.Catalogue, or brochure or photos for each product arranged as mentioned in the invoice.Valid US Food and Drug Authority (FDA) registration certificate, or valid (ISO13485 and EC) quality certificates, or valid Free Sale Certificate (FSC) from the country of origin, or valid Good Manufacturing Practice certificate (GMP) (upon request).Product Minor Variation Certificate (MVC) - if any.Valid product classification certificate (upon request).Authorisation letter for distribution in the UAE from the manufacturer to the local agent - for the products that do not need to obtain marketing authorisation approval (as per their classificaiton).An import permit from the Federal Authority for Nuclear Regulation (FANR) - to import diagnostic radiological devices that emit ionizing radiation (X-ray and Gamma rays), for example: radiography, medical imaging and radiotherapy, fluoroscopy, mammography, Radiotherapy and CT scan.Batch Release Certificate (BRC) issued by MOHAP according to the batch number - in case the product contains human blood, plasma or tissue.European Directorate for Quality of Medicines and Healthcare (EDQM) Certificate of Suitability (if the product contains gelatin from an animal source).Import Authorization of Narcotic, Controlled or Semi-controlled Drugs - for Narcotic, controlled and semi-controlled drugs.In case of importing from the designated free zones in the country, the following must be provided:
- The second stage: Shipment Clearance Permission: The application is submitted when the freight bill is issued, and it requires attaching the following documents: Air Way Bill (Air) / Bill of Lading (Sea) / Truck Way Bill (Consignment Note) (Road), noting the necessity of shipping in temperature controlled containers, while adhering to the

Ministerial decree No. 22 of 2022.The packing list must include the total weight and the number of packages.Original Certificates of Analysis (C.O.A) for all imported batches and must include production and expiry dates and be issued by the batch releaser (to be viewed upon request from MOHAP inspectors) (for medicated medical devices).

Conditions & Requirements

1. Obtaining marketing authorization approval from Ministry Of Health & Prevention.
2. Products may only be imported by the local agent mentioned in the product's marketing authorization approval.
3. One commercial invoice is attached to each initial import permit application.
4. It is allowed to include more than one initial import permit application under the shipment clearance application, provided that they are all under the same Bill of Lading, Air Way Bill, Truck Way Bill (Consignment Note) provided that the shipment contains products subject to the Ministry of Health & Prevention only.
5. Obtaining electronic shipment clearance permits.
6. Inspection at the customs port by MOHAP inspectors.
7. Inspection to release the shipment for distribution in the local market (for medicated medical devices).

FAQ's

Service completion duration

- Pre-permit applications: Three working days - Shipment clearance applications: Two working days

Service fees

Service channels

Service locations

- MOHAP Website: www.mohap.gov.ae
- MOHAP smart App

Support

- Information Technology: mohap.appsupport@mohap.gov.ae
- Import & export regulation section: import.export@mohap.gov.ae
- Call Center: 80011111

Payment channels

- E- Payment

Target audience

- Medical store with a valid license issued from the Ministry of Health and Prevention

Resources

- Minister Resolution No 22 of 2022 Regulating the transportation storage and distribution of medicinal products or raw materials used in their manufacture - Available in Arabic - PDF 806KB

- User Manual - Issue of Permit to Import Medical Equipment - PDF 1317KB

Department name

Drug

Sector name

Health Regulation

Main service

Clearance, Import and Export Permits

Service Code

110-02-007-000

Service Classfication

Transactional

Service Type

Government to Business

Related Services

- Licenses, for all medical products.
- BRC (Batch Release Certificate) for biological products.
- Authorization to import narcotic, controlled or semi-controlled drugs, for narcotic products, controlled and semi-controlled substances.
- Import permit from the Federal Authority for Nuclear Regulation (FANR), for radioactive products, materials and radiation devices.
- Inspection before customs release of shipments and before distribution locally in the market (for medicated medical devices).

Service Bundle

This service is not linked to any bundles

Number of Users

40416

Number of Transactions

30314

Notes

None

Sustainable Goals

Good Health And Well-Being