	Guidelines for the exportation of pharmaceutical products	
Rev No: 02	**Doc No: PBSL/GL/017**	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

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ACKNOWLEDGEMENTS

EXECUTIVE SUMMARY

1.0 INTRODUCTION

This guideline is for the interest of all applicants engaged in the exportation of pharmaceuticals and other related products under Section 55 of the Pharmacy and Drugs Act, 2001.

This guideline is hereby made to provide guidance to applicants on the procedure for the exportation of pharmaceuticals and other related products.

Applicants who are engaged in the exportation of pharmaceuticals and other related products are encouraged to familiarize themselves with this document before submitting their applications.

2.0 OBJECTIVE:

To provide exporters of pharmaceutical products with the necessary information to enable them comply with the laws and regulations governing the exportation of pharmaceutical and /or biological products.

3.0 SCOPE:

This guideline applies to all exporters of pharmaceutical products.

4.0 SPECIFIC REQUIREMENTS

4.1 Exportation of Pharmaceutical Products

4.1.1 Categories of exporters

Exporters of pharmaceutical products shall fall under the following categories:

a) Registered local pharmaceutical manufacturers licensed by the Pharmacy Board of Sierra Leone.

b) Registered pharmaceutical importers, wholesalers or distributors licensed by the Pharmacy Board of Sierra Leone.
c) Clinical trial sponsors and investigators
d) Government and Non-Government institutions authorized by the Board to export.

4.1.2 Requirements for pharmaceutical products exporters

a) No person shall export pharmaceutical products out of the country without having a valid export permit issued by the Board.
b) All pharmaceutical products to be exported must originate from a registered manufacturer, importer or wholesaler in Sierra Leone.
c) Biological samples (e.g., blood, serum, plasma, etc.) intended to be exported should either be registered or authorized by the Board
d) All exporters must export pharmaceutical products through the official Port of Entry (PoE).

4.1.3 Procedures to export pharmaceutical products

i. Any persons intending to export pharmaceuticals shall request for export permit by submitting an application letter and a filled export permit request form (as prescribed under Annex I of this guideline).
ii. All applications should be submitted to the office of the Registrar of the Pharmacy Board located at Central Medical Stores, New England Ville, and Freetown.
iii. The application letter and export permit request form shall be stamped and signed by the applicant who desirably is a registered Pharmacist, before submission to the Board.
iv. The application form shall be accompanied by one original proforma invoice.
v. Proforma invoices shall state the following for each pharmaceutical product to be exported:
   a) Proforma Invoice number and date;
   b) Name and address of the exporter;

c) Name and address of the manufacturer;
d) Country of origin;
e) Country of destination;
f) Clear description of each pharmaceutical product, including brand and common name as declared in the information submitted to the Board.
g) The quantity to be exported for each pharmaceutical product, its unit value, total value in convertible currency,
h) The product registration number issued by the Board;
i) Batch or Lot number;
j) Manufacturing and expiring date;
k) Mode of shipment (sea, air, road);
l) Port of exit; and
m) Signature and stamp of the applicant or Pharmacist.

vi. If the application meets the prescribed requirements, the applicant will be required to pay an export permit fee of one hundred thousand Leones.
vii. The Board, upon payment of the export permit fee, will issue to the applicant an export authorization permit as set out in Annex 2 of these guidelines.
viii. The export permit will be valid for a period of one month from the date of issue.
ix. The export permit shall not be transferable and shall be issued to cover only one shipment.
x. All applications for export will be processed within three working days.
xi. The export permit must be valid before embarking on the shipment of the consignment.
xii. An application will be rejected if it does not meet any of the export requirements. An applicant will be officially informed stating clearly the reason(s) for the rejection

4.1.4 Special exportation requirements

All application requirements and procedures as prescribed under section 5.2

shall apply. However, in some special circumstances the following requirements will be applicable:

4.1.4.1 Exportation of biological samples (blood, serum, plasma, etc.)

Application for the exportation of the above products should be made by a clinical trial sponsor or Principal Investigator.The application letter should be accompanied by:

a) A filled export permit request form containing list of products to be exported,
b) Material Transfer Agreement document, and
c) A covering letter/note approved by the Chief Medical Officer.

4.1.5 Review and appeal procedures

a) Any applicant who is not satisfied by the decision of the Board in relation to any application to export of biological products may appeal for review of the decision to the registrar within a period of 14 days from the date of receipt of the decision.
b) The Board may review its decision, reject or vary the condition of approval.
c) After re-consideration of the application, if the applicant is not satisfied by the decision of the review, may appeal to the board.

