Requirements for Importation of Minimally Manipulated Biological Products Intended for Human Application

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Introduction

Purpose

The purpose of this document is to specifiy and clarify the importation requirements for minimally manipulated biological products intended for human application.

Scope

These requirements apply to following products and establishments:

A. minimally manipulated biological products (e.g. bone ligaments, tendons, fascia, cartilage, ocular tissues (corneas and sclera), skin, vascular grafts (veins and arteries except preserved umbilical cord veins), pericardium, amniotic membrane (when used alone without added cells for ocular repair), heart valve allografts), excluding the following:

   - vascularized organs (liver, kidney, lung, heart,….etc.)
   - major manipulation (e.g. advanced therapeutic drug, gene therapy, tissues engineering therapy)
   - biologic products imported for research purposes.
   - biologic products derived from non-humans sources.
   - biologically-derived medical devices

B. importers and healthcare providers importing for their own use.

Background

SFDA has issued these requirements in reference to article two of the "Implementation Regulation on The Law of Saudi Food and Drug Authority" issued by Saudi Food and Drug Authority Board of Directors decree no. (7-7-1428) dated 25/7/1429 H, stipulating that the SFDA is responsible for regulating biological products.

Requirements

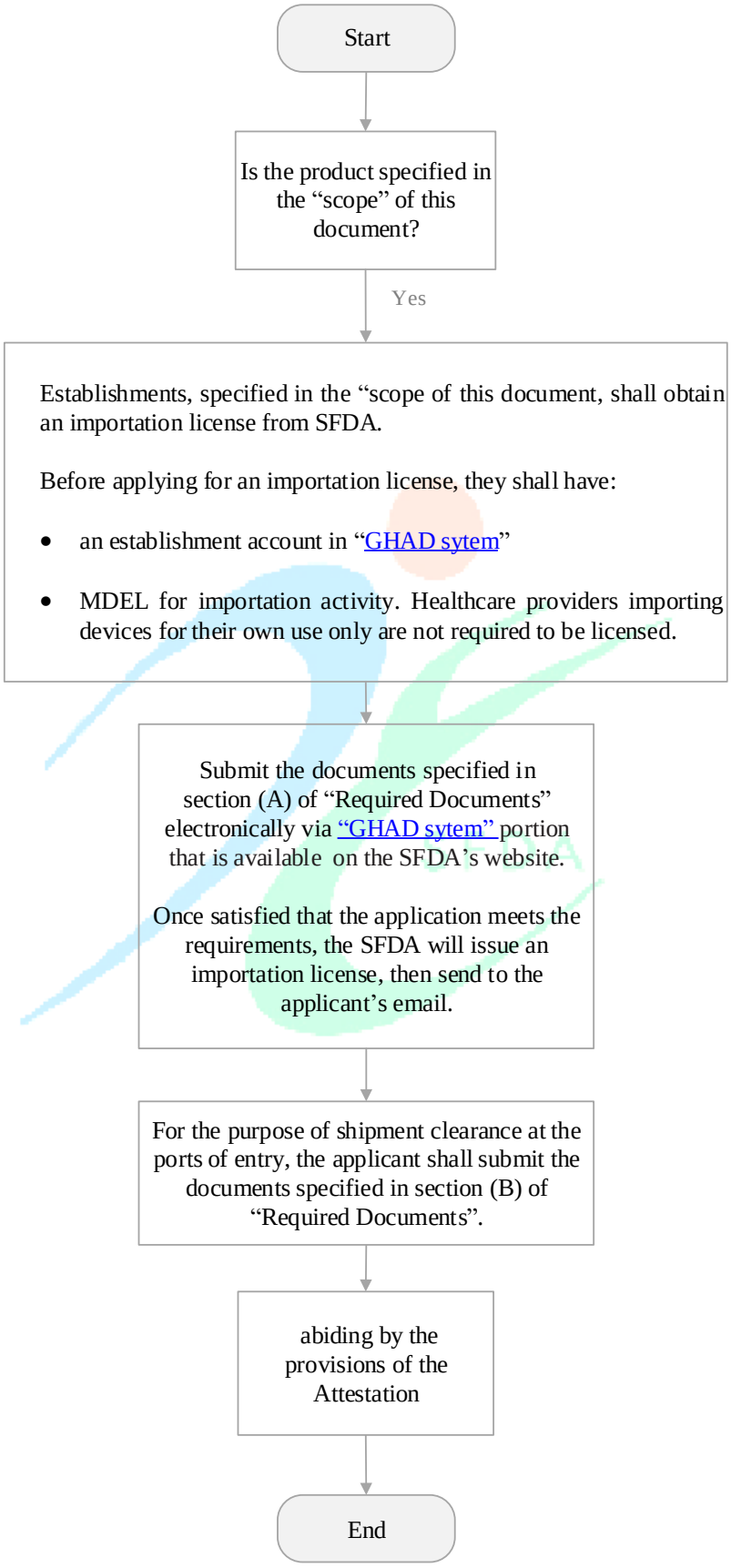
General	1	Minimally manipulated biological products intended for human application shall not be imported unless an importation license is obtained from SFDA.
Prerequisite	2	Before applying for an importation license, importers shall have: – an establishment account in "GHAD sytem" – MDEL for importation activity. Healthcare providers importing devices for their own use only are not required to be licensed.
Submitting to SFDA	3	Applicant shall submit the "Application Form for Importation of Biological Product (Annex1)" electronically via "GHAD sytem" on the SFDA's website, and provide "Required Documents" specified in section (A). Once satisfied that the application meets the requirements, the SFDA will issue an importation license, valid for (90*) days, then send it to the applicant's email. *Note: For special circumstances the SFDA may grant the importation license for one year to health care provider according to its annual need.
Shipment Clearance at the Ports of Entry	4	A. For the purpose of shipment clearance at the ports of entry, applicant shall submit documents specified in section (B) of "Required Documents" according to "Guidance on Requirements of Shipments Clearance (MDS-G21)". B. Each shipment that requires specific temperature for transportation and/or storage shall contain temperature indicator activated from the time of shipping.

