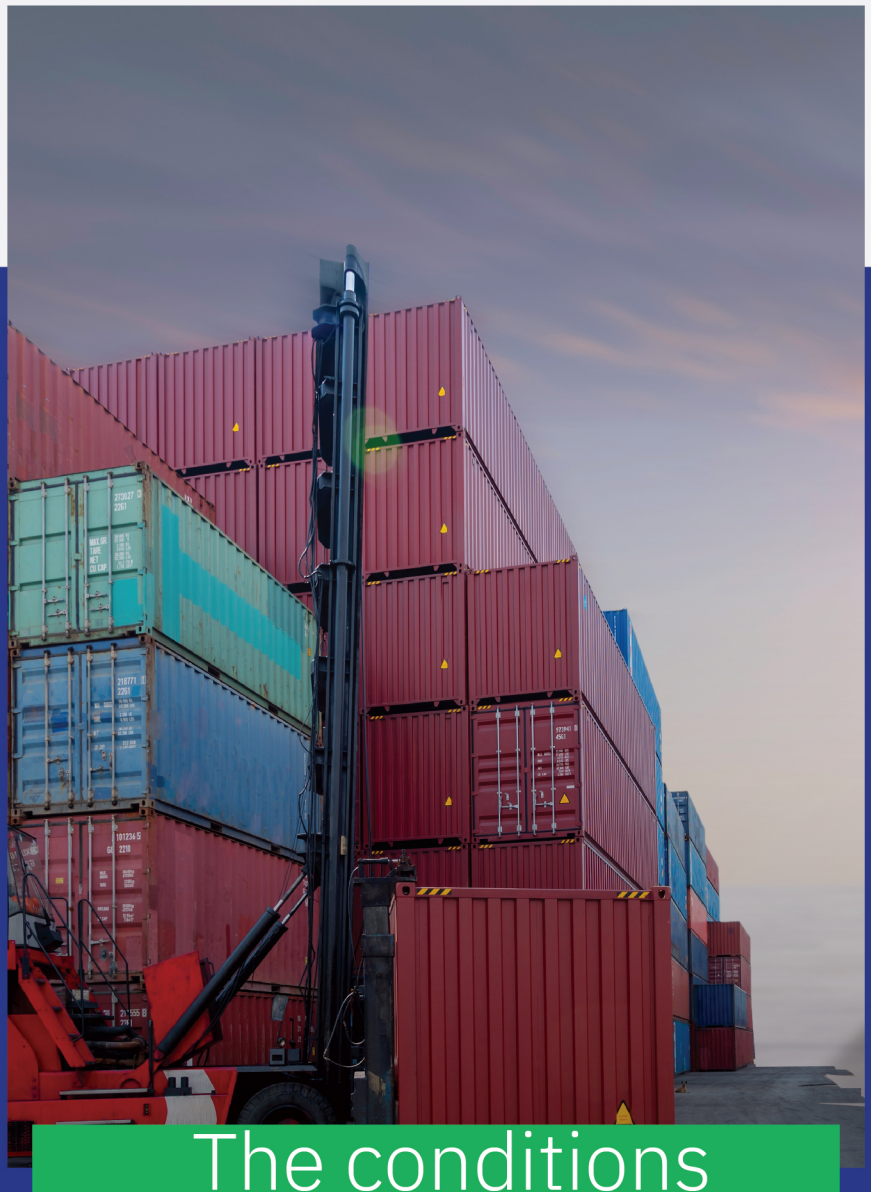
Kingdom of Saudi Arabia
Saudi Food & Drug Authority



The conditions

and requirements for Clearing re-imported products

Version No. (1)

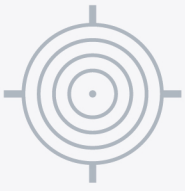
Contents

Introduction

In the context of the authority's efforts to regulate the process of clearing imported food, drugs, medical devices, and cosmetics, and to establish the controls and procedures regulating them, it has prepared this document outlining the conditions and requirements that must be implemented.

Objective

The aim of this document is to clarify the requirements and conditions for clearing products exported from the Kingdom (whether locally manufactured or re-exported) that have been returned to the Kingdom for commercial purposes, or due to rejection of clearance or marketing by the importing countries, or for maintenance purposes.



Scope:

Products subject to the control of the Saudi Food and Drug Authority

Which are products re-imported for the following purposes:

1. Products Exported (or have been exported) from the Kingdom and returned for violating the conditions and requirements of the exporting country.

2. Saudi or imported products for the Kingdom exported from the Kingdom and re-imported for displaying them in the local markets.

