



FOOD AND DRUGS AUTHORITY

GUIDELINES FOR PROCESSING OF EXPORT PERMIT AND CLEARANCE OF PHARMACEUTICAL PRODUCTS

Document No. : FDA/IEC/GL-POP/2019/02
Date of First Adoption : 2nd January 2019
Effective Date : 02 January 2020
Version No. : 02

Table of Contents

1.0 INTRODUCTION 1

1.1 Scope 1

1.2 Abbreviations..... 1

2.0 GLOSSARY 1

3.0 REQUIREMENTS..... 2

3.1 General Requirements 2

3.2 Applying for Export/Clearance Permit 2

4.0 SANCTIONS AND PENALTIES..... 4

5.0 APPENDIX 5

1.0. INTRODUCTION

Effective regulation of the importation and exportation of internationally traded pharmaceutical products is key in ensuring the protection of the health and safety of consumers around the world. Clearance of pharmaceutical products for export, as carried out by the Food and Drugs Authority (FDA), typically involves permit issuance and inspection, both of which are mandated by the Public Health Act, Act 851 of 2012.

These guidelines outline the processes and procedures involved in the application for and issuance of electronic permits as well as the inspection and release of consignments for exportation out of the country.

These guidelines are hereby promulgated for information, guidance and strict adherence by all concerned

1.1. Scope

In exercise of the powers conferred on the FDA by Part 7, section 118 of the Public Health Act 851, 2012, these guidelines apply to all pharmaceutical products that are to be exported from Ghana and are for the adherence by all exporters of these products.

Despite the above, all pharmaceutical products to be exported shall comply with existing Ghana Standards.

The purpose of these guidelines is to provide exporters of products with the requirements of the Food and Drugs Authority (FDA) and also provide a comprehensive procedure for bringing their activities into compliance with the law.

1.2. Abbreviations

FDA	Food and Drugs Authority
eMDA	Electronic Ministries Departments and Agencies
HS Code	Harmonised System Code

2.0. GLOSSARY

For the purpose of these guidelines, unless the context otherwise requires;

“Authority” means the Food and Drugs Authority

“Product” means Pharmaceutical Products, Vaccines other Biological Medicinal Products, Herbal Medicines, Food Supplements, Homeopathy, and Raw Materials.

“Non-compliant product” means unregistered, banned, substandard, falsified/counterfeit and any other product that shall be determined by the Authority.

“Reasonable quantities” shall be determined by the Authority

“Approved port” means Tema Harbour, Kotoka International Airport and any other sea or air borders, as may be approved by the Authority from time to time.

3.0. REQUIREMENTS

3.1. General Requirements

3.1.1. Only businesses duly registered with the Registrar General Department shall be permitted to export products.

3.1.2. Only registered products shall be permitted to be exported unless given special approval by the Authority in accordance with Part 7, section 118 & 124 of the Public Health Act, Act 851 of 2012.

3.1.3. Products that shall require special approval by the Authority include:

3.1.3.1. Prescription product for personal use

3.1.3.2. Samples for Registration and promotions

3.1.3.3. Clinical trial products/samples

3.1.3.4. Donated products

3.1.4. The product to be imported for distribution or sale shall not have a shelf life of less than sixty per cent. The drug or herbal product with a shelf life of less or equal to twenty-four months whose remaining shelf life is less than eighty per cent shall not be exported.

3.2. Applying for Export/Clearance Permit

3.2.1. An applicant, for clearance to export products shall submit the following:

a. An application letter in writing addressing to:

**The Chief Executive
Food and Drugs Authority
P.O. Box CT 2783
Cantonments- Accra.**

- b. Batch numbers, quantities per batch, pack sizes and total quantity.
- 3.2.2. Exporters shall be required to secure an eMDA permit for all exports/ consignments of products. The following information must be submitted at the “item details” column on the eMDA portal during application;
- a. Full name (including Brand Name) of the product
 - b. Active Ingredients and corresponding strengths
 - c. Current FDA Product registration number (in full)
 - d. Name, phone number and registration number of the superintendent pharmacist
 - e. Name, address and relevant details of manufacturer (in case of raw materials)
- 3.2.3. The following information should also be provided or selected at the appropriate column:
- a. Appropriate HS Code for the product
 - b. Unit of the quantity (for e.g. ml, L, kg)
 - c. Postal and location address of exporter
 - d. Phone #, Fax # and E-mail addresses of both Importer and Exporter
 - e. 'For Export' must be indicated at the space provided for 'Purpose of Import/Export'.

Response/Feedback

The applicant must monitor the status of the application on-line. Applicants are expected to go beyond the track status to approval history by opening the document.

- 3.2.4. Only approved electronic permits (eMDA) shall be used for clearance of products at the port of exit.
- 3.2.5. Permits issued for exportation of products shall be presented to Customs only once.

- 3.2.6. The FDA shall prior to clearance, conduct inspection of the consignment to ensure compliance with the Law.
- 3.2.7. Export consignments of antiretroviral, antimalarial and antibacterial drugs shall have samples picked randomly for mini lab testing for product monitoring purposes.
- 3.2.8. Export clearance will attract appropriate fee as per the approved Fees & Charges (LI 2386, 2019)
- 3.2.9. The applicant shall be held responsible for any consignment of products found to be non-compliant after the consignment has been inspected, passed and an export permit issued by the Food and Drugs Authority, or if the consignment or part of the consignment, is concealed.
- 3.2.10. Any consignment, batch or lot of products found to be non-compliant shall be refused an export permit. Consignments whose non-compliance(s) could be brought into conformance would be reconsidered by the Authority when duly reworked.
- 3.2.11. Any consignment, batch or lot of products found to be unwholesome shall be quarantined and safely disposed of under the supervision of the Food Drugs Authority.
- 3.2.12. The Food and Drugs Authority shall charge a fee as per the Fees & Charges (LI 2386, 2019) for the supervision of safe disposal of unwholesome consignments.

4.0. SANCTIONS AND PENALTIES

- 4.1. The Food and Drugs Authority, in accordance with Part 7, Section 129 of the Public Health Act, Act 851 of 2012, may impose a fine for the breach of these guidelines as per the approved Fees & Charges (LI 2386, 2019)

5.0. APPENDIX

Change History

SN.	Date	Ver No.	Description of Change (section)
1.	02/01/2019	01	Initial issue
2.	02/02/2020	02	<ul style="list-style-type: none"> • Revision of sections 3.1 and 3.2.8, 3.2.12;4.1 • Change of document number and logo