
	Title: Guideline for the importation and Clearance of controlled substances	
Rev No: 02	Doc No: PBSL/GL/023	Version no. 03
Issue date: 15 May 2024	Effective date: 17 May 2024	Approved by: Registrar

Adopted By PBSL	
Start of public Consultation	
End of public Consultation	
Agreed by QMS committee	
Approved by Board	

**Pharmacy Board of Sierra Leone,
PMB 322
Central Medical Stores Compound
New England Ville
Freetown**





	Title: Guideline for the importation and Clearance of controlled substances	
Rev No: 02	Doc No: PBSL/GL/023	Version no. 03
Issue date: 15 May 2024	Effective date: 17 May 2024	Approved by: Registrar

Table of Contents

Acknowledgements.....	3
Executive Summary.....	3
1.0 INTRODUCTION	3
2.0 OBJECTIVES.....	3
3.0 SCOPE.....	3
4.0 SPECIFIC REQUIREMENTS	4
5.0 GLOSSARY	8
6.0 REFERENCES AND INFORMATION SOURCES.....	9
7.0 ANNEXES.....	10

	Title: Guideline for the importation and Clearance of controlled substances	
Rev No: 02	Doc No: PBSL/GL/023	Version no. 03
Issue date: 15 May 2024	Effective date: 17 May 2024	Approved by: Registrar

Acknowledgements

Executive Summary

1.0 INTRODUCTION

These guidelines are for the interest of all applicants involved in the importation of Narcotics, Psychotropic substances, Precursor chemicals and Controlled solvents regulated under Section 55 of the Pharmacy and Drugs Act, 2001.

These guidelines are hereby made to provide guidance to applicants on the procedure for the importation and clearance of Narcotics, Psychotropic substances, Precursor chemicals and Controlled solvents in Sierra Leone. Applicants are encouraged to familiarize themselves with this document before submitting their applications.

These guidelines are also meant for obtaining 'Permits' to import or clear narcotics, psychotropic substances, precursor chemicals or controlled solvents.



Please note that no Narcotics, Psychotropic substances, Precursor chemicals or Controlled solvents shall be imported, exported, advertised, sold or distributed in Sierra Leone unless it has been registered and/or listed in accordance with the provisions of Section 55 of the Pharmacy and Drugs Act, 2001.

2.0 OBJECTIVES

To ensure that all controlled substances are granted importation and clearance permits before marketing.

3.0 SCOPE

Regulation and control of Narcotics, Psychotropics and Precursor chemicals and the handling (supply, manufacture, distribution, storage and use) and

	Title: Guideline for the importation and Clearance of controlled substances	
Rev No: 02	Doc No: PBSL/GL/023	Version no. 03
Issue date: 15 May 2024	Effective date: 17 May 2024	Approved by: Registrar

safety monitoring of them

4.0 SPECIFIC REQUIREMENTS



4.1 SUBMISSION OF APPLICATION

1. Application for permit or authorization to import narcotics, psychotropic substances, precursor chemicals or other controlled substances



- a) An applicant shall apply for import permit for the importation of a controlled Drug (s) meant for meant for research and medical use.

The applicant shall be any one of the following:

- i. Corporate body duly registered by the Registrar-General's Department and licensed by the Pharmacy Board.
 - ii. Registered Import and wholesale pharmaceutical company, licensed by the Pharmacy Board.
 - iii. Governmental, Quasi-governmental agencies or Non-Governmental Organizations (NGOs) that run health programs and facilities, and approved by the Ministry of Health and Sanitation.
- b) An application, preferably with a letter head shall be forwarded to the office of the Registrar of the Pharmacy Board of Sierra Leone using the under-mentioned address:
C/o Central Medical Stores compound
New England Ville
Freetown, Sierra Leone
West Africa
- c) The application shall be accompanied with an application letter or request and shall include the following:

	Title: Guideline for the importation and Clearance of controlled substances	
Rev No: 02	Doc No: PBSL/GL/023	Version no. 03
Issue date: 15 May 2024	Effective date: 17 May 2024	Approved by: Registrar

- i. The name of product, dosage form, strength per unit dose, pack size (if applicable)
quantity and total weight (Kg) of each of the product per consignment to be imported.
 - ii. The name and full address of the importer
 - iii. The name and address of the supplier from the exporting country
 - iv. The purpose for the importation
 - v. The route of importation (air, land or sea)
 - vi. The signature of the Pharmacist working for any one of the institutions stated in
1(b) above.
- d) Copies of documents to accompany the application shall include:
- i. Current annual license to practice as a Pharmacist.
 - ii. Current license of Premises (If private company or establishment).
 - iii. Proforma Invoice.
 - iv. Any supporting document to request large quantities of controlled substance (e.g. Government Tender Award)
 - v. Pharmacy Board Product Registration Certificate (where applicable).
 - vi. Copy of current attestation letter from the Ministry of Health and Sanitation and the drug distribution plan for the controlled substances to be imported (if it is an NGO, Government institution, Bilateral and Multilateral health partners)
 - vii. The Distribution Records or Returns of previous imports must be submitted before a fresh application for permit to import can be received (Repeat applications only)
- e) Original of documents (i - vii) above must be sighted at the time of submission.

