	Title: GUIDELINE OF GUIDEELINES	
Rev No: 01	**Doc No: PBSL/GL/001**	Version no. 02
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

TABLE OF CONTENTS

Acknowledgement

This shall include: Global Health Protection Program Pharm Train and any other that contributed to the successful preparation of the documents.

Executive Summary

This shall provide an overview of the main points written to share with individuals who may not have time to review the entire document. The reader should be able to make a decision based only on reading the executive summary. The guideline of guidelines is a document developed to guide the respective department of the Pharmacy Board of Sierra Leone in the preparation of departmental guidelines in a systematic and uniform manner for continual quality improvement.

1.0 INTRODUCTION

2.0 OBJECTIVE

This guideline provides the requirement for development and review of guidelines.

2.0 SCOPE

The guideline of guideline covers the preparation of new guideline, their review, provides template and a flow chart of the guideline.

3.0 GLOSSARY

Guideline
Flowchart
Review number
Effective date
Issue date
Document number
Version number

5.0 REQUIREMENTS

The cover page shall have a header with the title of the guideline, the revision number (Rev No), Document number, version number, Effective date, issue date and Approved by the Registrar. The left bottom of this page will contain the name and address of the institution.

The format of the body of all guidelines shall include the following:

Table of Content 1.0 Introduction (Take into consideration the legal basis), 2.0 Objective, 3.0 Scope, 4.0 Glossary 5.0 Requirements, 6.0 Reference and information sources and 7.0 Annex

Each page will be numbered with the format, Page x of y on the bottom right side of each document.

All guidelines shall have font type Verdana and font size 11

The last page of each guidelines shall be authorized and contain the authored by/Prepared by (the name and Head of department responsible for the preparation of the guidelines), Reviewed by (the name and Head of department of Quality Assurance) and Approved by (the name of the Registrar of the institution).

All guidelines shall be reviewed when necessary using the required process for amendment or change for documents (PBSL-SOP-08).

3. Steps to develop a guideline

Flow chart of the process for development of guideline is included in Annex I.

3.1. Selection of topic

The <responsible person(s)/body/board at the Pharmacy Board of Sierra Leone identifies the requirement of a guidance document with a certain topic. New guidelines (including replacement/renewal of existing guidelines) are needed if

• no guideline exists for a certain topic/subject

• there has been progress in the development of new technologies, new practices or new therapeutic areas

• frequently encountered problems and/or questions appear with established services and products, indicating the need for a clearer guidance document

• input arises from cooperation with other (international) regulatory authorities

3.2. Selection of the approach

3.2.1 Adoption of an existing international guideline

Before initiating the development of a new national guideline, clarification should be sought as to already existing guidelines for the same topic, their applicability and acceptability to the national regulatory context.

The benefits of this approach include:

a) Facilitation of global harmonization of drug regulation

b) Optimal use of resources (financial/personal)

An assessment should be made using the decision flow chart with additional information about reliable regulatory authorities/organizations (included in Annex II).

Optional: Preparation of Pharmacy Board of Sierra Leone specific annotations to complement the adopted guideline.

Proceed with Section 3.2.2.5

Upon adoption of an international guideline by the Pharmacy Board of Sierra Leone, stakeholders will be notified accordingly (see sections 3.2.2.8 and 3.2.2.9).

3.2.2 Development of guideline

3.2.2.1 Appointment of Department/responsible person /writer

Once the topic has been selected, one person in charge of this guideline, is appointed from the relevant unit. In the case of a guideline prepared by a scientific committee, the relevant rules of procedure will apply to the appointment of Department/responsible person .

The Department/responsible person is responsible for drafting {optional: the concept paper and} subsequent versions of the guideline with the support of the relevant working party, group or committee. It is strongly recommended to avoid the 'committee' approach to writing a guideline. One person should be responsible for writing, while the rest of the group reviews and endorses the document. This ensures coherence, clarity and accuracy.

3.2.2.2 Optional: Development of concept paper

A concept paper is a public document that is primarily intended to convey the need for discussing specific issues, innovations or controversial key-points at any stage of the development of guideline. It should point out the issues to be covered in the guideline, but should not elaborate already on solutions.

The concept paper should be written in English and should not exceed 2 pages. The document should carry a version number and contain line numbering to facilitate subsequent discussions.

The concept paper should contain an

- Introduction
- Problem statement
- Discussion (on the statement) and
- Recommendation(s) (points to be addressed, including proposed objective and scope and options for solutions where possible).
- Timetable for release the draft and final guidelines

• Resource requirements for preparation

• Impact assessment (anticipated benefit to industry, regulatory authorities and other interested parties. Interest parties potentially affected by a particular topic (applicants, patients …)

• References to literature and guidelines.

If more than one working party/group and/or department/scientific committee are in charge of drafting a guideline (multidisciplinary or joint guidelines), the concept paper, draft guideline, and final guideline should be discussed and agreed by all concerned working parties before adoption and publication.

3.2.2.3 Optional: Adoption and release for consultation of concept paper

Following adoption by the committee/board, the concept paper is released for consultation to relevant interested parties through emails, meetings and publication on the PBSL website (www.pharmacyboard.gov.sl) for a period of 2 to 3 months (PDF format). The elaboration of a guideline can be accelerated if there is an urgent reason (e.g. in the case of editorial changes, or proposed changes to existing guideline are minor).

Comments collected on the concept paper will be considered in the development of the future guideline, see below. Possible solutions for developing the guideline should be provided by interested parties, as part of the overall response to the concept paper. Preparation of the initial draft guideline may proceed in parallel to the consultation period. Concept papers

will normally not be revised as they are superseded by the draft and final guidelines, respectively.