5.0 GLOSSARY

5.1 Definition of Terms:

For the purpose of this guideline the following terms shall be defined as follows:

Act
Means the Pharmacy and Drugs Act, 2001

Applicant

Means any person or institution or company that applies formally to get market authorization for one or more pharmaceutical products.

Assay
Means investigative (analytic) procedure in laboratory for qualitatively assessing or quantitatively measuring the presence, amount or functional activity of a target entity (the analyte).

Board
Means the Pharmacy Board of Sierra Leone, or its acronym "PBSL" established under section 2 (two) of the Pharmacy and Drugs Act, 2001

Certificate
Means a certificate issued by the Board.

Clearance permit
Means a permit issued to an importer by the Board, authorizing him/her to clear his or her pharmaceutical product(s) at the official port of entry.

Consignment
Means a quantity of pharmaceutical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include pharmaceutical products belonging to more than one batch.

Container
Means any material employed in the packaging of a pharmaceutical product. It could be a bottle, jar, box, sachet, strip, blister or other receptacle which contains the finished pharmaceutical product.

Controlled drug
Means any narcotic drug, psychotropic substance or precursor as described under
Part VI of the Pharmacy and Drugs Act, 2001.

Donation

Means an act of presenting pharmaceutical products free of cost to recipients in emergency situations or as a part of development aid in none-emergency situations.

Donor
Means a governmental or nongovernmental organization or individual who voluntarily donates pharmaceutical products as a donation.

Importer
Means person or institutions authorized to export drugs out of the country.

Export Permit
Means a permit issued to exporter by the Authority, authorizing him to export pharmaceuticals from the country.

Label
Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a container of any pharmaceutical product when it is being supplied.

Authorized Representative / Local Responsible Person or Agent
A person residing in the country or cooperate body registered in the country who has received a legal mandate from the applicant to act on his behalf with regards to matters pertaining to registration, importation and/or clearance of pharmaceutical products in the country.

Manufacturer
Means a company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of pharmaceutical products

Medical Device
Any instrument, apparatus, laboratory equipment and reagents, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article which is intended by manufacturer

to be used, alone or in combination for human beings or other animals for one more of the specific purpose(s) of:

a) Diagnosis, prevention, monitoring, treatment or alleviation of diseases or compensation for an injury;
b) Investigation, replacement, modification or support or the anatomy or of a physiological process;
c) Supporting or sustaining life;
d) Control of conception;
e) Disinfection of medical devices;
f) Providing information for medical or diagnostic purposes by means of in vitro examination or specimens derived from the human body or other animal; and does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Orphan/Specialised Drug
Means a pharmaceutical product (a drug medical device, diagnostic reagent or test kit) which remains commercially undeveloped due to low commercial returns, or intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders, or intended to treat rare diseases that the sponsors are reluctant to develop them under usual marketing conditions.

Pharmaceutical product
Any product presented in its finished dosage form, intended for use as a medicine or as a remedy for the purpose of medical, dental or veterinary treatment. It includes medicines, chemical substances, nutritional agents, medical devices, cosmetics and vaccines.

Prescription
Means a lawful written direction by a medical practitioner, dentist, or veterinary surgeon for the preparation and dispensation of a drug by a pharmacist.

Recipient
Means a governmental, non-governmental or private health Institution that voluntarily receives pharmaceutical products as a donation.

5.2 Abbreviations

CTA	Clinical Trial Approval
CCT	Certificate of Clinical Trial
EBC	Ethical Board Clearance
EO	Ethylene Oxide
MOHS	Ministry of Health and Sanitation
NGO	Non-Governmental Organization
NRA	National Revenue Authority
PBSL	Pharmacy Board of Sierra Leone
PoE	Port of Entry.

6.0 REFERENCES

NONE

7.0 ANNEXES

Annex 1

Name of Exporter…… Date: ……

Address of Exporter: ……

Name and Contact Address of Country/Organization/Company product Exported to:
……
……

Route of Export: Air: …… Sea …….. Road ……

Reason/Purpose of Export: ……..

NO.	PRODUCT DESCRIPTION Brand name Generic name		DOSAGE FORM	STRENGTH	BATCH NUMBER (IF AVAILABLE)	PACK SIZE	QUANTITY TO BE EXPORTED
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10							
11							
12							
13							
14							
15							

Name and Signature of Pharmacist:

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