Regulatory Guideline

For the Rules and Procedures Governing Manufacturing for Export Purposes

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First: Manufacturing for Export of Medical Products

1- Scope:

The system shall apply to Medical products. However, pesticide products and products containing substances listed in the schedules attached to the Egyptian Anti-Narcotics Law No. 182 of 1960 are excluded from the application of the Manufacturing for Export system.

2- Definitions:

• **Manufacturing for Export System:** A system that permits the manufacture of Medical products not registered with the Egyptian Drug Authority in local factories, provided that all manufactured quantities are exported and not circulated within the Arab Republic of Egypt.

• **Country of Origin:** The country in which the product has been registered or is under registration.

• **Country of Marketing / Distribution:** The country to which the product will be exported, whether the product is **registered, under registration**, or unregistered therein, provided that authorization for marketing the product in that country exists.

• **Applicant Company:** An Egyptian company licensed by the Egyptian Drug Authority to manufacture pharmaceutical products.

3- Main Subject

1. The company shall submit an **application to the Export Support and Follow-up Administration to obtain the approval of the Egyptian Drug Authority for manufacturing for export purposes before commencing importation, manufacturing, and export activities (Annex 1)**, accompanied by the following documents:

- Registration **notification** of the product in the country of origin, along with proof that the product is permitted for marketing in the importing country, if different from the country of origin, **clearly indicating the License Holder.**
- **A composition statement of the product** approved in the country of origin and/or the importing country.
- In the case of products **under registration in the country of origin** and submitted **for manufacturing of**

- **a pilot batch**, a letter from the product owner in the country of origin confirming submission for registration shall be provided, provided that approval from the Authority is renewed immediately upon completion of product registration in the country of origin.

- The manufacturing agreement between the applicant company and the product-owning company (or its representative, supported by proof thereof), authenticated by the Chamber of Commerce and the Egyptian Embassy.
- A **statement** from the company regarding the production line to be used for manufacturing and its licensing status.

- **The company shall submit the following undertakings (Annex 2):**
- To import the raw materials, manufacture the product, and export the entire finished product under its sole responsibility.
- Not to circulate the manufactured product or use any remaining quantities of raw materials within the Arab Republic of Egypt.
- Not to use raw materials imported for products manufactured under the **Manufacturing for Export system in the manufacture of locally registered products with the Egyptian Drug Authority**, and likewise not to use raw materials imported for products registered with the Egyptian Drug Authority in the manufacture of products under the Manufacturing for Export authorization system.
- That the products to be manufactured and exported shall comply in composition, specifications, and requirements with the regulations of the country of marketing/distribution.
- That responsibility for ensuring the safety, efficacy, quality, and suitability of the active raw materials contained in the product, and their intended purpose, rests solely with the company, without any liability whatsoever on the Egyptian Drug Authority.
- That such products do not contain any explosive materials, radioactive materials, prohibited substances, or active substances listed in the schedules attached to the Egyptian Anti-Narcotics Law No. 182 of 1960.

2. The company's application, together with all attached undertakings, shall be referred to the **Pharmaceutical Inspection Administration of the Egyptian Drug Authority** to provide its opinion regarding the **possibility of permitting the manufacturing process.**

3. After obtaining the **Pharmaceutical Inspection Department's approval**, confirming the suitability of the production line, and reviewing the required documents, **an approval letter permitting manufacturing for export purposes shall be issued to the applicant company** by the Export Support and Follow-up Administration (Annex 3).

Such approval shall remain valid for a period of **two years** from the date of issuance. A new application must be submitted if the company is unable to complete **production and export** within the prescribed period.

4. If the company requests an amendment to a valid approval, the company shall submit a request to the Export Support and Follow-up Administration specifying the required amendment and pay the prescribed service fee.

For renewal of the approval upon expiry, concerning the same product, active ingredients, same company, and any other contracts or destination countries, previously issued approvals by the Authority shall be attached for reference and status update purposes.

5. The company shall have the right to import after obtaining approval for **Manufacturing for Export purposes** without the need to obtain a separate import approval.

An application for **Medical Customs Release** shall be submitted for shipments of raw materials imported for this purpose, and the reserved **Medical Customs Release shall be issued within one working day**, after fulfilling the following required documents:

- Release application.
- Invoice and shipping bill of lading.
- Certificate of analysis for the imported batches.
- Egyptian Drug Authority Approval for Permitting the Manufacturing of the Product for Export Purposes
- In the case of raw materials requiring specific health requirements, the necessary certificates shall be provided.
- In the case of pre-mixed and pre-prepared raw materials, a composition statement from the foreign manufacturer shall be submitted.

