

General Rules for Importation in Accordance with the Law Regulating Blood Operations, Plasma Collection for the Manufacture of Its Derivatives, and Their Exportation, issued under Law No. 8 of 2021 2025

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First: Importation (Re-importation) of Intermediate Plasma Derivatives (Bulk Filling Concentrates or Finished Products) after dispatch

1. Egyptian companies registered with the Egyptian Drug Authority, whose primary purpose is the collection, dispatch, export, manufacture, or import of plasma and plasma derivatives for pharmaceutical industry purposes, shall apply to the General Administration for Importation and Medical Customs Release for an importation plan or approval prior to shipment, subject to presentation of the dispatch permit issued by the Authority and compliance with the applicable procedures.
2. Importation shall be permitted for finished products registered with the Egyptian Drug Authority, as well as for products that are still under registration, provided that such products shall not be circulated until completion of the registration procedures.
3. The importation plan/approval shall be issued within two working days, provided that all required documents have been duly submitted, and it shall remain valid for one year from the date of issuance.
4. The importation plan/approval shall be issued as valid for total and/or partial shipment, provided compliance is maintained with the form in which the products are expected to be returned (bulk filling concentrates (bulk) / finished products), their trade names, the expected quantities to be returned, and the expected timing/period for re-importation. The importation approval shall also indicate the relevant codes/serial numbers of the related dispatch authorization.

5. The company may submit a request to the General Administration for Importation and Medical Customs Release to amend a previously issued importation plan/approval in the event of any change to the expected returned form of the products (bulk filling concentrates (bulk) / finished products), their trade names, the quantities expected to be returned, or the expected timing/period for re-importation.
6. The amendment to the importation plan/approval shall be issued within two working days, provided that all required documents have been duly submitted.

Second: Authorized Medical Customs Release of Intermediate Plasma Derivatives (Bulk Filling Concentrates (Bulk) or Finished Products) after Dispatch

1. The shipment documents shall be matched against the issued importation approval in accordance with the applicable procedures in this regard, and an authorized release shall be issued. Final release shall only be granted upon fulfillment of the requirements of the Central Administration for Biological, Innovative Products and Clinical Trials, the Biological Products Laboratory Evaluation Administration, and the Central Administration for Inspection of Pharmaceutical Institutions.
2. The authorized medical customs release letter shall be issued within one working day, provided that all required documents have been duly submitted.

Third: Authorization for Importation and Medical Customs Release of Plasma, Intermediate Plasma Derivatives, Bulk Filling Concentrates (Bulk), or Packaging Materials

1. In the case of importing locally manufacturing requirements (active raw materials, plasma and its derivatives, inactive raw materials, manufacturing concentrates, and intermediate plasma derivatives).
- Importation shall be permitted for the Egyptian company owning the licensed manufacturing facility, provided that its primary purpose is the collection, dispatch, export, manufacture, or importation of plasma and plasma derivatives for pharmaceutical manufacturing purposes, for use in manufacturing registered biological products for its own account or for third parties.



- All procedures and regulations established by the Egyptian Drug Authority for the importation of locally manufacturing requirements used in the manufacture of products registered with the Authority, as set out in the Regulatory Guideline for Importation and Medical Customs Release, shall be fully complied with. An authorized medical release shall be granted for the incoming shipment, while final release and follow-up shall be conducted by the Authority.
2. Blood plasma samples or plasma derivatives shall be imported for manufacturing purposes or manufacturing research purposes related to biological products intended for registration, under registration, or already registered with the Authority, in accordance with the applicable procedures and controls established by the Authority for the importation of such samples and published in the Regulatory Guideline for Importation and Medical Customs Release.