	Title: GUIDELINES FOR THE LISTING OF SPECIALISED OR ORPHAN PRODUCTS FOR IMPORTATION IN SIERRA LEONE	
Rev No: 02	**Doc No: PBSL/GL/028**	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 intended to assist applicants to who intend to apply for medical product listing at a minimal quantity and for diseases that are rare. It provides recommendations for applicants preparing application for the listing of medical products in Sierra Leone. Applicants are encouraged to carefully acquaint themselves with this guideline, especially on the specified provisions.

2.0 OBJECTIVE

This guideline has been designed to assist in the following;

- Provide guidance on the eligibility of medical products listing.

- To help facilitate the availability of products that are meant for rare disease conditions.

3.0 SCOPE

In pursuance of section 55 of the Pharmacy and Drugs Act, these guidelines are hereby made to provide guidelines to Applicants on the procedure for listing of specialized products in Sierra Leone.

These guidelines are intended for use by pharmaceutical manufacturers and importers in the public and private sectors.

4.0 SPECIFIC REQUIREMENTS

4.1 ADMINISTRATIVE REQUIREMENTS

4.1.1 A new application for the listing of a specialized product shall be made in the prescribed form and addressed to:

The Registrar

Pharmacy Board of Sierra Leone

Central Medical Stores

New England Ville

Freetown

4.1.2 The Application shall be forwarded by a manufacturer and/or Local Agent working with a registered Pharmacist.

4.1.3 The Application shall be accompanied by:-

a) Samples of the product in the final package

b) Payment of a non-refundable application fee

4.2 RENEWAL OF APPLICATION FOR LISTING

4.2.1 An application for renewal of listing shall be made 3(three) months before the expiration of the last listing.

4.2.2 The Application shall be accompanied by:

(i) A covering letter

(ii) Samples of the finished product in the final container

(iii) Payment of a Non-refundable application fee

4.3 TECHNICAL REQUIREMENTS

A product can be considered for listing provided it is used for the prevention, treatment or diagnosis of **rare or neglected disease**

conditions in the country. The listed product must fulfill the following requirements:-

4.3.1. Must comply with WHO's current certification scheme of pharmaceutical product moving in international commerce

4.3.2 Must be registered for use in the country of origin or any other two countries.

4.3.3 The retention of the listed product in the register of listed products will be for a duration of 12 (twelve) months and is renewable subject to review at the end of the retention period.

4.3.4 The annual importation of the listed product per importer should not exceed:

a) 50,000 tablets/capsules of oral solid dosage forms
b) 5,000 bottles of oral liquid dosage forms (e.g. syrup, suspension etc.)
c) 5,000 vials/ampoules of injectables
d) 2,000 tubes of semi-solid dosage form (e.g. cream, ointments etc.)
e) 5,000 bottles of Intravenous infusions
f) 5,000 bottles of eye/drops, ointments

4.3.5 The samples of the listed product submitted must have:

(i) Name and full address of the pharmaceutical company manufacturing the product

(ii) The Batch number

(iii) Manufacturing and Expiry dates

4.3.6 Each dosage form and individual strength of a pharmaceutical product must be listed separately.

4.3.7 The samples of the listed product submitted must have at least two-third (2/3) of its shelf-life

5.0 GLOSSARY

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. Representatives of licence holders may not hold themselves as applicants unless they own the product.

c) **"Specialized /Orphan Product",** means any pharmaceutical product that is required for the treatment, prevention or diagnosis of disease conditions that are very rare in Sierra Leone. The

specialized product may by a medicinal product, medical device, diagnostic reagent or test kit that may help in the treatment, prevention or diagnosis of rare disease conditions in Sierra Leone.

d) **Medical Device:** any instrument or apparatus including components, parts and accessories of it, manufactured, sold or represented for use in the diagnosis, treatment, mitigations or prevention of disease, disorder or abnormal physical state, or the symptoms of it in man or animal. A medical device can be:
(a) Condom (b) Test-Kit (c) Needle and Syringe etc.

e) **Diagnostic reagent/Test Kit** – any substance used for diagnostic purposes.

6.0 REFERENCES

- https://www.who.int/medicines/regulation/en/
- Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. In: *Twenty-eighth World Health Assembly, Geneva, 13-30 May 1974. Part 1: Resolutions and decisions, annexes.* Geneva, World Health Organization, 1975: 94-95 (Official Records of the World Health Organization, No. 226).

- The Pharmacy and Drugs Act, 2001

7.0 APPENDICES

7.1 Application fee must be paid for processing the application

7.10 Processing fee for newly listed product is US$50

7.11 Processing fee for renewal of listing is US$50

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