PHARMACY BOARD OF SIERRA LEONE

(PBSL)

GUIDELINES FOR MEDICINAL PRODUCT REGISTRATION

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FOREWORD

The purpose of Drug Registration is to ensure that a pharmaceutical product has been adequately tested and evaluated for safety, efficacy and quality, and that the product information provided by the manufacturer is accurate. It also allows the pharmaceutical product to be placed on the market until the registration period for the product has expired.

The Pharmacy Board of Sierra Leone has developed and adopted the Guidelines for the registration of medicinal products for Human use

These guidelines are intended to facilitate the registration process of medicinal products, and are meant to be adopted and implemented by all stakeholders intending to market medicinal products in Sierra Leone.

The overall goal of these guidelines is to achieve the highest practicable standards of the quality of medicinal products imported into Sierra Leone and in addition to ensure the safety, quality and efficacy of these products for the protection of public health as envisaged by the Pharmacy and Drugs Act.
It should be noted however, that these guidelines are subject to review as and when necessary by the Pharmacy Board of Sierra Leone.

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Bassie S. R. Turay

Chairman, Pharmacy Board of Sierra Leone

PHARMACY BOARD OF SIERRA LEONE

REQUIREMENTS FOR SUBMISSION OF PRODUCT APPLICATION (HUMAN)

In pursuance of Section 55 of the Pharmacy and Drugs Act, these guidelines are hereby made to provide guidance to applicants on the procedure for registering a medicinal product in Sierra Leone. Applicants are encouraged to familiarize themselves with this document and the above law before completing the registration form.

1 INTERPRETATION

1.1 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) "Medicinal Product" means - any product or substance other than a medical device, which is to be administered to one or more human beings on its own, or as an ingredient in the preparation of a substance, for a medicinal purpose and includes Drugs, Cosmetics, Control-cosmetics and Nutritional Agents as defined by the Pharmacy and Drugs Act.

d) "Medicinal Purpose" means - use for treating or preventing a disease, diagnosing or ascertaining the presence and extent of a physiological function, contraception, inducing anaesthesia, altering normal physiologic function permanently or temporarily in any way in humans.

e) "Variation" (modification) means - a change in the indication(s), dosage recommendation(s), drug classification and/or patient group(s) for a previously registered drug being marketed under the same name in Sierra Leone. A variation also includes, but is not limited to, a change in the product name, site of manufacture and/or source of ingredients and labelling and packaging changes.

f) "New Chemical Entity" means - a chemical or biologically Active Pharmaceutical Ingredient (API) that has not previously been issued with a marketing authorization as an ingredient of any pharmaceutical product in Sierra Leone.

g) "Lead Market Brand" means- a branded product which has been determined by criteria including but not limited to the following:

- Sales volume
- Safety profile
- Number of prescriptions
- Expert opinion

h) "International Non-proprietary Name (INN)" means the approved chemical name of the product.

i) "Innovator Drug" means - a drug for which a New Drug Application (NDA) has been submitted to a regulatory authority and marketing authorisation granted.

j) "Generic Drug" means a finished product based on an active substance that is off-patent and which is marketed under a different name from that of the original branded medicinal product.

k) "Marketing Authorization Holder" means a person / organization to which a legal document is issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. The Marketing Authorization Holder ideally should be a pharmacist or a pharmaceutical company authorized to practise in Sierra Leone.

l) "Accredited Manufacturer's Representative" means a person / organization with a valid licence of the manufacturing company who has been appointed to promote and sell their products.

2 REGISTRATION

2.1 NEW APPLICATION

2.1.1 An application for the registration of a drug, either locally manufactured or imported, shall be made in writing.

2.1.2 An application form shall be completed in accordance with the sequence of appendices and shall be dated, signed and stamped by the applicant/license holder.

2.1.3 If the applicant is a foreign company, it shall appoint a local agent through whom an application shall be submitted.

2.1.4 The local agent shall be a registered Pharmaceutical Importation Company or an accredited manufacturer's representative registered as a pharmacist in Sierra Leone..

2.1.5 Applications shall be accompanied by:

a) A duly signed covering letter

b) Two (2) completed application forms

c) Samples of the product in the final package as specified in sample Schedule…

d) Reference/working standard for Active Pharmaceutical Ingredient and related impurities where necessary.

e) All supporting documents as specified on the application form and product Dossier.

f) Clinical trial and/or bioequivalence trial certificate where applicable

g) Non-refundable application fee as specified in Board's fee schedule.

