Notice to applicant

General Rules for importation according to blood processing regulations and Plasma collection for derivatives manufacturing and exportation, promulgated by law No. 8 for 2021

Year 2022

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First: Importation (Recovery) of plasma intermediate derivatives (plasma concentrates (Bulk) or finished products) after Plasma Exportation

1. Egyptian companies, having main purpose of collecting, importing, exporting, and manufacturing plasma, or plasma derivatives for pharmaceutical industry, and enrolled within the Egyptian Drug Authority, are permitted to apply for a plan/importation approval before shipping, to the General Directorate for Importation and Custom Release, provided presenting the plasma exportation permit issued from the Authority, as per the applicable procedures in this regard.
2. Importation is allowed for finished products registered within EDA, as long as those under registration, provided that the latter shall not to be marketed until completing their registration procedures.
3. The Importation plan/approval shall be issued within two working days, provided submitting all required documents, and is valid for one year from date of issuance.
4. The importation plan/ approval shall be valid for total and/or partial shipping, provided the adherence to the expected form of recovery (concentrates (bulk) / finished products), trade names, quantities expected to be recovered and timing/duration within which the recovery is predicted. Importation approvals shall include relevant plasma exportation approval codes/serial numbers.
5. It is permissible for the company to submit a request to the General Directorate for importation and Custom Release in order to make an amendment to the previously issued import approval, in case of alternation to the expected form of recovery (concentrates (bulk)/ finished products), trade names, quantities expected to be recovered or timing/duration within which the recovery is predicted.
6. The amendment of the importation plan/ approval shall be issued within two working days, provided submitting all required documents.

Second: Sealed Customs Medical Release of Intermediate plasma derivatives plasma Concentrates (Bulk) or Finished Products) after Plasma Exportation.

1. The received shipment documentation shall be accorded by the issued importation approval in accordance with the procedures applicable in this regard, and a sealed release shall be issued. Final release shall not be granted except after fulfilling the requirements specified by the Central Administration of Biological products innovative products & clinical studies (Biological products Control Labs), and Central administration of operations (Biological Factories Inspection).
2. Sealed custom release letter shall be issued in one working day, provided submitting all required documents.

Third: Permission for Importing and Customs Medical Release of Plasma, Intermediate plasma derivatives (plasma Concentrates (Bulk) or Finished Products) or Packaging Requirements.

1. In case of importing local manufacturing requirements (active pharmaceutical ingredients -plasma and its derivatives -inactive pharmaceutical ingredients -bulk products and intermediate plasma derivatives):
   - An Egyptian Company owning a licensed factory, provided that its main purpose collecting, importing, exporting, and manufacturing Plasma, or its derivatives, for pharmaceutical industry, shall be authorized to import, to be utilized m manufacturing registered biological products for itself or for the third parties.
   - In case of manufacturing for third parties (Toll), the company holding the registration notification, provided that its mam purpose collecting, importing, exporting, and manufacturing Plasma, or its derivatives, for pharmaceutical industry, shall be authorized to import plasma and its derivatives for manufacturing purposes, provided supplying such products to the licensed manufacturing. factory.
   - All procedures and rules applicable by the Egyptian Drug Authority regarding importing local manufacturing requirements utilized in manufacturing products registered within the Authority, announced in the guideline for import and customs medical release shall be applied. The Authority shall issue and track sealed medical release for the incoming shipment, and its final release.
2. Importation of blood plasma samples or its derivatives whether for manufacturing purposes or researches related to manufacturing of biological products that is planned to be registered, or already submitted for registration or registered by the Authority, as per the procedures and rules applicable within the Authority for importing samples as published in the guideline for importing and customs medical release by the Authority.