Required Documents

	Required Documents	Note
	A. Required Documents for Importation License	
1	Purchase Order (PO) from the Beneficiary	– It shall contain: ○ product name (trade and scientific) ○ quantity ○ country of origin ○ manufacturer name ○ start and end date of importing – It is not required if healthcare provider importing for their own use
2	Declaration of Conformity with Relavent Regulation	– It shall issued by the manufcaturer – It shall contain: ○ manufacturer name and address ○ regulation Applied and Registration info. ○ the applied qaulity management syatem ○ product detailes (brand name , product type, description , intended pupose/use and sizes) .
3	Purchase Invoice	– It shall be stamped by the concerned authority for trade in the country of origin (if applicable) – It shall include detailed description of the shipment, quantity, expiration date (if applicable), model/part number and lot/serial number
4	Certificate of Saudi Center for Organ Transplantation for the beneficiary	– It is required only if the product is cornea. – It can be provided under the section “Other” within the application
5	Evidance that the source of the product is registered/accredited in the country of origin.	– It may includes: ○ Establishment registration ○ Accreditation Certificate – It can be provided under the section “Other” within the application
6	Labelling of each product	– It shall cover all models – It can be provided under the section “Other” within the application
7	Documentation accompanying the products to the end users (such as instruction of use IFU)	– It can be provided under the section “Other” within the application
8	Attestation	– See Annex (2), click here for printable and editable version

		– It can be provided under the section “Other” within the application
B. Required Documents for Shipment Clearance		
9	Importation License	– It shall be valid
10	Purchase Invoice	– It shall be authenticated by the chamber of commerce in the country of origin – It shall contain the invoice number, manufacturer’s name, products name, quantity, and unit price – Model/part numbers and lot/serial numbers shall be indicating in the invoice or packing list – The quantity mentioned in the purchase invoice will deduct from annual need quantity for health care provider. (if the importation license for annual need
11	Bill Of Lading (B/L) or the Air Waybill (AWB)	–

Flowchart


Start
Is the product specified in the “scope” of this document?
Yes
Establishments, specified in the “scope of this document, shall obtain an importation license from SFDA.
Before applying for an importation license, they shall have:
an establishment account in “GHAD sytem”
MDEL for importation activity. Healthcare providers importing devices for their own use only are not required to be licensed.
Submit the documents specified in section (A) of “Required Documents” electronically via “GHAD sytem” portion that is available on the SFDA’s website.
Once satisfied that the application meets the requirements, the SFDA will issue an importation license, then send to the applicant’s email.
For the purpose of shipment clearance at the ports of entry, the applicant shall submit the documents specified in section (B) of “Required Documents”.
abiding by the provisions of the Attestation
End