2.1.6 An Applicant should apply for import permit for the importation of product samples meant for registration.

(a) Only the following shall be permitted to import a product:

(i) Corporate bodies duly registered by the Registrar-General's Department and licensed by the Pharmacy Board

(ii) Registered Import and wholesale pharmaceutical companies, licensed by the Pharmacy Board

(iii) Governmental, Quasi-governmental agencies and Non-Governmental Organizations (NGO's) that run health programmes and facilities, and approved by the Ministry of Health and Sanitation.

(b) The above, notwithstanding the importation of samples for registration, samples of medical materials for promotion, clinical trials, as well as the importation of specialised (orphan) drugs may be permitted.

2.1.7 The approval for the granting of Marketing Authorization for a product(s) is subject to the payment of USD 7,500 (seven thousand five hundred United States dollars) as fees for the Good manufacturing Practice (GMP) inspection of the facility (ies) where the product(s) is/are manufactured.

2.1.8 A site master file of the plant of facility (ies) in which the product was manufactured must be submitted.

2.1.9 The Board shall approve the application before any importation of the product, other than those used as samples for the purpose of this application, shall be made into the country.

2.2 RE-REGISTRATION

2.2.1 .An application for the re-registration of a drug shall be made three (3) months before expiration of the last registration.

2.2.2 The application shall be accompanied by:

a) A covering letter

b) Supporting documentation for any variations since the product was last registered

c) Samples of the finished product in the final package as specified in the sample schedule

d) A non-refundable application fee as specified in Board's fee schedule

2.2.3 An Applicant shall apply for import permit for the importation of the product samples meant for re-registration.

2.2.4 The re-registration shall be approved by the Board before any importation of the product, other than those used as samples for the purpose of this application, shall be made into the country.

2.2.5 Periodic Safety Update Report (PSUR) must be submitted by an applicant during the renewal of a new chemical entity or innovator product.

2.3 REGISTRATION VARIATION (MODIFICATION)

2.3.1 An application for a variation of the registration of a product prior to its re-registration becoming due may be made to the Board.

2.3.2 The application shall be accompanied by:

a) A duly signed covering letter

b) Documentation in support of the variation

c) Samples reflecting the variation as specified in Board's sample schedule.

d) A non-refundable variation fee as specified in Board's fee schedule.

2.3.3 An Applicant shall apply for import permit for the importation of the product samples meant for the variation

2.3.4 This variation shall be approved by the Board before any importation of the varied product, other than those used as samples for the purpose of this application, shall be made into the country.

3 SPECIFIC REQUIREMENTS

3.1 SAMPLES

3.1.1 The presentation of the product shall not have any resemblance in spelling and pronunciation of name or packaging to another product that has been previously registered by the Board.

3.1.2 All products submitted for registration shall have at least 60% of its shelf life remaining. This notwithstanding, products with a shelf life of less than 24 months shall have at least 80% of its shelf life remaining at the time of submission.

3.1.3 All samples of oral liquid preparations (solutions, suspensions, syrups) shall have an appropriate graduated plastic measure included in the final package.

3.1.4 All samples submitted shall conform to labelling regulations in force in Sierra Leone (Refer to *Pharmacy Board of Sierra Leone Guidelines for Packaging and Labelling of Pharmaceutical Products* for Registration)

3.1.5 The use of an International Non-proprietary Name (INN) as a brand shall not be permitted.

3.1.6 The brand name of the product shall not have any resemblance in spelling and pronunciation to the INN.

3.1.7 The packages of all products submitted for registration shall include package inserts /patient information leaflets.

3.1.8 All Documents submitted must be in English, and must be legibly printed and not hand written.

3.2 NEW CHEMICAL ENTITIES OR INNOVATOR PRODUCTS

3.2.1 Registration in Sierra Leone shall normally not be permitted within the first two years of the first registration of the drug on the international market.

3.2.2 Verifiable information shall be provided regarding the date of expiry of the patent.

3.2.3 Although clinical trial data derived from studies in other countries will be considered in taking a decision with any application, the Board reserves the right to request for local clinical evaluation, based on existing guidelines for clinical trials, where necessary. (Refer to *Pharmacy Board of Sierra Leone Guidelines for Conducting Clinical Trials*). The cost of this trial shall be borne by the applicant.

