THE PHARMACY BOARD OF SIERRA LEONE (PBSL)

APPLICATION FORM FOR THE RE-REGISTRATION OF A MEDICINAL PRODUCT
(FORM J)

CHECK LIST

Applicant's check list		PBSL double check
☐	Covering Letter	☐
☐	Signed Declaration	☐
☐	Fully Completed Application (Appendix I-IV)	☐
☐	Name and Address of Qualified Persons	☐
☐	Samples of the Product	☐
☐	Primary Standards	☐
☐	Four (4) Copies of Label and Packaging Material	☐
☐	Four (4) Copies of Package Insert	☐

Applicant	**PBSL Staff**
Name:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Name:_ _ _ _ _ _ _ _ _ _ _ _ _
Signature:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Signature:_ _ _ _ _ _ _ _ _ _ _
Date:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Date:_ _ _ _ _ _ _ _ _ _ _ _ _

APPLICATION FORM FOR THE RE- REGISTRATION OF A MEDICINAL PRODUCT

(To be submitted in duplicate)

Cover letter addressed to:

THE PHARMACY BOARD
OF SIERRA LEONE
64 SIAKA STEVENS STREET
FREETOWN
SIERRA LEONE
P. M. B. 322
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:

Restricted prescription-only distribution ☐
(specify, e.g, hospitals only)

Scheduled narcotic ☐

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 THE APPLICANT

Certification

I the undersigned certify that all the information in the accompanying documentation concerning this application for re-registration 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:.....

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?

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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

(c)State estimated shelf-life of drug .....

.....

*Refer to PBSL Guidelines for Registration of Medicinal Products

APPENDIX III

ADMINISTRATIVE STATUS OF THE PRODUCT

Name of Drug .....

Name of Applicant.....

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

(a) Attach a copy of Certificate of Pharmaceutical Product issued by the competent authority in accordance with the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

(b) Has the drug been registered in Sierra Leone?

YES NO

(i) If YES, attach a copy of the certificate of registration in respect of such drug issued by the Pharmacy Board of Sierra Leone.

(c) Has an application for the registration of the drug been made in any other country?

YES NO

(i) If YES, list countries

.....

.....

(d) Has the drug been registered in any other country?

YES NO

(i) If YES attach copies of certificates of registration in respect of such drug issued by the appropriate authority established for the registration of drugs in the country.

.....

(e) Has the registration of the drug been rejected, refused, deferred or cancelled in any country?

YES NO

(i) If YES, state details

.....

(f) Is the drug manufactured in other countries?

YES NO

(i) If YES, state details and list manufacturing plants from which imports can be made to Sierra Leone.

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APPENDIX IV

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*)