	Guidelines for licensing of import, wholesale and retail pharmaceutical outlets	
Rev No: 00	**Doc No: PBSL/GL/043**	Version no. 01
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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1.0 INTRODUCTION

In pursuance of Part V section 39 to 41 of the Pharmacy and Drug Act 2001, these Guidelines are hereby made to provide prospective applicants with information on the general requirements for the establishment of Pharmaceutical industries.

The guideline is a regulatory document that outlines the procedures and requirements for the licensing of local pharmaceutical manufacturers, importers, wholesalers and retailers.

The licensing process forms an integral part of the regulatory process to ensuring that local manufacturing companies comply with regulatory requirements and that pharmaceutical importers, wholesalers and retailers comply with Good Pharmacy Practice (GPP), including Good Storage Practices (GSP) and Good Distribution Practices (GDP).

Adherence to this guideline by applicants will facilitate the timely review and processing of licenses.

2.0 OBJECTIVE

The main purpose of this objective is to give guidance on the requirements and procedures for licensing of local pharmaceutical manufacturing companies as well as pharmaceutical importers, wholesalers and retailers.

3.0 SCOPE

This guideline applies to all pharmaceutical outlets (private and public) regulated by the Pharmacy Board of Sierra Leone, including import and wholesale pharmaceutical outlets, pharmacy retail outlets, chemical stores, drug stores, cosmetic shops, medical device shops and patent medicine shops.

4.0 REQUIREMENTS:

4.1 Issuance of New License

4.1.1 Administrative Requirements

a) Applicants applying for licensing of a new pharmaceutical manufacturing facility (e.g. a factory) or a new retail pharmaceutical outlet (i.e., license for new pharmacy retail, drug store, patent medicine shop or cosmetic shop) must first apply to the Board for suitability of location (also called location clearance). This is also applicable for applicants applying for import and/or wholesale license. The proximity between premises must be 300M

b) Applicants that pass suitability of location or location clearance to establish a new manufacturing factory/industry or to operate a new retail pharmaceutical business shall apply to the office of the Registrar for license to operate.

c) The size of the premises must be 20X20 for retail pharmacy and drug stores

d) Applicants that pass suitability of location or location clearance to operate a new manufacturing factory/industry or a new retail pharmaceutical business may obtain from the office of the Pharmacy Board the 'Eligibility Criteria Form (ECF)', and shall be allowed to proceed with the application process using the form as a guide.

e) Applicants that fail the suitability of location or location clearance may be rejected and not be allowed to proceed with the application process.

f) Applicants applying for the manufacturing, importation, wholesaling or retailing of pharmaceutical products must first obtain license from the office of the Pharmacy Board before embarking on manufacturing, importation, wholesaling or retailing process.

g) The manufacturer's facility or the warehouse or outlet of the importer, wholesaler or retailer may be inspected for suitability before a license can be granted by the Board.

h) No new dual license for both wholesale and retail can be granted by the Board. Separate license for each category can be granted.

4.1.2 Submission of Application

4.1.2.1 General Requirements for Submission of Application

a. An application for a license to manufacture a product shall be made in writing to the Board.

An applicant for license to manufacture, import, wholesale or retail pharmaceutical products shall also submit an application in writing to the office of the Registrar located at the Central Medical Stores Compound, New England Ville; Freetown.The application shall be submitted together with:

i. Duly filled ECF provided by the Board, and shall be dated, signed and stamped by the applicant.

ii. A Copy of a valid business registration certificate showing proof of the business name
iii. Domestic Tax Clearance issued by the National Revenue Authority (NRA)
iv. Local Tax Clearance from City Council
v. Local Service Receipt (e.g. NPA bills, Water bills, House Rent bills, etc.)
vi. Police clearance
vii. Evidence of payment of prescribed application fees to Pharmacy Board of Sierra Leone's account
viii. Capital Investment (i.e., bank account balance or statement of account)
ix. Attestation letter (i.e., must produce attestation from two referees who must be citizen of Sierra Leone)
x. Current Practising license of Pharmacy Professional(s) (Not applicable to Patent medicine and Cosmetic shops)

a) The Board shall require the following minimum information from the applicant as part of the application process:
   i. The name, address, including mobile number (s) and educational background of the applicant;
   ii. Name and type of business, full address of the business (i.e., location or site address of the business)
   iii. The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship)

4.1.3 **Specific Requirements for Submission of Application**

In addition to the general requirements for submission of application mentioned in 4.1.2.1, the applicant is also required to comply with the following specific requirement(s) depending on the type pharmaceutical business:

