FOOD AND DRUGS AUTHORITY

GUIDELINES FOR IMPORTATION OF CONTROLLED SUBSTANCES

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1 INTRODUCTION

In pursuance of Section 126 of the Public Health Act, 2012 (ACT 851), the Food and Drugs Authority shall regulate the narcotics, psychotropic substances and precursor chemicals in accordance with the underlisted multilateral conventions which are currently in force:

a. The Single Convention on Narcotic Drugs of 1961 (**1961 Convention**), as amended by the 1972 Protocol;

b. The Convention on Psychotropic Substances of 1971 (**1971 Convention**) and, adopted in 1988,

c. The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (**1988 Convention**).

The above mentioned Conventions and other related resolutions of the Economic and Social Council provides the framework for international cooperation in preventing the diversion of narcotic drugs, psychotropic substances and precursors. They contain special provisions relating to the international trade of controlled substances and impose a general obligation on States parties to cooperate in limiting the use of controlled substances to medical and scientific purposes, whilst preventing their diversion to illicit trade and abuse.

This guideline is hereby promulgated for information, guidance and strict adherence by all concerned.

SCOPE

This guideline is made to provide guidance to applicants on the procedure for importing all controlled substances for medical, scientific and research purposes.

GLOSSARY

a) **"FDA"** means Food and Drugs Authority

b) **"Controlled Substances"** means a Narcotic drug, Psychotropic substance or Precursor chemical.

c) **"Narcotic drugs"** means substances listed in Schedules I and II of the 1961 Convention**.** The esters and ethers and the salts of esters and ethers of the narcotic drugs in Schedule I are also subject to control.

d) **"Psychotropic substance"** means those natural or synthetic substances or any natural material listed in the four Schedules of the 1971 Convention. The salts of those substances, where they exist, as well as preparations containing those substances, are subject to the same control requirements as the base substance.

e) **"Precursor chemical"** means those substances listed in Tables I and II of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 (1988 Convention) frequently used in the illicit manufacture of narcotic drugs and psychotropic substances under the international control.

f) **"Importer"** means a licensed pharmaceutical company registered with the FDA to import drugs into Ghana.

g) **"Permit for the Importation of Narcotics and Psychotropic Substances"** is a valid document issued by the FDA to an importer for the importation of controlled substances.

h) **"Advice of Receipt"** is a document submitted by an importer to show that a product covered by a controlled substance import permit has been duly imported into Ghana.

i) **"Returns"** is a document submitted by an importer to show the utilization and distribution records of a controlled substance that has been duly imported into Ghana.

j) **"GMP"** means Good manufacturing practices.

3 REQUIREMENT

3.1 General Requirements

(a) The company shall be registered as an importer or manufacturer with the FDA [*refer to guidelines for licensing of manufacturing industries (drugs, cosmetics, household chemical substances and medical devices)].*

(b) For importers of finished products

- The company shall register the finished products containing controlled substance with the FDA.(*refer to Guidelines for the registration of allopathic drugs*)

(c) For Local manufacturers

- The company shall have a License to manufacture [*refer to Guidelines for licensing of manufacturing industries (drugs, cosmetics, household chemical substances and medical devices)]*.

- The company shall register pharmaceutical preparations containing the controlled substance. (*refer to Guidelines for the registration of allopathic drugs*)

(d) Local manufacturers who have intentions to manufacture finished products (medicines) with controlled substances are expected to have been manufacturing other allopathic drugs for at least five (5) years.

(e) Controlled substance (Raw materials) imported into the country cannot be sold or transferred to another manufacturer or person.

3.2 Conducting Inspections on controlled substances

(a) Inspections shall be conducted on controlled substances imported into the country

(b) The inspection shall either be announced or unannounced however, for announced inspections, FDA shall issue a letter communicating to the entity/company the scheduled date for the inspection.

(c) Companies/entities which may fail to be available for the scheduled date of inspection shall fill and complete an inspection re-scheduling form indicating reason(s) for re-scheduling and may attract a re-scheduling fee as defined by the Authority.

