	Title: GUIDELINES FOR THE REGISTRATION OF PRODUCTS FROM WHO LISTED AUTHORITIES	
Rev No: 01	**Doc No: PBSL/GL/021**	Version#: 02
Issue date: 15 may 2024	**Effective date: 17 Feb 2024**	Approved by: Registrar

Pharmacy Board of Sierra Leone

PMB 322

Central Medical Stores Compound

New England Ville

Freetown

	Title: GUIDELINES FOR THE REGISTRATION OF PRODUCTS FROM WHO LISTED AUTHORITIES	
Rev No: 01	**Doc No: PBSL/GL/021**	Version#: 02
Issue date: 15 may 2024	**Effective date: 17 Feb 2024**	Approved by: Registrar

TABLE OF CONTENTS

1.0 Introduction

2.0 Objective

3.0 Scope

4.0 Abbreviations

5.0 Specific Requirements

6.0 Reference and Information sources

7.0 Appendices

	Title: GUIDELINES FOR THE REGISTRATION OF PRODUCTS FROM WHO LISTED AUTHORITIES	
Rev No: 01	**Doc No: PBSL/GL/021**	Version#: 02
Issue date: 15 may 2024	**Effective date: 17 Feb 2024**	Approved by: Registrar

INTRODUCTION

This guideline applies only to allopathic medicines that are generic. It prescribes the minimum information required for submission of documentation.

It provides recommendations for applicants preparing application for the registration of generic medicines that have been manufactured and/or licensed in the United Kingdom. Applicants are encouraged to carefully read this guideline, fill in the appropriate application form, prepare the requisite documents, and submit one original hard-copy and one electronic copy on a flash-drive or readable CD-Rom).

OBJECTIVE

This guideline has been designed to assist in the following;

- Provide guidance on the technical and other general data requirements for the registration of UK Generics.
- To help shorten the timelines required for the registration of medicines
- Promote effective and efficient processes for the evaluation of these applications and the subsequent issuance of Marketing Authorization.

SCOPE

This Guideline is developed in pursuance of Section 44 of the Pharmacy and Drugs Act 2001. This Guideline applies only to allopathic medicines and

prescribes the minimum information required for submission of documentation. It provides recommendations for applicants preparing applications for registration of UK Generics for submission to the Pharmacy Board of Sierra Leone.

ABBREVIATIONS

AIDS: Acquired Immune Deficiency Syndrome

API: Active Pharmaceutical Ingredient

CoA: Certificate of Analysis

FPP: Finished Pharmaceutical Product

GMP: Good Manufacturing Practice

HIV: Human Immune-deficiency Virus

ICH: International Conference on Harmonization

INN: International Non-proprietary Name

MHRA: Medicines and Healthcare products Regulatory Agency (MHRA)

PBSL: Pharmacy Board of Sierra Leone

UK: United Kingdom

5.0 SPECIFIC REQUIREMENTS

1. Completed Application Form.

2. Samples as per the PBSL sample schedule.

3. Prescribed application fee.

4. Dated and signed specification(s) of active pharmaceutical ingredient(s) (APIs).

5. Certificate(s) of analysis (COA) of the active pharmaceutical ingredient(s) (APIs).

6. Declaration by the finished pharmaceutical product (FPP) manufacturer of the API source.

7. Dated and signed release specification of the FPP.

8. Certificates of analysis for at least three (3) batches of FPP.

9. GMP certificate of the manufacturer of the FPP.

10. Shelf life of imported medicines should be in accordance with existing Guidelines on Importation of Allopathic Medicines.

N/B.

For products which applicant can submit evidence of approval from Pharmacy Board of Sierra Leone (PBSL), only requirements 1, 2, 3 and 10 will apply. Additionally, a declaration of sameness of the product to Sierra Leone to that approved by PBSL should be submitted by the FPP manufacturer.

Imported consignments of registered products from WHO listed authorities would be sampled periodically at the port of entry at a frequency that will be determined by the Pharmacy Board.

This Guideline is not applicable to the following

- Products with non-pharmacopoeia standards/monographs.
- Sterile products.
- Program medicines (malaria, tuberculosis, HIV/AIDS, reproductive health, neglected tropical diseases), that is medicines intended for treatment, cure or prevention of malaria, tuberculosis, HIV/AIDS, reproductive health, neglected tropical diseases.
- New drugs and new chemical entities

6.0 REFERENCES

https://www.fdaghana.gov.gh/branches.php

http://www.hc-sc.gc.ca/dhp-mps/vet/legislation/guide-ld/vdd_nds_guide-eng.php#7

7.0 APPENDICES

7.1 FORMAT LANGUAGE

Application and supporting documents shall be in English and legible. Where material is not originally in English, a copy in the original language and a full translation should be submitted, the accuracy of the translation is the responsibility of the applicant. Authentication of the translation has to be done at the nearest Sierra Leone Embassy or by the National Drug Regulatory Authority of the country from where the document originates. Reports submitted only in a language other than English will not be accepted.

7.2 DATA PRESENTATION

All information, data, attachments must be legible of font size 12 or more and shall be presented on in soft copy on CD-ROM. All pages shall be numbered sequentially with the format page numbered as page x of y. Before submitting the completed form, check that you have provided all requested information. Acronyms and abbreviations should be defined the first time they are used in each part.

7.3 SUBMISSION OF APPLICATION

An application for the registration of UK Generics shall be made in writing via a cover letter.

The application shall be submitted through the authorized local agent by the regulatory contact person to the following address:

The Registrar

Pharmacy Board of Sierra Leone

Central Medical Stores Compound

New England Ville, Freetown

7.4 GLOSSARY

The definitions provided below apply to the words and phrases used in these guidelines. Although an effort has been made to use standard definitions as far as possible, they may have different meanings in other contexts and documents. The following definitions are provided to facilitate interpretation of the guidelines.

Applicant: Company paying the application fee.

The Board: The Pharmacy Board of Sierra Leone

New Chemical Entity: A chemically Active Pharmaceutical Ingredient (API) that has not previously been registered as an ingredient of any pharmaceutical product.

New Drug: means a generic copy of an innovator product that has not been previously registered as a pharmaceutical product in Sierra Leone, or which has been marketed in Sierra Leone for a period of not less than ten (10) years or any other period to be determined by the Pharmacy Board from time to time, for public health reasons.

Non-pharmacopoeia products- products for which no monograph exist.

UK Generics: means medicines originating from United Kingdom (UK) into the Sierra Leonean market, not branded but labeled as the international nonproprietary name (INN) and manufactured in accordance with standards

(British Pharmacopeia, United States Pharmacopeia, International Pharmacopoeia, Extra Pharmacopoeia and any other work of reference adopted and approved by the Board).