3.2.4 The applicant must submit a Pharmacovigilance plan for New Chemical Entity or Innovator drug.

3.3. GENERIC DRUGS

3.3.1. Verifiable evidence shall be provided and an undertaking made by the applicant to the effect that the patent of the innovator drug has expired.

3.3.2. A Bio-equivalence study report shall be submitted in line with existing guidelines in Sierra Leone (*Refer to Pharmacy Board of Sierra Leone Guidelines for Conducting Bio-equivalence Studies*)

3.3.3. Although Bio-equivalence data derived from studies in other countries will be considered in taking a decision with any application, the Board reserves the right to request for local clinical evaluation, based on existing guidelines for Bio-equivalence studies, where necessary. (Refer to *Pharmacy Board of Sierra Leone Guidelines for Conducting Bio-equivalence Studies*). The cost of this trial shall be borne by the applicant.

3.4 For all solid oral dosage forms, reports of dissolution studies will be required.

3.5 If the product is manufactured on contract basis, evidence of the contract shall be submitted. This information shall be clearly stated on the product label and package insert.

3.6 For both locally manufactured and imported drugs, the original certificate of analysis for the batch of the drug being submitted for registration and issued by a recognized public analyst, shall be submitted.

3.7 For imported drugs, a Certificate of Pharmaceutical Product (CPP) issued by the statutory national drug regulatory authority, in accordance with the World Health Organisation (WHO) Certification Scheme for Pharmaceutical Products Moving in International Commerce, shall be submitted along with the certificate of analysis.

3.8 A Drug Master File and process validation protocols shall be submitted for all applications.

3.9 Stability study reports conducted for three (3) trial batches of the product, and suited to the conditions specified below, shall be submitted :-

a) WHO Zone IV climatic conditions

Condition	Accelerated	Real Time
Storage Temperature	40 ± 2 ^{o}C	30 ^{o}C
Relative Humidity	75 ± 5 %	70 %
Duration	6 months	Until end of shelf life

b) The stability study shall be conducted in the container closure system in which it will be marketed in Sierra Leone.

3.10 Where the product is to be registered in more than one container closure system, stability data shall be provided for each presentation. Real-time stability data shall be required for all biologicals.

3.11 The result of the stability test shall be presented in both tabular and graphical forms and the proposed shelf-life and storage conditions shall be determined on the basis of these results.

3.12 The Board in considering an application:

a) Shall satisfy that there is need to have the drug registered in Sierra Leone.

b) Shall request the applicant to submit a manufacturer's authorization to register the drug.

c) May consult with other bodies and experts with knowledge of the drug.

d) Reserves the right to conduct a Good Manufacturing Practice (GMP) audit inspection on the manufacturing facility(ies) for the product at a fee prescribed by the Board.

e) May ask the applicant to supply such other information as may be required to enable it reach a decision on the application.

3.13 An appeal for the review of an application may be made in writing to the Registrar of the Board within thirty (30) days of receipt of the rejection notice.

3.14 Where the Board is satisfied that there is the need to register a drug, and all requirements for its registration have been satisfied, it shall do so and issue to the applicant a certificate of registration, subject to such conditions as may be prescribed by the Board from time to time.

3.15 The registration of a drug under these regulations, unless otherwise revoked, shall be valid for a period of one (1) year and may be renewed subsequently for a period of three (3) years.

3.16 The Board shall from time to time, publish a notice in the Gazzette notifying the registration of a drug under these regulations.

3.17 No information given in this application shall be disclosed by the Pharmacy Board to a third party except:-

a) With the written consent of the licence holder; or
b) In accordance with the directive of the Board of Directors of the Pharmacy Board of Sierra Leone or any other statutory organisation with the legal mandate to do so.

4. SANCTIONS AND PENALTIES

4.1 The Board shall cancel, suspend, or withdraw the registration of a drug if:-

a) The grounds on which the drug was registered is later found to be false.

b) The circumstances under which the drug was registered no longer exist.

c) Any of the provisions under which the drug was registered has been contravened.

d) The standard of quality, safety and efficacy, as prescribed in the documentation for registration is not being complied with.

e) The premises, in which the drug or part thereof is manufactured, packaged or stored by or on behalf of the holder of the certificate of registration is unsuitable for the manufacture, packaging or storage of the drug.

