
	<b>APPLICATION FORM FOR THE RE-REGISTRATION OF A MEDICINAL PRODUCT</b>	
	PBSL-F-73/04	

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-IV)        | <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"/> Primary Standards                                  | <input type="checkbox"/>     |
| <input type="checkbox"/> Four (4) Copies of Label and<br>Packaging Material | <input type="checkbox"/>     |
| <br><input type="checkbox"/> Four (4) Copies of Package Insert              | <br><input type="checkbox"/> |

**Applicant**

**PBSL Staff**

Name: \_\_\_\_\_



Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

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PBSL-F-73/04		

**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  
CENTRAL MEDICAL STORES COMPOUND  
NEW ENGLANDVILLE  
JOMO KENYATTA ROAD  
FREETOWN  
SIERRA LEONE  
P. M. B. 322  
E-mail: [pharmbdsl@hotmail.com](mailto: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.

<b>A. PARTICULARS OF PRODUCT</b>
----------------------------------

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

	<b>APPLICATION FORM FOR THE RE-REGISTRATION OF A MEDICINAL PRODUCT</b>	
	PBSL-F-73/04	

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.



**APPLICATION FORM FOR THE  
RE-REGISTRATION OF A  
MEDICINAL PRODUCT**



PBSL-F-73/04

**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.



**APPLICATION FORM FOR THE  
RE-REGISTRATION OF A  
MEDICINAL PRODUCT**

PBSL-F-73/04





**D. PARTICULARS OF LOCAL AGENT**

Name of local agent:.....

Business address:.....

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

E-mail:.....

	<b>APPLICATION FORM FOR THE RE-REGISTRATION OF A MEDICINAL PRODUCT</b>	
	PBSL-F-73/04	

**E. CERTIFICATION BY A RESPONSIBLE PERSON IN THE APPLICANT COMPANY**

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:.....

	<b>APPLICATION FORM FOR THE RE-REGISTRATION OF A MEDICINAL PRODUCT</b>	
	PBSL-F-73/04	

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.

	<b>APPLICATION FORM FOR THE RE-REGISTRATION OF A MEDICINAL PRODUCT</b>	
PBSL-F-73/04		

(d) Give specifications of packaging materials (where no specifications for packaging materials exist, this must be mentioned)

.....  
 .....



(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.



	<b>APPLICATION FORM FOR THE RE-REGISTRATION OF A MEDICINAL PRODUCT</b>	
	PBSL-F-73/04	

## 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**

	<b>APPLICATION FORM FOR THE RE-REGISTRATION OF A MEDICINAL PRODUCT</b>	
	PBSL-F-73/04	

**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

	<b>APPLICATION FORM FOR THE RE-REGISTRATION OF A MEDICINAL PRODUCT</b>	
PBSL-F-73/04		

.....

.....

(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.

.....

	<b>APPLICATION FORM FOR THE RE-REGISTRATION OF A MEDICINAL PRODUCT</b>	
	PBSL-F-73/04	

## 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*)