






## Issue of Permit to Import Medical Equipment

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

 <b>Department name</b> Drug	 <b>Sector</b> Health Regulation	 <b>Main Service</b> Clearance, Import and Export Permits	 <b>Service Code</b> 110-02-007-000
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 <b>Service Classification</b> Transactional	 <b>Variation / Auxiliary</b> Variation	 <b>Service Type</b> Government to Business
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## Service Process

- 01 Login to the MOHAP website or smart app using the UAE PASS
- 02 Submit an initial import permit application before shipping from the country of origin, and then pay the application fee.
- 03 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.
- 04 In the second stage, the applicant needs to submit 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.
- 05 If the requirements and conditions are met, the approval will be obtained electronically, and the permission is printed from the e-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 and the inspection for the release to local 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 letter issued by MOHAP (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 classification).
- 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:**

- A valid MOHAP marketing office license of Marketing Authorization Holder (MAH).
- A valid certificate of Good Storage and Distribution Practice (GSDP) issued by MOHAP to MAH (Marketing Authorization Holder).

**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).



## Requirements & Conditions

- Obtaining marketing authorization approval from Ministry Of Health & Prevention.
- Products may only be imported by the local agent mentioned in the product's marketing authorization approval.
- One commercial invoice is attached to each initial import permit application.
- 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.
- Obtaining electronic shipment clearance permits.
- Inspection at the customs port by MOHAP inspectors.
- Inspection to release the shipment for distribution in the local market (for medicated medical devices).

## Service Channels



MOHAP Website: [www.mohap.gov.ae](http://www.mohap.gov.ae)



MOHAP Smart App



MOHAP offices at customs ports: only to release the shipment directly to the importing medical store after printing the electronic shipment clearance permit and presenting the documents related to conformity to the Ministry's inspectors, and before distribution in the local market (for medicated medical devices)

## Resources

- MOH - ImportExport-AgentManual V4
- Ministerial decree No. 22 for the year 2022 regarding organizing the transportation, storage and distribution of medical products or the raw materials used in their manufacture

## FAQs

### 1. How to know the pharmaceutical or therapeutic product or alternative that has obtained marketing approval in the country?

Through the following link: <https://www.mohap.gov.ae/ar/services/Pages/drug-directory.aspx>, In the event that a search result does not appear in the above link, please send the inquiry to the Import and Export Regulation Department through the e-mail: [Import.export@mohap.gov.ae](mailto:Import.export@mohap.gov.ae)

### 2. How can I obtain the import authorization of the Regulation of Controlled Substances and products for Narcotic Drugs, Controlled or semi-controlled products?

Through the following link: <https://smartforms.moh.gov.ae/DEI>

### 3. How can I apply for a Batch Release Certificate (in case the product is a biological derivative and vaccine - issued by the Ministry of Health & Prevention according to the batch number)?

Apply through the link below: <https://smartforms.moh.gov.ae/DEI>

### 4. How can I issue an import permit from the Federal Authority for Nuclear Regulation (mandatory for radioactive products and materials)?

Communicate with the authority through the website link: <https://www.fanr.gov.ae/ar/Pages/default.aspx>

### 5. How can I inquire about how to obtain marketing approval for the product?

Communicate with the Medical Products Regulatory Department through e-mail: [DrugReg.inquiries@mohap.gov.ae](mailto:DrugReg.inquiries@mohap.gov.ae)



### Average Service Time

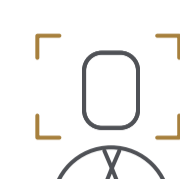
Pre-permit applications:  
3 working days

Shipment clearance applications:  
2 working days



### Payment channels

E- Payment



### Target Audience

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



### Service Locations

- MOHAP Website  
[www.mohap.gov.ae](http://www.mohap.gov.ae)

- MOHAP Smart App



### 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



### Contact Details

#### Information Technology:

[mohap.appsupport@mohap.gov.ae](mailto:mohap.appsupport@mohap.gov.ae)

#### Import & export regulation section:

[import.export@mohap.gov.ae](mailto:import.export@mohap.gov.ae)

#### Call Center

80011111



## Service Fees

### Application fee:

AED 100

### Shipment clearance issuance fee:

%1 of the invoice value for the CIF price, not less than

AED 200 per invoice

## Sustainable Development Goals



## Notes

None