Annexes

Annex (1): Application Form for Importation of Minimally Manipulated Biological Products Intended for Human Application

نموذج طلب استيراد منتجات حيوية علاجية

(يعبأ إلكترونياً عبر موقع الهيئة)

A. Importer information	أ. بيانات المستورد
Importing Type:	نوع الاستيراد:
Manufacturer Name:	اسم المصنع:
Country	البلد
City	المدينه
Postal Code:	الرمز البريدي:
Manufacturer Details:	تفاصيل المصنع:
Email:	البريد الإلكتروني:
Telephone Number:	الهاتف:
Mobile Number:	رقم الجوال :
B. Shipment Information	ب. بيانات الشحنة
Product Type:	نوع المنتج:
Purpose of Importing:	الغرض من الاستيراد:
Shipment Country:	بلد الشحن:
Shipment Company:	شركة الشحن:
Shipment Policy Number:	رقم بوليصة الشحن:
Arrival Port:	ميناء الوصول:
Storage Place:	مكان التخزين:
Benificiary Name:	إسم المستفيد:
Beneficiary Mobile:	رقم هاتف المستفيد:
Beneficiary Address:	عنوان المستفيد:
Benificiary Email:	البريد المستفيد الإلكتروني:
C. Products	ت. المنتج
Product Name:	اسم المنتج
Status	الحالة
Quantity:	الكمية
Has MDMA:	لدية MDMA
Registered:	مسجل
Ingredients / Components:	المكونات
Invoice Number:	رقم الفاتورة
Related to List:	ذات الصلة إلى القائمة:
D. Documents	ث. المستندات
Shipment Policy	بوليصة الشحن
Agreement Letter with the beneficiary	تعميد الشراء/ امر الشراء من الجهة المستفيدة
Other Files	ملفات أخرى

Annex (2): Attestation for Importers of Minimally Manipulated Biological Products Intended for Human Application

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يطبع على الورق الرسمي الخاص بالمورد التاريخ

تعهـــــــــــــد

نحن ..... وإشارة إلى طلبنا استيراد المنتجات الطبية الحيوية الاتية:

م	اسم المنتج	عدد البنود	المصنّع	بلد الصنع
١				
٢				
...				

نتعهد بالآتي:

١. تقديم فاتورة مفصلة مع كل شحنة قادمة.
٢. النقل والتخزين حسب متطلبات المصنّع.
٣. إبلاغ المصنّع والهيئة من خلال المركز الوطني لبلاغات الأجهزة والمنتجات الطبية بشكل عاجل عن أي تفاعل ضار يحدث بسبب استخدام المنتج.
٤. تعقب/تتبع المنتج اثناء الاستخدام والاحتفاظ بالمستندات والسجلات ذات العلاقة.
٥. استخدام المنتجات في الغرض الذي جلبت من أجله.
٦. بنود الشحنة الواردة تحتوي على:

٦,١. مواد مشعة ☐ نعم ☐ لا

اسم المادة المشعة: ..... (إذا كانت الإجابة نعم)

٦,٢. مواد كيمائية خاضعة لرقابة الأمن العام ☐ نعم ☐ لا

اسم المادة الكيمائية: ..... (إذا كانت الإجابة نعم)

٦,٣. مواد مخدرة ☐ نعم ☐ لا

اسم المادة المخدرة: ..... (إذا كانت الإجابة نعم)

ولكم جزيل الشكر والتقدير ،،،،

اسم الشخص المسؤول :

المسمى الوظيفـي :

الختم التوقيـــع :

التاريـــخ :

Annex (4): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDEL	Medical Device Establishment License
National Center for Medical Device Reporting (NCMDR)	an organization managing a database of information on safety and/or performance related aspects of medical devices and employing staff capable of taking appropriate action on any confirmed problems.
Labeling	means written, printed or graphic matter A. Affixed to a medical device or any of its containers or wrappers. B. Information accompanying a medical device, related to identification, technical description. C. Information accompanying a medical device, related to its use, but excluding shipping documents.
Human cells, tissues, or cellular or tissue-based products (HCT/Ps)	means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea
Human Application	means the use of tissues or cells on or in a human recipient and extracorporal applications.
Minimal Manipulation for Structural Tissue	means processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement.
Minimal Manipulation for Cells or Nonstructural Tissues	means processing that does not alter the relevant biological characteristics of cells or tissues.