6. The **active raw materials used in manufacturing the product shall be released** after verifying their conformity with the reserved customs Release approval, the certificates of analysis accompanying the raw materials, the appropriate storage conditions, and the cold chain requirements in the case of materials requiring refrigerated shipment. The quantities manufactured shall be monitored to ensure that they are not used in any production operations for other products, while observing the following:

- **The imported active raw materials may only** be used in manufacturing the product for which approval has been granted.
- Raw materials imported for manufacturing for export purposes may not be used in manufacturing products circulated in the local market. Likewise, raw materials imported

for products registered with the Egyptian Drug Authority may not be used in manufacturing products under the Manufacturing for Export authorization system.

- The loaning/advance-use system for raw materials imported for Manufacturing for Export products shall not be permitted.

7. Following the release of the shipment contents, the company shall be permitted to commence manufacturing. Upon completion of the final product manufacturing process, the quantities of raw materials used in producing **the final product shall be reconciled, and a report shall be prepared detailing the production batches and quantities manufactured and stored in the company warehouses**. An inspection report shall also be prepared, accompanied by the company's undertaking not to circulate these products or any remaining quantities of raw materials within the Arab Republic of Egypt.

8. If the company wishes to destroy the product, whether due to the manufactured product's non-compliance with the **requirements of the company holding the manufacturing rights** — according to the manufacturer QC report — or for any other reason, the company shall submit a destruction request to the competent inspection administration.

The non-compliant produced quantities shall be **seized and destroyed** in the presence of the pharmaceutical inspector. The inspection report shall remain valid for six months from the date of production. Upon expiry, the company shall apply to the Pharmaceutical Inspection Administration of the Authority to request re-inspection.

9. Upon expiry of the approval without renewal, the company shall be obligated to re-export the remaining raw materials or destroy them in accordance with the rules of pharmaceutical inspection.

10. The company shall submit an **application to obtain export approval**, accompanied by the following documents, provided that the **export approval shall be issued within one working day**. The approvals issued for such products shall be monitored by the competent departments of the Egyptian Drug Authority (Pharmaceutical Inspection), in coordination with the Customs Authority where necessary:

- Pharmaceutical inspection report indicating the quantities produced for export.

- Export request on the exporting company's official letterhead, stamped with the company seal and approved by the responsible official (head of the entity or authorized representative), indicating the approval number for Manufacturing for Export purposes (Annex 4).
- Declaration on the company's official letterhead, stamped with the exporting company's seal, stating that the export process is under the sole responsibility of the company, with no liability whatsoever on the Egyptian Drug Authority (Annex 5).
- Original invoice on the exporting company's official letterhead, stamped with the company seal, plus two photocopies.
- Export form addressed to Customs requesting approval for export of the items listed in the attached invoice.
- Copy of the receipt evidencing payment of the required service fee.

11. The company shall undertake to submit the customs declaration (immediately upon issuance) to the Export Support and Follow-up Administration in order to verify the export of the approved quantities.

Second:

Manufacturing for Export of Medical Devices

1- Scope

The system shall apply to medical devices. However, factories subject to a production line suspension decision shall be excluded, whereby the importation of raw materials for export purposes shall be suspended and export activities prohibited.

2- Definitions

Manufacturing for Export System: A system that permits licensed medical devices factories to import the raw materials and components necessary for manufacturing medical devices not registered with the Egyptian Drug Authority in local factories, provided that all manufactured quantities are exported and not circulated within the Arab Republic of Egypt.

Applicant Manufacturer: An Egyptian manufacturer holding a valid license issued by an approved licensing authority, such as: **(**Industrial Development Authority **-** General Authority for Investment and Free Zones **-** Suez Canal Economic Zone)

(The manufacturer is not required to obtain quality certificates such as CE or ISO 13485:2016.)

3- Main Subject

1. The manufacturer shall submit an application to the Central Administration for Medical devices to obtain import approval for raw materials and production components, accompanied by the following documents:

- A copy of the invoice for which customs release is requested.
- A copy of the manufacturer license (indicating the manufacturer activities) issued by the licensing authority.
- An undertaking stating that the contents of the imported invoice shall be used solely for the production of medical devices intended for export only and not for circulation in the local market.