4.2 Where the registration of a drug is suspended, withdrawn or cancelled, the Board shall cause the withdrawal from circulation of that drug and shall accordingly cause the suspension, cancellation or withdrawal to be published in the Gazzette. The cost of the withdrawal shall be borne by the Marketing Authorization (MA) holder.

NOTE

(a) Provisional Registration period for new registration of products is 12 (twelve) months.

(b) Provisional registration period for new drug entity is 12 (twelve) months

(c) Renewal of registration period for a drug already in the market is three (3) years.

(d) Drug for public tender especially for Central Medical Stores (CMS) should be registered.

(e) Drugs for donation should be registered.

(f) Pharmaceutical products are registered for dispatching through authorized distribution channels. Whenever registered products are in parallel markets, the local agent of the manufacturer is responsible for the withdrawal.

(g) The applicant must submit a Pharmacovigilance plan for New Proprietary Drug.

(h) The period of registration process is Three (3) months after submission of samples and a complete drug dossier for each pharmaceutical product to be registered.

THE PHARMACY BOARD FEE SCHEDULE FOR REGISTRATION AND RE-REGISTRATION OF PHARMACEUTICAL PRODUCTS

1. Application fees for the registration of New Drug specialities and of new proprietary drugs fees USD 720 (Seven Hundred and twenty Dollars) or its equivalent in Leones. (Non refundable)

2. Renewal fees for new drug specialities and new proprietary drugs are USD 520 (Five Hundred and twenty Dollars). (Non refundable)

3.Application fees for new registration of products are:

a)Branded products USD 270 (Two hundred and seventy Dollars) or its equivalent in leones. (Non refundable)

b)Generic products USD 250 (Two hundred and fifty Dollars)

N.B: Period of validity is One (1) year. (Non refundable)

4. Application fees for the Renewal of registration of pharmaceutical products with previous Marketing Authorisation in Sierra Leone.

a) Branded drugs USD 270 (Two hundred and seventy Dollars) or its equivalent in Leones. (Non refundable)

b) Generic drugs USD 250 (Two hundred and fifty Dollars) or its equivalent in Leones. (Non refundable)

N.B: Period of validity is three (3) years.

5. Application fees for modification/variation of drugs already registered:

Application fee for modification/variation is USD 300 (Three Hundred Dollars) or its equivalent in Leones. (Non refundable)

PHARMACY BOARD SAMPLE SCHEDULE FOR REGISTRATION

AND RE-REGISTRATION OF PRODUCTS

A. SOLID DOSAGE FORMS (TABLETS /CAPSULES)

Pack Size	Quantity
1 x 1	200
1 x 2	100
1 x 6	35
1 x 10	20
10 x 10	2
1 x 20	10
3 x 25	3
1 x 30	7
1 x 50	4
1 x 100	2
1 x 200	2
1 x 500	2
1 x 1000	2

B. LIQUID DOSAGE FORMS (SYRUPS, SUSPENSIONS, and SOLUTIONS etc.)

Pack Size	Quantity
1 x 50ml	20
1 x 100ml	12
1 x 200ml	8
1 x 500ml	3
1 x 1000ml	2
1 x 2L	2
1 x 4.5L	2

C. SMALL VOLUME PARENTERALS (< 100ML)

Pack Size	Quantity
1 x 5	40
1 x 10	20
1 x 20	10
1 x 50	4
1 x 100	2

D. LARGE VOLUME PARENTERALS (> 100ML)

Pack Size	Quantity
100ml	20
500ml	12
1000ml	6

E. DRY POWDERS FOR RE-CONSTITUTION(PARENTERALS)

Weight	Quantity
	Minimum of
100mg	50 vials
100mg – 500mg	50 vials
500mg – 1g	50 vials

F. TOPICAL APPLICATIONS (CREAMS, LOTIONS, OINTMENTS etc.)

Pack Size	Quantity
➢ 15g and above (20ml)	15

G. EYE / EAR PREPARATIONS

Pack Size	Quantity
➢ 1 – 5ml	50
➢ 10 – 20ml	30
➢ > 20ml	20

H. INHALATIONAL PREPARATIONS

➢ 10 packs

I. POWDER / SACHETS

Pack Size	Quantity
SACHET	
➢ 1 x 25 (10 – 50g)	4
➢ 1 x 50 (10 – 50g)	2
➢ 1 x 100 (10 – 50g)	2
➢ 1 x 200 (10 – 50g)	2
HDPE CONTAINER	
➢ 1 x 50g	10
➢ 1 x 100g	5
➢ > 100 – 500g	2

THE PHARMACY BOARD OF SIERRA LEONE

DOSSIER REQUIREMENT (CONTENTS OF A DOSSIER) FOR THE REGISTRATION OF MEDICINAL PRODUCTS.