3. Saudi or imported products for the Kingdom, exported from the Kingdom and re-imported for maintenance purposes.

Definitions:

Products subject to the control of the Saudi Food and Drug Authority

Re-imported products:

Products that have been exported from the Kingdom of Saudi Arabia to other countries and then re-imported to the Kingdom, whether from the same source or another importer.

Pharmaceutical Product (Drug):

Any product manufactured pharmaceutically containing one or more substances used, externally or internally, either for treating or for preventing diseases in humans.

Veterinary Product:

Any substance or combination of substances used for treating or preventing diseases in animals, or used for diagnosing disease conditions, or for restoring, correcting, or modifying physiological functions in animals.

Cosmetic Product:

Any cosmetic product containing one or more substances intended for use on the external parts of the human body, including the skin, hair, nails, lips, or external genital organs, or on the external parts of the oral cavity mucosa; for cleaning, perfuming, protecting, maintaining them in good condition, changing their appearance and improving it, or changing the body odor and improving it.

Food:

Anything prepared for human consumption, whether raw, fresh, manufactured, or semi-manufactured. Any substance used in the manufacturing, preparation, or processing of food is considered food.

Medical Devices:

Any machine, instrument, appliance, application software, implant, reagent, material, or other similar or related article intended for medical use:

A . Manufactured to be used alone or in combination with other devices for one or more of the following purposes:

- Diagnosing, preventing, monitoring, treating, alleviating, or mitigating diseases.

- Diagnosing, monitoring, treating, alleviating, compensating for injuries, or disabilities.
- Examination, replacement, modification, anatomical support, or functional support of body parts.
- Life support or sustenance.
- Regulating pregnancy.
- Sterilizing medical devices.
- Providing information for medical or diagnostic purposes through laboratory tests on samples taken from the human body.

B. Devices that cannot achieve their intended purpose in or on the human body by means of pharmacological, immunological, or metabolic agents, but only help in achieving their effects.

Temporary Export:

Export of medical devices registered in the authority's systems for maintenance purposes.

General Conditions and Requirements:

1 . Damaged, improperly transported, or expired products are not allowed to be re-imported unless they are manufactured in the Kingdom, in which case the local manufacturer will be responsible for their disposal.

2. The authority has the right to withdraw representative samples of all incoming products in each shipment and refer them to routine laboratory tests to ensure their compliance with the approved technical regulations and requirements. The importer shall bear the costs of these tests at laboratories accredited by the authority.

3. Importers must retain the original documents for a period of five years from the date of clearance.

4. Compliance with all procedures, requirements, and circulars issued by the authority is mandatory.

First:

Re-imported Shipments due to Non-Compliance with the Conditions and Requirements of the Destination Country

1 . Attach a letter from the importer with the clearance documents submitted in the customs ‘FASAH’ system, explaining the reason for the rejection of the shipment from the Destination country, supported by evidence. The letter should also include a pledge not to market the product in the local market in case of non-compliance with the technical regulations and standards of the Kingdom of Saudi Arabia or the requirements or circulars specific to marketing products in the Kingdom.

2. Copy of the statement issued by the Zakat, Tax and Customs Authority.

3. Copy of the packaging list or invoice.

4. The expiry date of the products should not be less than that specified in the clearance requirements for imported products for commercial purposes.

5. Compliance with the conditions of transportation and storage of re-imported products, including:

Food:

Gulf Technical Regulation No. (GS0323) General Requirements for Transportation and Storage of Chilled and Frozen Foods. Gulf Standard Specification No. (GSO2504) "General requirements for the transportation of food (Non-chilled and frozen)" and all technical regulations and standards related to the transportation of food materials.

Pharmaceuticals and Cosmetics:

Code for the transport and storage of products under the supervision of the Drug Sector through customs Ports.

Medical Devices and Products:

Guidance manual for storage, transport, and handling of medical devices and products.

Second:

Shipments Imported for Display in the Local Markets

The conditions and requirements for the clearance of imported products are applied according to the nature of the imported products and published on the authority's website (www.sfda.gov.sa)

Third:

Shipments Imported for Maintenance

1 . Used medical devices intended for maintenance or refurbishment in the Kingdom, then re-exported, require obtaining a marketing authorization for their importation or prior approval from the authority for their importation, re-exportation, and non-trading in the Kingdom, by obtaining an export permit.

2. Used medical devices intended for maintenance, calibration, display as marketing samples, or correction according to a safety alert requiring it, or testing them outside the Kingdom, provided that:

   A. They are re-imported within (6) months from the date of export and in accordance with the purpose for which they were exported. (Attach a copy of the export statement)

   B. Obtain a valid marketing authorization.

   C. Declaration from the manufacturer accepting responsibility for the operations carried out on those devices.

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