4.1.3.1 Specific Requirements for a new Pharmaceutical Manufacturing Company

a) The application submitted shall be accompanied with the following:
   i. Site Master File
   ii. Permit from the Environmental Protection Agency (EPA)
   iii. Basic floor plan showing plant installation
   iv. Architectural engineering permit issued by the local authority
   v. Notarized copy of the degree (or its equivalence if applicable) of the Supervising Pharmacist
   vi. Notarized valid Practising license of the Pharmacist
   vii. Curriculum vitae of the Pharmacist

b) The content of a Site Master File shall include, but not be limited to, the following:
   i. General information
   ii. Personnel
   iii. Premises
   iv. Sanitation
   v. Equipment

vi. Production
vii. Quality control
viii. Contract manufacturing analysis
ix. Self-inspection
x. Disposal of equipment
xi. Complaints, distribution and production recall
xii. Waste disposal

c) The information of he company that may be required shall include the following:
   i. Name of company
   ii. Office address of the company
   iii. Factory address of the company
   iv. Short description of the site (taking into consideration the total area in square meters)
   v. Nearby industrial units and the waste generated by these industries
   vi. Any other manufacturing activities carried out on the site
   vii. Dosage forms or type of products intended to be manufactured
   viii. Number of employees expected to be engaged in production, quality control, storage and distribution
   ix. Short description of the quality management system that will be put in place
   x. Use scientific, analytical or other technical services from countries abroad in relation to manufacturing and analysis

4.1.3.2 Specific Requirements for a new Pharmaceutical importer, wholesaler or distributor

The application shall be accompanied with the following:

a) Notarized copy of the degree (or its equivalence if applicable) of the Superintending or full time Pharmacist
b) Notarized copy of valid Practising license of the Pharmacist
c) Curriculum vitae of the Pharmacist
d) A copy of contract agreement between the Managing Director of the import and wholesale pharmacy business and the pharmacy professional in case the Managing Director is not the authorized personnel;
e) Copy of the identity card or passport of both the Managing Director and the authorized personnel;
f) Written commitment from the pharmacist to respect the laws and regulations relating to the pharmacy practices;
g) Signed resignation letter/proof of service delivered issued by the last employer of authorized personnel, if applicable;
h) Copy of valid contract agreement between authorized personnel and proprietor of the pharmacy.

4.1.3.3 Specific Requirements for licensing of a new Pharmacy Retail Outlet

The application shall be accompanied with the following:

a) Notarized copy of Degree (and equivalence if applicable) of Authorized personnel (Pharmacy Professionals i.e. pharmacist and/or pharmacy technician)

b) Notarized valid license to practice pharmacy profession issued by Pharmacy Board of Sierra Leone
c) Curriculum vitae of the authorized personnel (pharmacist and/or pharmacy technician);
d) Professional agreement between the proprietor/proprietress of the pharmacy and the authorized personnel (pharmacy professional) in case the proprietor is not the authorized personnel;
e) Copy of the identity card or passport of both the proprietor/proprietress and the authorized personnel;
f) Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practice;
g) Signed resignation letter/proof of service delivered, issued by the last employer of authorized personnel, if applicable;
h) Copy of valid contract agreement between authorized personnel and proprietor of the pharmacy

4.1.3.4 Specific requirements for licensing of a new drugstore outlet

The application shall be accompanied with the following:

a) Notarized copy of Diploma certificate pharmacy technician
b) Notarized copy valid license to Practice Pharmacy Profession
c) Curriculum vitae of the pharmacy technician;
d) Copy of the identity card or passport of both the proprietor/proprietress and the pharmacy technician
e) Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices;

f) Signed resignation letter/proof of service delivered, issued by the last employer of authorized personnel, if applicable;
g) Provide evidence that he/she notified the previous employer as stated in their contract agreement
h) Copy of valid contract agreement between authorized personnel and proprietor of the pharmacy technician

4.1.3.5 Specific requirements for a new patent medicines shop

The application shall be accompanied with the following:

a) Two (2) letters of attestation from authorities residing in the rural community where the outlet is intended to be opened
b) Evidence of payment of prescribed application fees to the Pharmacy Board of Sierra Leone's account;
c) Evidence of established patent medicine shop

4.1.3.6 Specific requirements for licensing of cosmetic shop

The application shall be accompanied with the following:

a) Two (2) letters of attestation from authorities residing in the rural community where the outlet is intended to be opened
b) Evidence of payment of prescribed application fees to the Pharmacy Board of Sierra Leone's account
c) Evidence of established cosmetic medicine shop

4.1.4 Pre - evaluation of files of Applicants

Applications shall be previewed by technical staff of the Pharmacy Board to ensure that they are complete. An applicant may be required to submit additional application, where applicable.

4.1.5 Inspection of a pharmaceutical outlet or manufacturing facility for suitability

Based on the outcome of the evaluation in 4.1.3, inspection of the manufacturing facility, warehouse or a pharmaceutical outlet of the applicant will be conducted by Pharmacy Board inspectors.

