Notice to applicant

Regulatory Rules for Importation of Cadaveric Skin

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Regulatory Rules for Importation of Cadaveric Skin

- Cadaveric skin : It is a biological tissue that is not subject to the rules and procedures for registering biological products, in accordance with the rules applied by the U.S. Food and Drug Administration (FDA). Internationally recognized FDA rules in this regard are applied by allowing its importation—without registration—upon fulfilling the required documents while monitoring safety throughout the period of use, as presented to the Specialized Scientific Committee for Biological Products.
- Importation of cadaveric skin is permitted from reference countries only.

The requesting entity shall submit the following documents—prior to shipment—to the General Administration for Import and Medical Customs Clearance to obtain an import permit letter from the Egyptian Drug Authority:

1. An import request submitted by the requesting entity specifying: (Item Name – Imported Quantity – Foreign Manufacturer Name – Country of Origin).
2. A proforma invoice containing complete details.
3. Product documents issued from one of the reference countries, provided that all documents are recent and valid in accordance with the following:
    - A declaration from the foreign manufacturer (*Declaration of Conformity with relevant Regulations*) stating that the product complies with the relevant regulations issued by the regulatory authority in the country of origin, specifying: (Name and address of the foreign manufacturer – Regulations applied to the item in the country of origin – Quality management system implemented at the facility – Details of the imported item "Product Name – Product Description – Product Indications/Intended Use").
    - A certificate proving that the foreign manufacturer of the imported item is registered/accredited in the country of origin (one of the reference countries) (*Establishment Registration or Accreditation Certificate*).
    - A quality certificate issued to the foreign manufacturer by an accredited body.
    - Outer label and package insert of the product.

- Instructions for Use (*IFU*) of the imported item.

4. A letter from the requesting entity confirming compliance with the following points regarding use controls:

   - Using the imported item under the supervision and responsibility of the treating physicians within the hospital premises, and ensuring that the transport process is carried out by a specialized physician.
   - Ensuring the integrity of the packaging and expiry date, as well as guaranteeing proper transport from the country of origin to the point of use while verifying storage at the temperature specified in the product insert (*Maintaining Cold Chain conditions*).
   - Obtaining an "Informed Consent" form signed by the patient prior to use, provided that this consent includes the side effects listed in the product insert, and retaining a signed copy of this document at the hospital/point of use.
   - Refraining from donating or selling the product to any other hospitals except after consulting the Egyptian Drug Authority to ensure transport safety and adherence to the required transport temperature.
   - Ensuring the inclusion of the product in a *Tracking System* within the facility to track the number and data of recipient patients, batch number, and expiry date.
   - Designating a focal point person with a baseline knowledge of adverse event reporting principles to report any safety issues related to the product, whose contact details shall be provided to the Egyptian Drug Authority.

5. Upon arrival of the shipment, the entity shall submit the following to obtain a letter addressed to customs allowing the customs clearance of the shipment:

- A commercial invoice containing complete details (Item Name – Manufacturer Name – Country of Origin – Quantity – Unit Price).
- Bill of Lading.
- Packing list.
- Certificate of Conformance (COC) for the imported item, certifying product testing and freedom from infectious diseases.
- Customs declaration number.