If a concept paper does not develop into a final guideline or once a final guideline has been published, the concept paper is considered a historical document and will be archived.

3.2.2.4 Preparation of initial draft guideline

The Department/responsible person prepares the draft text in consideration of existing national, international laws and guidelines (taking cognisance of documents of other regions that may apply in our context). The PBSL Template for Guidelines serves as template for preparation of guidelines. Comments received during the consultation period on the concept paper should be taken into account in the guideline draft. The Department/responsible person may consult appropriate experts to provide input.

Presentation style: Language is English, letter size 12, letter type Arial, add line numbering in draft (remove in final version).

(PBSL Guideline template – New development approach (included in Annex III) /

Guideline template – Adoption approach (included in Annex IV)).

Structure of the draft guideline: The guideline should, where appropriate, contain the following, in addition to its scientific and technical content

- (see PBSL Guideline template – New development approach (included in Annex III) /

- Guideline template – Adoption approach (included in Annex IV)):
- Cover page (including PBSL symbol, guideline title, reference number of the document (edition/version), date of approval, responsible authority
- In foot section: PBSL address, email, phone and page number e.g. page 1 of 50)
- Timetable of guideline development process (starting from first date of guideline release to final revision)
- Keywords of the document
- Table of contents
- Acknowledgements (if applicable)
- Executive summary
- troduction (background including objectives)
- Scope
- Legal basis (e.g. Act)
- Main guideline text
- (Proposed timetable (including timetable for discussion with other concerned working parties/committees/boards))
- Definitions

- References (scientific and/or legal and including a reference to the concept paper)
- Annex

The scope should indicate whether the guideline concerns a selected area of services/medicinal product development, where limited experience is available and knowledge is fast evolving, requiring the need for easy updates and flexibility.

This draft is considered by the relevant working party/scientific advisory or inspectors group. The document is regarded as internal document, which is revised by the department following each discussion in the working party/committee/board and/or the written comments of the other members of the working party/group.

QUALITY ASSURANCE

Developed/Prepared document are forwarded to the quality assurance department for review and onward submission to the quality management system committee for review and validation before submission for approval to the Board.

3.2.2.5 Release for consultation of draft guideline

When the guideline has been developed to a point where the views of the members of the working party/group are clearly presented, the draft guideline are released for consultation on the PBSL website and by other means (email and meetings) (PDF format). The cover page of the draft guideline states that it is open for consultation and gives the date by which

comments should be received. A common consultation period lasts for 1-2 months.

Specific procedures or provisions for appropriate for public consultation. Clients, patients, health care professionals and interested parties may provide comments. To facilitate collection and review of comments, a template for submission of comments is included in Annex V.

3.2.2.6 Collection of comments

Comments are expected from different interest groups; e.g. national and international (regulatory) authorities and organizations (e.g. Ministry of Health, WHO), industry associations, scientific/academic societies, health care professionals, patients/consumer groups. Specific interested parties should be encouraged to give comments or other input on the draft.

All comments received are carefully considered and discussed by the department responsible for the guideline. If necessary, PBSL may convene a meeting with relevant interested parties to discuss aspects of a draft guideline in detail.

An overview of the main comments with an explanation for their acceptance or non-acceptance shall be given by the Department/responsible person. This overview shall be approved by the committee within 1-2 months (in consideration of the meeting schedule) and subsequently the draft is published by PBSL on the website.

3.2.2.7 Preparation of final version of guideline

After the period of consultation, all comments received are considered by the department. Comments considered relevant are accounted during revision of the guideline. The final text is submitted to the relevant scientific committee and the QMS committee for adoption, together with a proposed date for implementation.

Structure of the final guideline: The guideline should, where appropriate, contain, in addition to its scientific and technical content (see PBSL Guideline template – New development approach (included in Annex III) / Guideline template – Adoption approach (included in Annex IV):

- Cover page (including PBSL symbol, guideline title, reference number of the

  document (edition/version), date of approval, responsible authority
- Timetable of guideline development process (starting from first date of guideline release to final revision)
- Keywords of the document
- Table of contents
  - Acknowledgements (if applicable)
    - Executive summary
    - Introduction (background including objectives)
    - Scope
    - Legal basis (e.g. Act)

- Main guideline text
- Definitions
- References (scientific and/or legal and including a reference to the concept paper)
- Annex

3.2.2.8 Adoption of final guideline for publication

The QMS committee adopts the final guidelines either at a plenary meeting or by written procedure. The guideline is then forwarded to the Board through the drugs and Quality Assurance committee for approval.

The guideline (PDF format) is published on the website of the PBSL (https://www.pharmmacyboard.gov.sl, while previous draft(s) and the concept paper are archived. The document reference number of the concept paper, draft and final guideline and any revisions will facilitate document tracking.

3.2.2.9 Implementation

Unless otherwise indicated, guidelines come into operation within three months after their adoption. While applicants may, with the agreement of PBSL, choose to apply the guideline in advance of this period. The PBSL should wait until this period has expired before requiring the guideline to be taken into account by applicants.

The exact timelines for implementation should be publicly communicated at the stage of release of draft guideline for consultation.

6.0 REFERENCES

WHO, World Health Organization, Handbook for Guideline Development – 2nd Edition 2014 https://apps.who.int/iris/handle/10665/145714.

7.0 ANNEX

Prepared by	***Reviewed by***	***Approved by***
Head of DERD	Head, Quality Assurance	Registrar
Dr Sheku S Mansaray	Dr Michael Lahai	Dr James P. Komeh