الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Frequent Observations on Shipments of Pharmaceutical, Herbal and Cosmetic Products

Version 2.0

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The Frequent Observations on Shipments of Pharmaceutical, Herbal and Cosmetic Products

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
1	Executive Directorate of Inspection and Law Enforcement	01 January 2020	-
2.0	Governance and clearance development directorate	12 December 2024	Update (Next page shows the updated details

What is New in version no. 2.0?

The following table shows the update to the previous version:

Section	Description of change
Title of the document	**Amendment:** Changing the title of the document from "The Frequent Observations on Some Imported Shipments to the Kingdom" to "The Frequent Observations on Shipments of Pharmaceutical, Herbal and Cosmetics Products".
Introduction, Scope, Objective, Related Regulation and Guidelines.	**Addition**
Observations on the External Package (outer Package)	**Addition:** Supplying the unregistered products in other languages which have different language other than Arabic and English Languages. **Delete:** Removing the registration number and price (in Arabic Language)
Frequent Observations	**Addition:** • Stop submitting applications through the clearance platforms like (exchange clearance - Authority clearance) and attach documents to them. • Not applying for import permission before the arrival of the unregistered products. **Delete:** The product's price and/or expiry date which are printed on the packaging do not match the registration data of the products at the Authority

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1. INTRODUCTION:

Based on the Authority's efforts to improve the investor experience and increase the awareness level and commitment to ensure the safety of preparations and products as well as enhance their availability, the Authority noted some repeated observations on the shipments of pharmaceutical products that were arrived through the approved ports for clearing it. This may lead to delay or rejection of these shipments. Therefore, the Authority wishes to clarify these frequent (repeated) observations.

2. SCOPE:

The received shipments of human, veterinary, herbal and cosmetic products to the Kingdom's ports.

3. PURPOSE:

Clarifying the most frequent observations on some shipments of human, veterinary, herbal and cosmetic products to the Kingdom's ports that may affect their clearance by rejection or delay.

4. RELATED REGULATIONS AND GUIDELINES:

4.1 The conditions and requirements for clearance of pharmaceutical products, raw materials used in their manufacturing, and medicinal plants.

4.2 Guidance for Presenting the Labeling Information, SPC and PIL.

4.3 The guideline for the transport and storage of products under the supervision of the drug sector through the custom ports.

4.4 Good Distribution and Storage practices guideline.

4.5 Guidance for the Storage and Transport of Time- and Temperature–Sensitive Pharmaceutical Products.

4.6 Frequently Asked Question for Temperature Monitors.

4.7 Conditions and requirements for clearing drugs, pharmaceuticals, and cosmetics products for individuals for personal use

4.8 Regulations and Requirements for the clearance of medicines, pharmaceutical products, medical devices, and food products that arrive for pilgrims use

4.9 Clearance conditions of cosmetic products and raw materials involved in their manufacture.

5. THE FREQUENT OBSERVATIONS ON SOME SHIPMENTS TO THE KINGDOM (EXAMPLES):

5.1 Fail to respond to the Authority's office observations at the port or central clearance office within the specified period.

5.2 Frequent observations on some shipments of human and veterinary products:

5.2.1 Failure to comply with the Authority's clearance requirements:

- When the applicant does not submit an import permission application before the arrival of the unregistered product shipment.
- Failure to include the manufacturer's and marketing authorization name and their nationality on the invoice
- When the applications were not submitted through the clearance platforms (clearance customs- the authority's clearance platforms) and attaching their related documents.

5.2.2 Failure to comply with the Authority's requirements for transportation and storage:

- Transport in non-refrigerated containers.
- Transportation in conditions of transport and storage that incompatible with the transport requirements of the received products.
- Fail to provide temperature measuring indicators with the incoming shipments, or provide non- activated indicators (not working).
- Failure to print serial numbers of temperature indicators in one of the shipping documents.
- Using temperature indicators that do not comply with the Authority specifications.
- Indicators stop recording shipment temperatures before they reach the Local distributor warehouses.

5.2.3 Non-zcompliance with the Authority's requirements for the pharmaceutical product's external / outer package:

5.2.3.1 Failure to ensure that plastic and glass beverage containers are sealed and equipped with the Tamper Proof.

5.2.3.2 Failure to comply with the specifications of the label and the information to be provided. *****

5.2.3.3 The storage conditions are not printed on the package in the Arabic language. *****

5.2.3.4 Providing the unregistered products in a language other than Arabic or English. *****

5.2.3.5 The name and nationality of the manufacturer company are not printed on the package. *****

5.2.3.6 Failure to print the manufacturing and expiry dates in accordance with the guidelines of the internal leaflet, the health practitioners' bulletin and the pharmaceutical external label requirements.

5.2.3.7 Not printing the phrase (free samples) on the free samples for the local market in Arabic.

5.2.3.8 Provide registered products with different expiry period other than what registered with the Authority.

5.2.3.9 Not printing the phrase (for veterinary use) with red color in Arabic on veterinary products.

5.2.3.10 Printing images of unapproved targeted animals on veterinary product packages.

5.2.3.11 Print information that is not compatible with the information mentioned in the internal leaflet of the veterinary product package.

5.2.3.12 Printing unapproved withdrawal period on veterinary packaging.

5.2.3.13 Printing unapproved medical claims on veterinary product package. *****

* This requirement is for products registered in the Kingdom only.

5.3 Frequent observations on some shipments of cosmetic products:

5.3.1 Fail to comply with the Authority's requirements for clearance:

5.3.1.1 Fail to meet the safety requirements in cosmetic products according to the technical regulation No. SFDA.co GSO 1943 2016.

5.3.1.2 Fail to meet the requirements of cosmetics product medical claims according to technical Regulation No. SFDA.co GSO 2528 2016.

5.3.1.3 Not listing the products in GHAD system.

5.3.1.4 The product dose not match its listed data in the GHAD system.

5.3.1.5 Not providing the conformity certificates or didn't pass the tests.

5.3.1.6 The product contains prohibited substances.

5.3.1.7 Medical claims on the received products.

5.3.2 Non-compliance with the Authority's requirements for transportation and storage:

5.3.2.1 Fail to use appropriate means of transportation in transporting the shipments.

5.3.2.2 Any leaks in the cosmetic product.