SECTION 1: INFORMATION FOR FINISHED PHARMACEUTICAL PRODUCT (FPP)

Details of Product.

1.1 Administrative Section.

a. Name, composition, dosage form, strength, shape and colour of product.

b. Approved generic name(s) (I.N.N If any).

c. Chemical name and pharmacologic group of product.

d. Pharmacokinetics and pharmacodynamics of the product.

e. Route of administration.

f. Indications / clinical uses of product.

g. Contra - indications.

h. Precautions and warnings.

i. Side effects / undesirable effects.

j. Interactions.

k. Direction for use and dosage.

l. Expiry date and storage conditions.

m. Incompatibilities.

n. Commercial Presentation of product.

o. Category of distribution.

p. Applicant's name and address.

q. Name and address of Local agent (depending on the existing regulation in the country).

r. Name and address of manufacturer - Please refer to 1.2 below.

1.2 Site of manufacture

State the name and street address of each facility where any aspect of manufacture occurs, including production, sterilization, packaging and quality control. Indicate the activity performed at each site. Provide phone number(s); fax number(s) and e-mail address. Include any alternative manufacturer(s).
For each site where the major production step(s) is / are carried out, attach a certificate issued by the competent authority in terms of the WHO certification scheme of the quality of pharmaceutical products moving in international commerce.

1.3 Schedule of ingredients.

1.3.1 Names and specifications of all ingredients used in the formulation (both active pharmaceutical ingredient(s) and excipient(s)
1.3.2 Packaging materials and specifications.
1.3.3 Quantity per dosage unit.
1.3.4 Overages (if applicable) and justification for quantity (ies) used.
1.3.5 Reason for inclusion of all in the formulation.
1.3.6 Justification of all in-house specification(s)
1.3.7 Safety data on novel excipient(s) if applicable

SECTION 2:

2 Regulatory Documents

2.1 A valid World Health organization (WHO) or European Union (EU) Certificate of Good Manufacturing Practice (GMP).

2.2 Regulatory status in exporting country (A certified true copy of the valid marketing authorization issued by the Drug Regulatory Authority of the country of origin). A marketing authorization from any other two countries (Stringent Regulatory Authorities (SRA), as defined by the World Health Organization (WHO), is desired.)

2.3 A free sale certificate issued by the competent authority of the country of origin.

2.4 A valid manufacturer's Licence

2.5 Certificate of registration in the country of origin, indicating date of registration. This date should precede by at least two (2) years the application in Sierra Leone, except for duly justified therapeutic reasons or any other two countries where product has been registered.

2.6 Filled Application Form for each product to be registered, renewed or modified

2.7 Application letter for the registration, renewal or variation of Pharmaceutical product(s) to the Board.

2.8 Certificate of pharmaceutical product (CPP)

2.9 Complete Filled Batch Manufacturing Records

2.10 A mutual acceptable plan for post-marketing surveillance should be settled in advance and included in the application as a condition of approval.

SECTION 3:

3. Common Technical Document (CTD) for new Drug entity.

3.1 MODULE 1- Regional Administrative Information (Application Forms, Label and Patient Leaflets).

3.2 MODULE 2- Table of Content of application

- Introduction
- Rationale of the need for the new drug
- Non Clinical overview
- Non Clinical summaries
- Clinical overview
- Clinical summaries

3.3 MODULE 3- Quality

- Drug Master File (DMF) of Drug substance and drug product.

SECTION 4:

3.1 Analytical Details -: For generic and branded Drugs, the analytical section should contain:

3.1.1 Complete Drug Master file (DMF) of Drug substance and Drug product or valid European Certificate of suitability.

3.1.2 Specifications for starting material, intermediates, and the final dosage form with validated analytical methods.

3.1.3 Analytical methods of the finished product and analytical method validation protocol and report plus representative tracings where applicable such as chromatograms, ultra-violet tracings, potentiometer records etc.

3.1.4 Analytical method and report of the samples submitted or finished product.

3.1.5 Analytical methods of the active and inactive raw materials plus certificate of analysis of each active and inactive raw material.