2. The import approval shall be issued to the applicant manufacturer within three working days.

3. The raw materials used in manufacturing the medical supply shall be released after verifying their conformity with the final customs release approval, the certificates of analysis accompanying the raw materials, and the appropriate storage conditions.

The quantities manufactured shall also be monitored to ensure that they are not used in any production operations for other medical devices, while observing the following:

- The imported raw materials may only be used in manufacturing the medical supply for which approval has been granted.
- Raw materials imported for manufacturing for export purposes may not be used in manufacturing medical devices intended for circulation in the local market.

4. If the manufacturer wishes to export medical devices not registered with the Egyptian Drug Authority, and the raw materials required for manufacturing are already available at the manufacturer, the manufacturer may manufacture the medical supply using the available raw materials after notifying the Medical devices Factories Inspection Administration of the required quantities under the purchase order.

An inspection report shall be issued by the inspector indicating the quantities produced for export, provided that the outer packaging bears the phrase “For Export Only,” and after verification that the same raw materials are used in manufacturing the registered medical device.

5. After reviewing the import approval issued for the raw materials, indicating that such materials are intended for export purposes, the following procedures shall be carried out:

- Permitting the manufacturer to commence manufacturing.
- Upon completion of manufacturing the final product, reconciling the quantities of raw materials used in the production process through the batch records.
- Preparing a report detailing the production batches and quantities manufactured and stored in the manufacturer warehouses.
- Verifying that the phrase “For Export Only” is printed on the outer packaging.
- The manufacturer shall undertake not to circulate these medical devices or any remaining quantities of raw materials within the Arab Republic of Egypt.

6. The export process shall be verified through the following documents:

- The invoice approved by the Export Support and Follow-up Administration of the Authority.
- The shipping bill of lading indicating the quantity to be exported.
- The customs declaration form.
- An official confirmation from the importing entity acknowledging receipt of the quantities.

7. The manufacturer shall be obligated to submit the following documents during periodic inspection visits conducted by the Medical Devices Inspection Administration:

- A mass balance study linking the quantity of each raw material to the quantity of the finished product, including calculation of waste percentage.
- A Batch Policy (batch numbering system) specific to the medical supply.
- Material Safety Data Sheets and Certificates of Analysis for raw materials.
- An approved supplier list for each raw material, subject to periodic updates in case of supplier changes.

8. In the event that the manufacturer uses export-designated raw materials for local manufacturing, a seizure and control notice shall be issued for the batches produced in violation.

Import approvals for raw materials used in these medical devices shall be suspended for one year, and export of this product shall be prohibited during the same period.

In case of repetition of the violation, the matter shall be referred to the competent committee for medical devices registration to consider doubling the penalty.

9. The manufacturer is permitted to export a small quantity of the finished product for the purpose of introducing modifications, provided that it is re-imported to assess the efficiency of the product after modification.

10. Cases of returned goods intended for carrying out certain modifications to the medical device shall be reviewed, provided that the shipment is released under custody, and completion of the modifications is monitored under the supervision of the Inspection Administration. Thereafter, the medical device shall be re-exported again upon submission of the documents evidencing exportation, with each case being reviewed individually.

11. The company shall submit **an application for export approval** accompanied by the following documents:

- An export request on the exporting company's official letterhead (Annex 7), stamped with the company seal and approved by the responsible person (head of the entity or authorized representative).
- A declaration on the exporting company's official letterhead, stamped with the company seal, stating that the export process is entirely under the company's responsibility, with no liability whatsoever on the Egyptian Drug Authority (Annex 5).
- Original invoice on the exporting company's official letterhead, stamped with the company seal, plus two photocopies.
- Export form addressed to Customs requesting approval for export of the items covered by the attached invoice (Annex 8).
- Copy of the receipt proving payment of the required service fee.
- Pharmaceutical inspection report indicating the quantities produced for export; this shall not apply in the case of medical devices manufactured for third parties (Owned Brand Label / Original Equipment Manufacturer), where the signed agreement between the Egyptian manufacturer and the foreign importing company shall be submitted. In case of contracts written in any language other than Arabic or English, the contract shall be translated by a certified translation office.
- Copy of the import approval for export purposes (if applicable).

12. The company shall be obligated to submit the customs declaration (immediately upon issuance) to the Export Support and Follow-up Administration, in order to verify that the approved quantities have been exported.