3.3 Allocation of Controlled Substances

(a) The importer shall submit a letter requesting for an allocation of a controlled substance for the following year to the FDA. Based on previous utilization and distribution records received, FDA shall allot to the company the needed quantities.

(b) New Importers shall formally request for an allocation of a controlled substance after satisfying the general requirements.

(c) Increase in allocation or addition of controlled substances to Ghana's legitimate requirements shall be justified.

3.4 Issuing of Controlled Substance Import Permit

3.4.1 Application for a Controlled Substance Import Permit

(a) The company shall apply for a controlled substance permit through the Ghana Community Network (GCNet) electronic permit system.

(b) The company shall enter the following details on the import permit application:

- Name, full postal address and telephone numbers of the importing company
- Name, full postal address and telephone numbers of the exporting company
- The purpose of import
- Item details – the following shall be stated
  - the full name of the controlled substance,
  - total quantity shall be stated in dosage unit. (For example, 2000 ampoules, capsules or tablets etc.)

- Transport details (NB. This section which includes the Mode of transport, Mode of Transport Description, Shipment date, Carrier, Port of Arrival, Port of Departure, Customs Office and Freight Station shall be fully stated).

(c) The company shall also require a controlled substance import permit for the following;

- importation of samples of finished product containing a controlled substance for registration purposes and/or

- importation of raw materials for research and development purposes.

3.5 Final Import Permit

Upon approval of a controlled substance permit application by the FDA, a final import permit (hard copy) shall be prepared by the FDA and collected by an authorized person of the importing company.

The permit shall bear the following:

(a) Permit Number

(b) Full name, address, telephone numbers and email address of the importer

(c) Name and the total quantity of the controlled substance intended for importation. If finished product (containing controlled substance) the brand name and generic name shall be quoted.

(d) Full name, address, telephone numbers and email address of the exporter

(e) Permit issued date

(f) Permit expiry date which shall be the 31st of December of the year permit be issued

(g) The Food and Drugs Authority seal

3.6 Rejection of Import Permit Application

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

(a) When the National quota for that particular controlled substance is exhausted,

(b) When the AOR or returns for previous import(s) have not been submitted,

(c) When the product to be imported has not been registered with FDA,

(d) When Drug Evaluation and Registration Department (DERD) raises objections to the importation of the product due to registration anomalies.

3.7 Schedule for samples

(a) For finished product, applicant shall refer to "Sample schedule for allopathic drugs".

(b) For raw materials please refer to the below:

i. Precursor chemicals at most 25kg
ii. Narcotics substances at most 5kg
iii. Psychotropic substances at most 25kg

The quantities of raw materials to be allowed for samples will also depend on the quantity of controlled substance available.

3.8 Submission of Reporting Documents

3.8.1 Advice of Receipt

The importer shall submit an advice of receipt of the controlled substance to the FDA not later than two weeks after it has been duly imported and cleared. This document shall be accompanied by a cover letter addressed to the Chief Executive from the company.

(Refer to Annex I for Advice of receipt form).

3.8.2 Returns

(a) The importer shall submit returns for the imported controlled substances quarterly. This document shall be accompanied by a cover letter addressed to the Chief Executive from the company.
(Refer to Annex II for Returns form)

(b) The returns shall be submitted prior to the application for another permit to import a controlled substance.

3.8.2.1 Completion of Returns Form

TABLE A: RAW MATERIALS ONLY

1. Provide the name and full postal address & telephone number of the importing company in the box.

2. State the name (Both the generic and brand name) of the narcotic drug, psychotropic substance or precursor chemical.

3. Provide the information requested in the spaces provided respectively.

   a) **Old stock** refers to the stock just used up before taking on a present consignment.

   b) **New stock** is the present stock being accounted for.

c) **Particulars** refer to the specific activities the substance is to be used for:

i. Laboratory samples.

ii. Issues to a client (In this case provide the name and location (city/town) of client).

iii. Production (State dosage form, strength and batch number of production and batch size).

iv. For every new consignment of controlled substance received, the import permit number should be stated.

