	Title: GUIDELINES FOR THE EXPEDITED REGISTRATION OF MEDICAL PRODUCTS	
Rev No: 01	**Doc No: PBSL/GL/024**	Version no. 02
Issue date: 15 Feb 2021	**Effective date: 17 Feb 2021**	Approved by: Registrar

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1.0 INTRODUCTION

This guideline applies only to medical products considered by the Pharmacy Board of Sierra Leone as being appropriate for an expedited or fast registration. It prescribes the minimum information required for submission of documentation as well as the correct format and organization of the requisite data.

This guideline provides recommendations for applicants preparing application for the expedited registration of medical products, meant for submission to the PBSL.

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).

2.0 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 medical products via a fast track or expedited mechanism.
- To help shorten the timelines required for the issuance of Marketing Authorization to products that are appropriate for a fast track mechanism.
- Promote effective and efficient processes for the evaluation of these applications and the subsequent issuance of Marketing Authorization.

3.0 SCOPE

This guideline covers the requirement and processing of all medical products considered by the PBSL for a fast track registration process. Currently, the following categories of applications are covered under this guideline:

- WHO prequalified products
- Public health programmes: These include products of HIV/AIDS, Malaria, Tuberculosis, Reproductive and Child Health, Neglected Tropical Diseases
- EPI Products.
- Ministry of Health tender purposes only.
- Products for trial purposes
- Products for emergency disease outbreaks
- Post approval variation.
- Product Registered by countries within the International Council on Harmonization (ICH) region, including SRA approved products.

4.0 GLOSSARY

In the context of this guideline, the following words/phrases are defined as follows.

- Applicant: The product owner or licence holder. Representatives of licence holders may not hold themselves as applicants unless they own the product.
- Drug, medicine or pharmaceutical product: means a substance or mixture of substances prepared, sold or represented for use in –

  (a) Diagnosis, treatment, mitigation or prevention of disease, disorders or abnormal physical state or the symptoms of it in man or animal

(b) Restoring, correcting or modifying organic functions in man or animal.

- Generic (multisource) product(s): Means products that are pharmaceutical equivalents or alternatives to innovator or reference products and which are intended to be therapeutically equivalent and can therefore be used interchangeably with the innovator or reference product. It is a pharmaceutical product usually intended to be interchangeable with the innovator product, which is usually manufactured without a license from the innovator company.

- Medicinal purpose: means treating or preventing a disease, diagnosing or ascertaining the presence and extent of a physiological function, contraception, inducing anaesthesia, altering normal physiologic function permanently or temporarily in any way in humans.

- PBSL officially recognized list of publications - British Pharmacopoeia, United States Pharmacopoeia, Extra Pharmacopoeia, International Pharmacopoeia and European Pharmacopoeia.

- Variation: Means a change to any aspect of a pharmaceutical product, including but not limited to a change to formulation, method and site of manufacture, specifications for the finished product and ingredients, container and container labelling and product information.

5.0 SPECIFIC REQUIREMENTS

5.1 WHO PREQUALIFIED MEDICINAL PRODUCTS OR SRA APPROVED PRODUCTS

• This guideline outlines the procedure for the application and registration of WHO prequalified allopathic drugs or SRA approved products by the Pharmacy Board of Sierra Leone (PBSL).

• This is based on a collaborative procedure between the WHO Prequalification of Medicines Programme (WHO/PQP) and the PBSL in the assessment and accelerated registration of WHO prequalified products or SRA approved products.

• Applicants with medical products that are either SRA approved or have been prequalified by the WHO/PQP can take advantage of this procedure for fast track registration of their products by the PBSL.

5.1.1 APPLICATION STEPS

1. Applicant should submit the product dossier for a WHO-prequalified pharmaceutical product or SRA approved products, together with samples to the Pharmacy Board of Sierra Leone. The dossier submitted to the PBSL should be the same as that submitted to the WHO-PQP or SRA-countries. Hence, the application should include;

a) A completed application form for the registration of allopathic drug by the PBSL, including the same technical information as that submitted to WHO/PQP or SRA-countries. The technical part of the dossier should be identical to the current version of the SRA or WHO/PQP dossier.

b) The following country specific documentation;

i) Executed batch manufacturing records of one production batch.

ii) Where applicable, long-term stability studies protocol and report conducted at Zone IVB conditions

iii) Copy of the current version of Quality Information Summary (QIS) submitted to the WHO.

c) Payment of the requisite application fees for the registration of the product (s) as per the fee schedule of the PBSL.

2. In situations where the applicant wishes to apply the Procedure to an application which is already pending with PBSL, the applicant should first update the dossier to ensure that the technical part of the information is the same as that submitted to WHO.

3. Submit an application letter, expressing your interest to use the WHO-PQ collaborative procedure, for the registration of the product.

4. The PBSL shall communicate its consent to apply the procedure to the application for registration of the product, and to request the WHO-PQ to share product specific information.

5. Applicant shall then request the WHO-PQP to provide full access to the information on the prequalified product or SRA approved products to the PBSL.

5.1.2 PROCESSING

The PBSL shall process the application and communicate its decision on the product to the applicant and WHO within 21 calendar days.

5.1.3 POST APPROVAL

All post-prequalification variations submitted to WHO shall be submitted simultaneously to the PBSL after the product has been registered by the PBSL.

5.2 PROGRAM DRUGS

Medicinal products under this category (as listed above) shall be considered for a fast track registration mechanism.

5.2.1 APPLICATION STEPS

Applicant for the registration of medical products under this category shall:

1. Submit full application as per the PBSL requirement for the registration of medical products.

2. Pay the required application fees for the registration of the product as per the fee schedule of the PBSL.

3. Submit the required number of samples of the product as per the Pharmacy Boards sample schedule.

5.2.2 PROCESSING

The PBSL shall process the application and communicate its decision on the product to the applicant within 21 calendar days.

6.0 Reference and Information sources

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

http://who.int

7.0 Appendices

7.1 List of countries considered as Stringent Regulatory Authorities (SRA) from 1st July 2009.

The national drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) are considered as Stringent Regulatory Authority (SRA) as per the Global Fund Quality Assurance Policy for Pharmaceutical Products from July 1, 2009. For details on ICH, please look at www.ich.org.

Please find below the list of countries which are members, observers and associates of ICH.

MEMBERS:

• European Union member States (Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, and United Kingdom

• Japan

• United States

OBSERVERS: European Free Trade Association (EFTA) represented by Swiss Medic of Switzerland, and Health Canada (as may be updated from time to time).

ASSOCIATES: Through mutual recognition agreements: Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).

For medicines used exclusively outside the ICH region, positive opinions or tentative approval under any of the following three special regulatory schemes are recognized as stringent approval:

- Article 58 of European Union Regulation (EC) No. 726/2004

- Canada S.C. 2004, c. 23 (Bill C-9) procedure

- United States FDA tentative approval (for antiretrovirals under the PEPFAR programme)

7.2 Abbreviations

AIDS: Acquired Immunodeficiency Syndrome

EPI: Expanded Program on Immunization

FDA: Food and Drug Administration

HIV: Human Immunodeficiency Virus

ICH: International Council on Harmonization

PBSL: Pharmacy Board of Sierra Leone

PQP: Prequalification Program

QIS: Quality Information Summary

SRA: Stringent Regulatory Authority

WHO: World Health Organization

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