FOOD AND DRUGS AUTHORITY

GUIDELINE FOR IMPORTATION OF MEDICAL DEVICES

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TABLE OF CONTENTS

1.0 INTRODUCTION

In pursuance of Section 148 of the Public Health Act, 2012, Act 851, these Guidelines are hereby made to provide guidance to prospective importers on the procedure for importing products into Ghana. Importers are required to familiarize themselves with this document and the above law before initiating product importation.

These guidelines must be read and used in conjunction with the enabling legislation, the Public Health Act, 2012, Act 851, Part 7, as well as any other relevant Guidelines and Regulations issued by the Food and Drugs Authority.

2.0 GLOSSARY

In these Guidelines, unless the context otherwise states:
Authority: means the Food and Drugs
Authority ***Product:*** means medical device.

Non-compliant product: means unregistered, counterfeit, substandard and any other product that shall be determined by the Authority.

Reasonable quantities: shall be determined by the Authority

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

3.0 REQUIREMENTS

3.1 General Requirements

3.1.1 Only Companies duly registered by the Registrar-General's Department and licensed by the Authority shall be permitted to import a product.

3.1.2 All products imported shall have at least 60% of their shelf-life remaining on arrival at the port. This notwithstanding, a product with a shelf-life of less than 24 months shall have at least 80% of its shelf-life remaining, on arrival at the port of entry.

3.1.3 Only registered products shall be permitted to be imported.

3.2 Specific Requirements

3.2.1 **Condoms**

Imported Condoms shall be released from the port of entry based on the results of a batch-to-batch analysis.

4.0 PRODUCT IMPORT PERMIT

4.1 Except otherwise provided by these Guidelines, import permits shall be granted before the importation of a product.

4.2 Permits issued for importation of products shall be presented to Customs, Excise & Preventive Service (CEPS) ONLY ONCE, and shall not be represented for a second time in case goods are short-landed.

4.3 Where goods are short-landed, a new import permit shall be obtained from the Authority.

4.4 Permits shall be valid for **ONE CALENDAR YEAR** from the date of issue.

4.5 A fee shall be charged for the processing of a permit submitted for importation. This shall be determined by the Authority from time to time.

4.6 Vetting of an application for importation and accompanying pro-forma invoices may take up to 24 hours or one working day

5.0 COMPLETION OF IMPORT PERMIT APPLICATION FORM

5.1. All import permits shall bear the following:

5.1.1 Full name, postal address and premises address of both the importer and exporter

5.1.2 Name/description of product

5.1.3 Total quantity of product, in dosage units

5.1.4 Product registration number

5.1.5 Name of manufacturer and country of origin

5.1.6 Batch number

5.1.7 Total CIF value

5.1.8 Name of port of shipments and approved port of entry

5.1.9 Date, company stamp and signature

5.2. Additionally for medical devices, the permit shall bear the Brand name and Generic name of the product.

5.3. For non-pharmaceutical companies and products, the permit shall be signed by a duly authorized person(s).

5.4. Products imported shall be inspected by officials of the Authority at the port of entry before they are released to the importer.

5.5. The above notwithstanding, any statute governing importation procedures and tax liabilities shall apply to an imported product.

5.6. An application for importation of a product may be rejected for several reasons. This may include, but not limited to:

5.6.1 A product not registered with the Authority.

5.6.2 A product with a potential for abuse

5.6.3 A product found to be fake, substandard and/ or adulterated.

5.7. All importers are required to renew their company license with the Authority annually.

6.0 SANCTIONS AND PENALTIES

6.1 **Non-Compliant Products**

The Authority may apply the following in case of the importation of a noncompliant product after detention and issuance of appropriate detention notice:

6.1.1 Order the re-export of the product at the cost of the importer.

6.1.2 Confiscate a non-compliant product, which may be destroyed and the cost of destruction borne by the importer, who may be prosecuted accordingly.

6.2 **Bringing Into Compliance**

6.2.1 The Authority may permit an importer to bring an imported non-compliant product into compliance with the law. Any sorting, processing, labeling/ relabeling or analysis shall be supervised by an officer of the Authority at the expense of the importer.

6.2.2 Where the non-compliant product is unregistered, the importer shall be made to submit the product for registration and pay the appropriate fees in addition to a penalty to be determined by the Authority.