General Requirements

For the Rules and Procedures Governing the Export of Pharmaceutical Products and Medical Supplies

Code: NP.PPMA.007

Version No: 1

Version date: 2020

Effective date: 2020

Documents

1. Documents Required to Obtain Export Approval:

1.1. An export request on the exporting company's letterhead **stamped with the company seal and approved by the responsible official** (the head of the entity or their authorized representative).

1.2. A declaration on the company's letterhead, **stamped with the exporting company's seal, stating that the export process is the sole responsibility of the company**, with no liability whatsoever on the Egyptian Drug Authority.

1.3. The original **invoice** on the exporting company's letterhead, stamped with the company seal, plus two photocopies.

1.4. The **export** form addressed to Customs requesting approval for the export of the items listed in the attached invoice.

1.5. A copy of the receipt evidencing payment of the required service fee.

1.6. A valid registration notification for each pharmaceutical product / medical supply, or proof of re-registration if the notification has expired.

1.7. Approval for (adding an export pack size / changing the name of a product for export purposes) shall be attached if any item listed in the invoice requires such documentation, in the case of pharmaceutical products of all types.

1.8. The company shall submit a (Declaration of Conformity - DoC) on the company's letterhead, stamped with the company seal and under the company's responsibility, clarifying the classification of the medical device, in the case of medical devices not subject to registration.

1.9. A copy of the factory license, industrial register, and the Authority laboratories' conformity reports for the items listed in the invoice shall be attached, in the case of diagnostic and laboratory reagents.

2. Documents Required to Obtain Re-export Approval:

2.1. An export request on the exporting company's letterhead stamped with the company seal and approved by the responsible official (the head of the entity or their authorized representative).

2.2. A declaration on the company's letterhead, stamped with the exporting company's seal, stating that the re-export process is the sole responsibility of the company, with no liability whatsoever on the Egyptian Drug Authority.

2.3. The original invoice on the exporting company's letterhead, stamped with the company seal, plus two photocopies of the invoice, (provided that the invoice includes the name of the consignee, the destination country, the invoice number, the RGA number (if any), the invoice date, the name of the product to be re-exported, the quantity, and the batch number).

2.4. A copy of the customs release invoice for the original goods, plus a copy of the import approval for the relevant items.

2.5. Approval from the foreign supplier to receive back the goods intended for re-export.

2.6. A quality report issued by the company stating the reason for rejecting the shipment or the non-conformity findings issued by the Egyptian Drug Authority laboratories.

2.7. The shipment opening report issued by the Factory Inspection Department of the Egyptian Drug Authority (if available), or the customs declaration for the final release of the shipment.

2.8. An inspection report issued by the pharmaceutical inspection of the Authority in the event the shipment has been seized for technical reasons and the company wishes to re-export it.

2.9. The export form addressed to Customs requesting approval for the re-export of the items listed in the attached invoice.

2.10. A copy of the receipt evidencing payment of the required service fee.

In the above cases, the company shall receive the following: The original approved invoice after being stamped with the Republic emblem seal (Eagle Seal); and A letter addressed to the customs ports confirming approval for the export of the items listed in the invoice.

3. Documents Required to Obtain Approval for Exporting Products for (Relief Aid / Donations / Grants)

3.1. A request on the donor/issuing entity's official letterhead approved by the responsible person within the entity and stamped with the entity's seal, clearly indicating the country requesting the aid.

3.2. A declaration from the donor entity on its official letterhead, approved by the responsible person within the entity and stamped with the entity's seal, stating that the donated items to be exported outside the country are not included in the lists monitored by the Shortages Department as of the date of the declaration.

3.3. A list of items specifying quantities and the manufacturing or importing company, on the issuing entity's official letterhead, stamped with the entity's seal, clearly stating that the items are provided free of charge and indicating the nature of the transaction (donation, gift, or grant), as well as specifying the destination country.

3.4. Purchase invoices for the items, clearly showing the name and address of the purchasing entity.

3.5. A copy of the receipt for payment of the required service fee.

The applicant entity shall receive the following:

The original certificate addressed to customs authorities regarding **approval for the export of the items listed in the relief shipment**, duly approved and stamped with the Republic seal (Eagle Seal) + The original list of items, also stamped with the Republic seal.

4. Documents Required to Issue a "Non-Jurisdiction Certificate"

4.1. The company submits a request to the Export Department to obtain a statement regarding the export shipment covered by the invoice containing items classified under the aforementioned category.

4.2. Export invoice.

4.3. The original industrial registration for review, along with a copy attached to the application.

4.4. Submission of a (**Declaration of Conformity - DoC)** for the items listed in the invoice.

4.5. A copy of the receipt for payment of the required service fee.

- **The company shall receive the following:**
  An original "Non-Jurisdiction Certificate" addressed to customs authorities regarding the items listed in the attached invoice, duly approved and stamped with the Republic seal (Eagle Seal), and the original invoice stamped with the Republic seal and endorsed as "Non-Jurisdiction".

5. Documents Required for Personal Export Approval

5.1. A personal export request stating the sender's name, recipient's name, exported items and their quantities, and the destination country.

5.2. A medical prescription in the name of the patient receiving the items, specifying the daily dosage.

5.3. National ID or identification documents of both the sender and recipient.

- **The applicant for personal export approval shall receive the following:** An approved certificate stamped with the Republic seal (Eagle Seal), including the names of the items, quantities sufficient for up to three months of treatment, and specifying the sender, recipient, and destination country.

Forms

(A) Export Request Form: To be printed on the company's official letterhead.

Export Request Form

To: Export Support and Follow-up Administration

Greetings,

Kindly provide approval regarding the export shipment with the following details:

Date of Request	
Company Name	
Invoice No.	
Invoice Date	
Invoice Value / Currency	
Type of Shipment (Commercial / Samples / Re-export) Specify the purpose of the samples in case of sample shipments. - Specify the reason for re-export in case of re-export shipments. -	
Destination Country	
Customs Port	

With best regards,

Responsible Manager – Job Title:
Name:
Signature:

** The request must be stamped with the company seal and printed on the company's official letterhead bearing the company logo.

(B) Declaration Form: To be printed on the company's official letterhead.

Export Declaration Form

To: Export Support and Follow-up Administration

Greetings,

- Regarding the export of the shipment covered by Invoice No. _____ to the country of _____, the company hereby undertakes that the export process is entirely under the company's responsibility, without any liability whatsoever on the Egyptian Drug Authority.

- The company also undertakes that the products listed in the invoice, as well as their raw materials, are the responsibility of the manufacturing company, and that no non-compliance decisions have been issued against them.

Responsible Manager – "Job Title":
Name:
Signature:
Date:

** The declaration must be stamped with the company seal and printed on the company's official letterhead bearing the company logo.*