FOOD AND DRUGS AUTHORITY

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Technical Advisory Committee on Safety of Medicines

Guideline on Importation of Drugs

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01/10/2018	01	Initial Issue
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Guideline on Importation of Drugs

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Executive Summary

This guideline specifies the minimum requirements for the importation of allopathic medicines in Ghana.

1. Introduction

In pursuance of Section 148 of the Public Health Act, 2012, Act 851, these Guidelines are hereby made to guide 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.

1.1 Legal Basis

This guideline applies to Marketing Authorization Applications for human and veterinary medicinal products submitted in accordance with Section 118 of the Public Health Act of 2012.

1.2 Scope

This guideline covers the importation of registered allopathic medicines.

The guideline does not apply to the importation of products to be used as samples for registration, registered products for medical promotion purposes, and products to be used in clinical trials per the Public Health Act 851.

It applies to licensed importers and other people requiring a permit to import medicines and related products. For requirements for licensing as an importer refer to Guideline for Licensing as Importer of Medicines and Related Products.

2. Definitions and Abbreviations

In these Guidelines, unless the context otherwise states,

"Authority" means the Food and Drugs Authority

"Product" means pharmaceutical products, vaccines and other biological medicinal products.

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

"Banned product" means a substance which is forbidden to be a component of a drug.

"Restricted product" means a product which is restricted to be imported into Ghana.

"Reasonable quantities" shall be determined by the Authority.

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

3. Main Guideline Text - Requirements

3.1 General Requirements

3.1.1 Only registered products shall be permitted to be imported.

3.1.2 Only the following shall be permitted to import a drug.

(a) Corporate bodies duly registered by the Registrar-General's Department and licensed by the Authority shall be permitted to import a product.

(b) Registered wholesale pharmaceutical companies, licensed by the Pharmacy Council and duly registered by the FDA as importers of drugs.

(c) Retail pharmacies may be permitted to import reasonable quantities for retail in their shops only.

(d) Patients with prescription for drugs that are not available on the Ghanaian market may import such drugs for their personal use once accompanied with a valid prescription.

3.1.3 The above notwithstanding, importation of samples for registration, medical promotion and/or clinical trials, as well as importation of specific prescriptions for particular patients, may be permitted.

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

3.2 Specific Requirements

3.2.1 Donated products should comply with all Ministry of Health Guidelines for Donation of Medicines

3.2.2 Parallel importation is permitted only after compliance to the FDA Guidelines for the Registration of Parallel Imported Drugs (FDA/DRI/DER/GL-PIM/2013/05)

3.3 Product Import Permit

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

3.3.2 When applying for a permit on the electronic platform, the following documents shall be submitted:

(a) A copy of the supplier's invoice.

(b) Electronically filled permit application form.

(c) Copy of the Bill of Lading.

3.3.3 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.

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

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

3.3.6 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.

3.3.7 Vetting of an application permit for importation and accompanying invoices may take **up to 24 hours or one working day.**

3.3.8 Applications which are found to fall short of any of the requirements above shall not be approved.

3.4 Compliance of Import Permit Application

3.4.1 All import permits shall bear the following:

a) Full name, postal address and premises address of both the importer and exporter
b) Name/description of product.
c) Total quantity of product, in dosage units
d) Product registration number
e) Name of manufacturer and country of origin
f) Batch number.
g) Total CIF value
h) Name of port of shipments and approved port of entry.

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

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

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

a) A product not registered with the Authority.
b) A product with a potential for abuse
c) A product found to be falsified, substandard, counterfeit, and/ or adulterated.
d) Controlled drug, when the national quota for that particular drug is exhausted. e.g. narcotic drugs and psychotropic substances.

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

3.5 Sanctions and Penalties

3.5.1 Non-Compliant Products

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

a) Order the re-export of the product at the cost of the importer.

b) Confiscate a non-compliant product, which may be destroyed, and the cost of destruction borne by the importer,

c) Prosecute the importer in accordance with the provisions of the Public Health Act.

3.5.2 Bringing into Compliance

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

b) 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.

3.6 Banned Substances

1. Iodochlorhydroxyquin line and its derivatives (0.1-0.5%)
2. Methaqualone and its salts
3. Phenylbutazone, its salts and derivatives (banned in use for Human or animals that are consumed by Humans (food producing), e.g., cattle, goat, pig, fowl, sheep, etc.)
4. Secobarbital (Quinalbarbitone)
5. All formulations with plain Ephedrine
6. Chloroquine for malaria
7. Nimesulide
8. Rofecoxib
9. Rosiglitazone
10. Ketoconazole Tablets

11. Codeine containing cough syrup.
12. Sulphathiazole

Any product containing a banned substance shall be confiscated and destroyed at a cost to the importer and attract a penalty.