4. Columns where details of quantities of substances **received are entered** should be **in bold type.**

TABLE B: FINISHED PRODUCTS ONLY

1. Provide the name and full postal address & telephone number of the importing company in the box.

2. State the name (Both the generic and brand name) of the narcotic drug, psychotropic substance or precursor chemical.

3. Provide the information requested in the spaces provided respectively.

(a) **Pack size** is the total number of product in a package.

(b) **Particulars** refer to the specific activities the substance is to be used for. (For every new consignment of controlled substance received, the import permit number should be stated)

i. Laboratory samples.

ii. Issues to a client (In this case provide the name and location (city/town) of client).

iii. For every new consignment of controlled substance received, the import permit number should be stated

4. Columns where details of quantities of **product received are** entered should be **in bold type.**

3.9 Annex 1

ADVICE OF RECEIPT OF IMPORTED NARCOTIC DRUGS, PSYCHOTROPIC SUBSTANCES & PRECURSOR CHEMICALS

<table>
<tr><td colspan="3" rowspan="4">Name & Premises Address of Importer:
Postal Address:
Tel. no.:
Fax:
Email:</td><td colspan="3">Import Permit Number :</td></tr>
<tr><td colspan="3">Import Permit Issue Date:</td></tr>
<tr><td colspan="3">Import Permit Expiry Date:</td></tr>
<tr><td colspan="3">Name & Premises Address of Exporter</td></tr>
<tr><td colspan="3" rowspan="3">Name of imported Narcotic Drug/Psychotropic Substance /Precursor Chemicals</td><td colspan="3">Dosage form</td></tr>
<tr><td colspan="3">Quantity</td></tr>
<tr><td colspan="3">Amount of Active Ingredients</td></tr>
<tr><td colspan="2">Bill of Lading No.</td><td colspan="2">Port of Entry</td><td colspan="2">Port of Export</td></tr>
<tr><td colspan="3">Date of Arrival at Port</td><td colspan="3">Date of Clearance from port</td></tr>
<tr><td colspan="4">Signature & Stamp</td><td colspan="2">Date form was received
(To be filled & signed by FDA officials)</td></tr>
</table>

3.10 Annex 2

Table A: RAW MATERIALS ONLY
RETURNS ON NARCOTIC DRUGS, PSYCHOTROPIC SUBSTANCES AND PRECURSOR CHEMICALS IMPORTED

NAME AND FULL ADDRESS OF COMPANY	**TEL. NO:**
NAME AND FULL ADDRESS OF COMPANY	**TEL. NO:**

NAME OF NARCOTIC DRUG, PSYCHOTROPIC SUBSTANCE AND PRECURSOR CHEMICAL:
BRAND NAME:
GENERIC NAME:

	PERMIT NUMBER	PERMIT ISSUE DATE	PERMIT EXPIRY DATE	REMARKS
OLD STOCK				
NEW STOCK				

STOCK UTILISATION INFORMATION (RAW MATERIAL)

DATE	PARTICULARS	OPENING STOCK	QUANTITY RECIEVED	QUANTITY ISSUED	CLOSING STOCK	QUANTITY PRODUCED	TOTAL ACTIVE	PERCENTAGE YIELD

Table B: FINISHED PRODUCTS ONLY

RETURNS ON FINAL PRODUCTS OF NARCOTICS, PSYCHOTROPIC SUBSTANCES AND PRECURSOR CHEMICALS IMPORTED

NAME AND FULL ADDRESS OF COMPANY	TEL. NO.:

NAME OF NARCOTIC, PSYCHOTROPIC SUBSTANCE AND PRECURSOR CHEMICALS:
BRAND NAME:
GENERIC NAME:
DOSAGE FORM:
STRENGTH OF PRODUCT:
PACK SIZE:
STOCK UTILISATION INFORMATION

DATE	PARTICULARS	INVOICE/ WAYBILL NUMBER	OPENING STOCK	QUANTITY RECIEVED	QUANTITY ISSUED	BATCH NUMBER	EXPIRY DATE	CLOSING STOCK

4 APPENDIX

4.1 Change History

SN	Date	Ver. No.	Description of Change (section)
1.	01/02/2013	00	Initial issue
2.	13/08/2018	01	Review of sections 2.0(g), 3.1, 3.2 and 3.2
3.	01/10/2019	02	General review of guidelines