



THE PHARMACY BOARD OF SIERRA LEONE (PBSL)



APPLICATION FORM FOR THE VARIATION OF A MEDICINAL PRODUCT (FORM K)

2035

CHECK LIST

Applicant's check list

PBSL double check

- | | |
|--|--------------------------|
| <input type="checkbox"/> Covering Letter | <input type="checkbox"/> |
| <input type="checkbox"/> Signed Declaration | <input type="checkbox"/> |
| <input type="checkbox"/> Fully Completed Application (Appendix I-III) | <input type="checkbox"/> |
| <input type="checkbox"/> Name and Address of Qualified Persons | <input type="checkbox"/> |
| <input type="checkbox"/> Samples of the Product | <input type="checkbox"/> |
| <input type="checkbox"/> Four (4) Copies of Label and Packaging Material | <input type="checkbox"/> |
| <input type="checkbox"/> Four (4) Copies of Package Insert | <input type="checkbox"/> |
| <input type="checkbox"/> Validated Documentation in respect of the variation | <input type="checkbox"/> |

Applicant

PBSL Staff

Name: _____

Name: _____

Signature: _____

Signature: _____

Date: _____

Date: _____

**APPLICATION FORM FOR THE VARIATION OF A
MEDICINAL PRODUCT**

(To be submitted in duplicate)

Cover letter addressed to:

**THE REGISTRAR
PHARMACY BOARD OF SIERRA LEONE
CENTRAL MEDICAL STORES
NEW ENGLAND VILLE
FREETOWN
SIERRA LEONE**

E-mail: pharmbdsl@hotmail.com

Samples and printed matter should be forwarded to the Board through the local agent; Customs duty and clearance to be effected by the applicant in all instances.

A. PARTICULARS OF PRODUCT

Proprietary name.....

Approved name (INN).....

Dosage form:.....Strength:..... Colour:.....

Commercial presentation(s):.....

Country of Origin.....

Category of distribution:

Schedule narcotic

Restriction prescription-only distribution
(Specify, for e.g., hospitals only)

POM (Prescription only medicines)

P (Pharmacy medicine)

OTC (Over-the-counter medicine)

Pharmacological classification:.....

B. PARTICULARS OF APPLICANT

Name of Applicant:.....

Business Address:.....

.....
.....
.....

Phone:..... Fax:.....

E-mail:.....

N.B Post office Box or Private mail Bag unacceptable.

C. PARTICULARS OF MANUFACTURER

Name of manufacturer:.....

Premises address:.....
.....

Postal address:.....

Phone:..... Fax:.....

e-mail

N.B Post office Box or Private mail Bag unacceptable.

D. PARTICULARS OF LOCAL AGENT

Name of local agent:.....

Business address:.....

Phone:..... Fax:.....

e-mail:.....

E. CERTIFICATION BY A RESPONSIBLE PERSON IN APPLICANT

Certification

I the undersigned certify that all the information in the accompanying documentation concerning an application for variation for:

Proprietary name:.....

Approved generic name(s)[INN]:.....

.....

.....

Strength(s) per dosage unit:.....

.....

Dosage form:.....

Applicant company:.....

.....

is correct and true, and reflects the total information available.

Name:.....

Position in company:.....

Signature:.....

Date:..... Official Stamp:.....

PLEASE TICK THE APPROPRIATE VARIATION(S) FOR WHICH APPLICATION IS MADE:

Analytical methodology for finished product.

Additional tests and limits for starting materials and finished products.

Alterations of methods of manufacture and manufacturing equipment.

Change in the content of an excipient of up to +/- 5%.

Changes to flavours, perfumes, or colours.

Alteration of the quantitative composition of a tablet or capsule coating amounting to less than 2% of the total weight of the tablet and capsule.

Changes to the volume of granulating fluid of up to +/-15%

Changes in batch size.

Changes to the quantitative contents of agents whose only function is to make the product viscous,

Changes to the container/closure system in Immediate contact with the product, or additional types of container/closure.

- Changes to parts of the container not in contact with the product, but not including labeling .
- Changes made to labeling.
- Changes made to pack layout (e.g. pictures, diagrams etc).
- Changes in imprints or marks on solid dosage forms.
- Changes to the marketing authorization holder (name, address and/or legal entity).
- Change in site(s) of manufacture.
- Changes or additions to pack size.
- Change in API to a different API.
- Inclusion of an additional API or removal of one API from a multi-component product.
- Change in the dose of one or more of the APIs
- A change in the dosage form
- Change in the route of administration
- Change in indication(s)
- Change in dosage recommendation(s)

Change in drug classification

Change in patient group(s)

Change in product name

Change in manufacturer(s)

Change in source of ingredients i.e active or inactive

Change in shelf-life.

APPENDIX I

GENERAL PRODUCT SPECIFICATIONS

Name of drug.....

Name of applicant.....

Dosage form..... Strength..... Colour.....

- (a) Attach list of all active ingredients in the format illustrated in the example below:

Approved chemical name	Quantity per dosage unit	Reason for inclusion of ingredient	Specification
Paracetamol	325 mg	Analgesic	BP
Diclofenac Sodium	50 mg	Analgesic/antiinflammatory	BP

- (b) Attach list of all non active ingredients in the format illustrated in example below:

Approved name of Ingredient	Quantity per dosage unit	Specification	Reason for inclusion of ingredient
Starch	112.6 mg	BP	Binder
Magnesium stearate	2.0 mg	BP	Lubricant

- (c) Additional raw materials (if any) used in the manufacturing process but not present in the final product.
- (d) Give specifications of packaging materials (where no specifications for packaging materials exist, this must be mentioned)

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.....

(e) List any ingredient liable to cause dependence and /or listed in the United Nations lists of psychotropic and narcotic drugs?

.....

Reference to the following publications will, where applicable be accepted:

- I. British Pharmacopoeia
- II. European Pharmacopoeia
- III. United States Pharmacopoeia
- IV. International Pharmacopoeia
- V. British Pharmaceutical Codex
- VI. Extra Pharmacopoeia
- VII. Such other works of reference as may be approved by the Board from time to time.

APPENDIX II

PARTICULARS OF MANUFACTURING PROCEDURE, RELATED CONTROLS AND DOCUMENTATION

Name of Drug.....

Name of Applicant

Dosage Form.....Strength Colour

(a) Give a brief summary of the manufacturing procedure

.....
.....
.....

(b) Indicate the particulars of manufacturer(s) of each raw material used in the table below:

Name of raw material	Name of manufacturer	Address

Attach the following:

(c) State estimated shelf-life of drug

(d) Provide stability data and justification on which shelf life has been predicted*

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*Refer to PBSL Guidelines for Registration of Medicinal Products

APPENDIX III

LIST OF ATTACHED DOCUMENTS AND MATERIAL

Name of Drug.....

Name of Applicant.....

Dosage Form..... Strength:Colour:.....

Attach 4 (four) copies of labels, package inserts and packaging materials proposed for marketing in this country.

The text of labels and written material should conform to labelling regulations in force in Sierra Leone (Refer to *the Pharmacy Board of Sierra Leone guidelines on packaging and Labelling*)