3.1.6 Analytical control Procedures.

3.1.7 Protocol and data of stability studies. Stability studies should done at 30^0C+/-2 and 75%RH for Real-time stability studies and at 40^0C+/- and 75%RH+/-5 for accelerated stability studies (Zone IVb).

3.1.8 Protocol and data of bioequivalence and bioavailability studies.

THE PHARMACY BOARD OF SIERRA LEONE
REGISTRATION DEPARTMENT
PACKAGING AND LABELLING REQUIREMENTS FOR THE REGISTRATION OF MEDICINAL PRODUCTS

In pursuance of the Pharmacy Board Regulations as amended by the Pharmacy and Drugs Act, these guidelines are hereby made to ensure the proper packaging and labelling of all drugs, cosmetics, nutritional agents, medical devices and chemicals.

INTERPRETATION

In these guidelines, unless the context otherwise states:

a) "Board" means The Pharmacy Board of Sierra Leone

b) "Product" means a drug, cosmetic, nutritional agent, medical device or Household chemical

c) "Container" includes strips, bottle, jar, box, sachet or any other receptacle which contains or is to contain in it a product regulated under this Act.

d) "Label" includes a legend, tag, brand, work or mark, pictorial or any other descriptive matters written, printed, stenciled, marked, embossed or impressed on or attached a container of a product regulated under this Act.

e) "Carton" means a large cardboard container or box in which goods are packed in smaller containers.

f) "Brand name" means the proprietary or trade name of the product.

g) "I.N.N" means International Non-proprietary name.

h.) "Generic" means a finished product based on an active substance that is not off-patent and which marketed under a different name from that of the original branded medical product.

I) "IUPAC" means International Union of Pure and Applied chemistry.

ADMINISTRATIVE REQUIREMENTS

(A) Packaging requirements

1. The container in which the product is contained shall be of good quality.

2. The product shall be provided by a primary and secondary container.

3. The container and closure shall be properly sealed so as to protect the product from the influence the outside environment.

4. Each sample should have an insert.

5. All oral liquid dosage forms shall have a dispensing spoon or graduated cup measure enclosed in the secondary container

B) Labelling requirements

6. .The labelling shall be informative and accurate and shall be written in English

7. The product information shall be printed on a label adhered to the container or printed directly on to the container itself. The print shall be in a clear, font, legible and indelible. The information on the label of the primary container must match with that on the label of the secondary container.

8. The information on a label shall include, but not limited to the Following:

a) The name of the product and where applicable, the generic or INN. The proprietary name of the product followed immediately below by the generic or INN of the active ingredient in equal print size where the product contains only one active ingredient.

b) A list of active ingredients using INN where applicable, showing the strength of each present in a dosage unit.

c) Names and strengths of specific excipients known to have recognized action or effect should be included.

d) Pharmaceutical dosage form and pack size in each container.

e) Name, postal address and premises address of the manufacturer, and distributor

f) The manufacturer's batch number or lot

g) Date of manufacture and expiry date

h) Directions for use, and any warnings or precautions that may be necessary

i) Any special storage conditions or handling precautions that may be necessary

j.) The product name, package or label shall not bear close resemblance to a previously registered product. In addition, the name of the product shall not be unethical, socially or traditionally unacceptable, superstitious or magical.

9. If the original label is in a local or foreign language, the product information shall be in English or a translation there of;

10. All products that are not recommended for use in or by children the statement "Not to be taken by children" shall be included.

11. .All labels shall bear the statement "keep out of the reach of Children"

12. .Products meant for external use shall bear the statement "For External Use Only"

13. The sample packages should bear the inscription "FREE MEDICAL SAMPLE, NOT FOR SALE" printed on the package or on adhesive label.
14. The samples submitted must come from the same batch.
15. The expiring date of the sample should not be less than two-third ($^2/_3$) of the shelf- life.
16. The batch number, manufacturing date and the expiring date should be clearly printed on the package and not on adhesive label.
17. The category of poisonous substance to which the product belongs with the inscription **"**DO NOT EXCEED THE PRESCRIBE DOSE**"** or any other similar indication approved by the Drugs/Medicines Registration committee, must clearly appear on the label.

18. Inscriptions on the packages, labelling and instructions should be in English.

C.) Other requirements

19. All pages in the dossier should be numbered appropriately
20. Each section in the dossier must have a table of content.
21. All Dossiers submitted to the Board must be file- bound and must be submitted by a Pharmacy Professional and should also be presented in English