4.1.5.1 Suitability Inspection of Warehouses of Pharmacy Importers and Wholesalers as well as Pharmacy Retail outlets, Drugstores, Patent Medicine shops and Cosmetic Shops

a) Suitability inspection will be conducted using Pharmacy Board's approved checklist for conducting suitability inspection
b) A suitability inspection report with recommendation(s) will be prepared by the **Pharmacy Board inspectors and forwarded to the office of the Registrar.**

4.1.6.Interview by members of the Application Committee

a) The applicant and/or his pharmacy professional(s), where applicable will be summoned to an interview by the Applications Committee of the

Pharmacy Board after suitability inspection of the outlet has been conducted.

b) A file of the applicant will be prepared for the interview containing complete documents as well as the suitability inspection report.

c) The applicant may be informed for any corrective action to be taken as indicated in the suitability inspection report or may be required to produce additional documents, where applicable.

d) The applicant may be required to submit a Corrective Action Report (CAR) in respect of the recommendations stated in the report. This shall be submitted to the Board not later than 6 weeks after receipt of the final recommendations. The CAR shall indicate among others timelines within which the applicant intends to complete each of the recommendations issued.

e) Upon successful implementation of the CAR, a follow-up inspection may be conducted by the inspection team to ascertain the effectiveness of the implementation (where applicable).

4.1.7.Issuance/Rejection of license

a) Based on the outcome of the interview, approval may be granted for issuance or rejection of licence.

b) A full approval may be granted for issuance of license if the applicant complies with all the requirements.

c) A tentative approval may be granted if the applicant is required to submit a Corrective CAR in respect of the recommendations issued.

d) The CAR shall be submitted to the Board not later than 6 weeks after receipt of the final recommendations. The CAR shall indicate among others timelines within which the applicant intends to complete each of the recommendations issued.

e) Upon successful implementation of the CAR, a follow-up inspection may be conducted by the inspection team to ascertain the effectiveness of the implementation (where applicable).

f) An application may be rejected with reason(s) given for the rejection.

4.1.8 Payment of license fee

A successful applicant will be required to pay license fee before commencing pharmaceutical operations.

4.1.8 Validity of license issued

The license issued expires on the 31st day of December of the year it is issued. The practising license of a Pharmacy professional expires on the 31st day of December of the year it is issued.

The above expiry dates will apply irrespective of the actual date of issue of the license in question.

4.1.9 Renewal of License

- All licenses issued by the Board and expiring on the 31st day of December of the year it is issued will be renewable annually.

- An application for renewal of license shall be made to the office of the Pharmacy Board with effect from 1st January of every year.

- A filled application form together with passport pictures of the applicant and the pharmacy professional, where, applicable, should be submitted to the office of the Pharmacy Board. The application form can be obtained from the office of the Pharmacy Board after paying a prescribed fee for the form.

- The application shall capture details of any variation applied for within the period. The following classes of variations are allowed for a pharmaceutical manufacturing facility or pharmaceutical outlet during the renewal process:
  i. Change of ownership
  ii. Additional production line
  iii. Expansion of establishment
  iv. Change of business name
  v. Change in address or location
  vi. Change of pharmacist or qualified person for manufacturing
  vii. Deletion of activity
  viii. Transfer/Addition of storage facility

ix. Change in the nature of business (i.e. upgrading or downgrading the business).

- Approval for the above changes shall be granted by the Board before a license can be granted for renewal.

- Suitability inspection of the manufacturing facility or pharmaceutical outlet shall be done as part of the renewal process. Premises, after re-assessment, which is unsuitable to carry out a pharmaceutical business, will not have his/her licenses renewed. A re-inspection of the premises for suitability will be conducted, and a re-inspection fee will have to paid for conducting the re-inspection exercise

- The applicant shall pay a renewal fee after approval has been granted by the Board to continue operation to manufacture or to operate as a pharmaceutical business.

5.0 GLOSSARY/DEFINITION

"Applicant"

Means any person, established within or outside Sierra Leone, seeking to obtain or having obtained the license

"Retailer"

Any entity that is authorized to carry on the business of dispensing or providing medical products directly to a patient.

"Inspector"

Means a person appointed, authorized, and designated by the Board in accordance with laws tasked with performing inspection-related duties.

"Medical product"

Includes human and veterinary drugs; human and animal vaccines and other biological products, poisonous substances, herbal medicines, medicated cosmetics, human and medical devices, laboratory and cleaning chemicals and pesticides

"Good Storage Practices

Means that part of quality assurance that ensures that the quality of products is maintained by means of adequate control throughout the storage thereof.

5.2 Acronyms/Abbreviations

CAR means Corrective Action Report

CGMP means Current Good Manufacturing Practice

ECF means Eligibility Criteria Form

EPA means Environmental Protection Agency

GDP means Good Distribution Practice

GMP means Good Manufacturing Practice

GPP means Good Pharmacy Practice

GSP means Good Storage Practice

NPA means

NRA

PBSL

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