3.7 Restricted Drugs for Local Manufacture

1. Aluminium Hydroxide Tablet
2. Aluminium Hydroxide or Magnesium Trisilicate Suspension.
3. Aluminium Hydroxide or Magnesium Trisilicate Tablet.
4. Amoxicillin Capsules (250mg, 500mg);
5. Amoxicillin Suspension (125mg/5ml,250mg/5ml); VI. Aspirin or Caffeine
6. Tablet.
7. Aspirin Tablet (300 mg).
8. Bendrofluazide Tablet.
9. Cetirizine Syrup (5 mg/ 5ml) and Cetirizine Tablet (10mg);
10. Chlordiazepoxide Capsules (5mg, 10mg);
11. Co-trimoxazole Suspension (40/200mg per 5ml) and Co-trimoxazole Tablet (80.400mg, 160/800mg).
12. Cough Mixture that is a cough mixture containing Carbocisteine, Diphenhydramine, Guaifenesin, or Ammonium chloride as a single ingredient or a combination with others.
13. Dexamethasone Tablet (0.5mg. 1mg).
14. Diazepam Tablets (5mg, 10mg)
15. Diclofenac Tablet (50mg)
16. Doxycycline Capsules (100mg).
17. Ferrous Ammonium Citrate

Annexure I

Executive Instrument for List of Medicines to Be Restricted For Importation And Reserved For The Local Market-2017

RESTRICTED LIST

The following is the list of medicines to be restricted from importation and reserved for local production only.

a. Aluminium Hydroxide Tablet.
b. Aluminium Hydroxide or Magnesium Trisilicate Suspension.
c. Aluminium Hydroxide or Magnesium Trisilicate Tablet.
d. Amoxicillin Capsules (250 mg, 500 mg).
e. Amoxicillin Suspension (125 mg/5ml, 250 mg/5ml).
f. Aspirin or Caffeine Tablet.
g. Aspirin Tablet (300 mg).
h. Bendrofluazide Tablet.
i. Cetirizine Syrup (5 mg/5 ml).
j. Cetirizine Tablet (10 mg).
k. Chlordiazepoxide Capsule (5 mg, 10 mg).
l. Co-trimoxazole Suspension (40/200mg per mi).
m. Co-trimoxazole Tablet (80/400 mg, 160/800 mg).
n. Cough Mixture that is cough mixture containing Carbocisteine, Diphenhydramine, Gualfenesin or Ammonium chloride as a single ingredient or in combination with each other.
o. Dexamethasone Tablet (0.5 mg, 1 mg).
p. Diazepam Tablets (5 mg, 10mg).
q. Diclofenac Tablet (50 mg).
r. Doxycycline Capsules (100 mg).
s. Ferrous Ammonium Citrate.
t. Ferrous Fumarate.
u. Ferrous Sulphate.
v. Ferrous Sulphate, Ferrous Fumarate or Ferrous Ammonium Citrate in combination with Folic Acid.
w. Folic Acid Tablet (5 mg).
x. Glibenclamide Tablets (5 mg).
y. Folic Acid Tablet (5 mg).
z. Glibenclamide Tablets (5 mg).
aa. Griseofulvin Tablet (125 mg, 500 mg)
bb. Hydrochlorothiazide Tablet.
cc. Ibuprofen Tablet (200 mg, 400 mg).
dd. Iron III Polymaltose tablet or syrup.
ee. Lisinopril Tablet (5 mg/10 mg/20 mg).
ff. Magnesium Trisilicate Suspension.

gg. Magnesium Trisilicate Tablet; GP “Metronidazole Suspension (100 mg/5ml, 200 mg/5ml).
hh. Metronidazole Tablet (200 mg, 400 mg).
ii. Multivitamin Syrup (Vitamins A Acetate, BI, B2, B12, D3, Nicotinamide, Calcium Pantothenate).
jj. Multivitamin Tablet (Vitamins A Acetate, Bi, B2, B12, D3, Nicotinamide, Calcium Pantothenate).
kk. Oral Rehydration Salts.
ll. Oxytetracycline Capsule (250 mg).
mm. Paracetamol Caffeine Tablet.
nn. Paracetamol Syrup (120 mg/5 ml).
oo. Paracetamol Tablet (500 mg).
pp. Paracetamol or Codeine Tablet.
qq. Paracetamol or Aspirin or Caffeine Tablet.
rr. Phenobarbitone Tablet (30 mg, 60 mg).
ss. Prednisolone Tablet (5 mg).
tt. Simethicone containing antacids.
uu. Simple Linctus Syrup.
vv. Tetracycline Capsules (250 mg); and
ww. Vitamin B Complex Tablet.

(For more information, refer to E.I. 181)