	Title: Guideline for the importation and Clearance of controlled substances	
Rev No: 02	Doc No: PBSL/GL/023	Version no. 03
Issue date: 15 May 2024	Effective date: 17 May 2024	Approved by: Registrar

2. Application for permit to clear imported narcotics, psychotropic substances, precursor chemicals or controlled solvents

i) Upon importation of the Narcotics, Psychotropic substances, Precursor chemicals or other controlled substances, an application letter addressed to the Registrar of the

Pharmacy Board and signed by the Pharmacist shall be submitted stating:

- a) Name of each Product, Dosage form, Pack size (as applicable), quantity, strength per unit dose and total weight of controlled substance per consignment in kilograms (kg).
- b) Port of entry



ii) Copies of documents to accompany application shall be:

- a) Single Goods Declaration Form
- b) Permit to import
- c) Bill of lading / Airway bill (where applicable)
- d) Commercial Invoice
- e) Packing List
- f) Certificate of Analysis/Quality Control Certification.

iii) Original documents (a – f) above must be sighted at the time of submission.

A. PROCESSING FEE

1. A processing fee shall be paid for processing of applications for the importation and clearance of Narcotics, Psychotropic substances, Precursor chemicals or other controlled substances.
2. Payment of processing fee shall be made in cash or cheque to the Finance Department of the Pharmacy Board of Sierra Leone as follows:
 - a. Permit for importing controlled substances = Le 75,000
 - b. Permit for clearing controlled substances at QEII Quay (By Sea) = Le 75,000

	Title: Guideline for the importation and Clearance of controlled substances	
Rev No: 02	Doc No: PBSL/GL/023	Version no. 03
Issue date: 15 May 2024	Effective date: 17 May 2024	Approved by: Registrar

c. Permit for clearing controlled substances at Lungi Airport (By Air) = Le 100,000

3. Import Permit must be obtained first, followed by clearance permit before the imported products can be cleared either at QE II Quay or Lungi International airport.

B. TIME LINE FOR PROCESSING OF APPLICATIONS

1. The processing time for issuing permit or authorization to import controlled substances is seven (7) working days after submission of complete documentation.
2. The processing time for permit to clear controlled substances is two (2) working days after submission of complete documentation.

C. LABELLING REQUIREMENTS:



All controlled substances must be properly labelled in accordance with the Pharmacy Board's labelling requirements for imported medicines, including controlled substances.

D. AUDIT INSPECTION

Audit inspection will be carried out in your premises once every quarter of the year:

- a) To ensure that the controlled drugs (narcotics, psychotropic substances and precursor chemicals) imported in the country are distributed and utilized within the **LICIT** distribution channels.
- b) To trace the authenticity of the distribution and usage of the controlled substances (narcotics, psychotropic substances and precursor chemicals) imported and to detect if there are any illicit diversions.

E. CORRESPONDENCES

	Title: Guideline for the importation and Clearance of controlled substances	
Rev No: 02	Doc No: PBSL/GL/023	Version no. 03
Issue date: 15 May 2024	Effective date: 17 May 2024	Approved by: Registrar



All correspondences in respect of these Guidelines should be addressed to the Registrar, Pharmacy Board of Sierra Leone using the following contacts:

- Website – www.pharmacyboard.gov.sl
- E-mail: - registrar@pharmacyboard.gov.sl
- Telephone: **(00 232 22) 229346**
(00 232 22) 228497
(00 232 22) 228351
- Mobile Number: **+ 232-76- 63- 10 – 14**

5.0 GLOSSARY DEFINITIONS

In these guidelines, unless the context otherwise states: -

- a) **"Board"** means Pharmacy Board of Sierra Leone (PBSL)
- b) **"Applicant"** means the product owner or licence holder. Representative of licence holder may not hold themselves as applicants unless they own the product.
- c) **Controlled Drug** - is any drug or therapeutic agent with a potential for abuse or addiction, which is held under strict governmental control.
- d) **Narcotic drug** 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 1 are also subject to control. e.g morphine, pethidine, fentanyl, tramadol, codeine, cocaine, heroin, etc
- e) **Psychotropic substances** mean those natural or synthetic substances or any natural material listed in the four Schedules of the 1971 Convention. E.g. diazepam, nitrazepam, lorazepam, pentazocine, phenobarbital, oxazepam, methamphetamine, midazolam, etc.
- f) **Precursor substances** means those substances listed in Tables I and II of the United Nations Convention against Illicit Trafficking. They are

	Title: Guideline for the importation and Clearance of controlled substances	
Rev No: 02	Doc No: PBSL/GL/023	Version no. 03
Issue date: 15 May 2024	Effective date: 17 May 2024	Approved by: Registrar

substances listed schedules I and II of the 1988 convention. They are frequently used in the illicit manufacture of narcotic drugs and psychotropic substances under international control.

- g) **Controlled Solvent** means those reagents or solvents frequently used in the illicit manufacture of narcotic drugs and psychotropic substances under international control. Examples include potassium permanganate, acetone, hydrochloric acid, sulphuric acid, ethyl ether, phenyl acetic acid, piperidine, toluene, methyl - ethyl ketone.
- h) **Returns** are documents submitted by importers of controlled substances that show how the controlled substances have been utilized. Returns cover the following:

Stock utilization records (for raw- materials, if any) – every batch is to be accounted for:

- Stock distribution records (for finished product)
- Quantities utilized for R&D, if any.
- Quantities submitted to QC for analysis, etc.

ABBREVIATIONS



NGO- Non Governmental Organization

QC- Quality Control

R & D- Research and Development

6.0 REFERENCES AND INFORMATION SOURCES

NONE

	Title: Guideline for the importation and Clearance of controlled substances	
Rev No: 02	Doc No: PBSL/GL/023	Version no. 03
Issue date: 15 May 2024	Effective date: 17 May 2024	Approved by: Registrar

7.0 ANNEXES

Import permit request form
Clearance permit request for

Prepared by

Head of ENC
Dr Joy B Johnson

Reviewed by

Head, Quality Assurance
Dr Michael Lahai

Approved by

Registrar
Dr James P. Komeh