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| | **Title: GUIDELINES FOR THE REGISTRATION OF COSMETICS AND HOUSEHOLD CHEMICAL SUBSTANCE** | |
| **Rev No: 02** | **Doc No: PBSL/GL/029** | Version no. 03 |
| **Issue date: 15 May 2024** | **Effective date: 17 May 2024** | Approved by: Registrar |

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| **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**

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**ACKNOWLEDGEMENTS**

**EXECUTIVE SUMMARY**

## 1.0 INTRODUCTION

This guideline is intended to assist applicants to make sure that the products they manufacture and apply for registration meet the requirements of the Pharmacy Board of Sierra Leone (PBSL). This is in accordance with provisions of the Pharmacy and Drugs Act, 2001 which among other things prescribes conditions of registration of cosmetics in Sierra Leone. The primary goal of the Pharmacy Board of Sierra Leone is to implement an efficient regulatory control system without compromising consumer safety. This regulatory system should be easy for both the industry and Authority to implement and evaluate.

This guideline describes the requirements for registration and explains how applications are made to the PBSL for the registration of cosmetics and household chemical substances.

Consumer safety is the fundamental principle of cosmetic and household chemical substance registration. The PBSL through the registration process gather adequate information for evaluation and assessment on the quality and safety of cosmetics and household chemical substances.

## 2.0 OBJECTIVE

This guideline has been designed to assist in the following;

- Provide guidance on the technical and other general data requirements for the registration of cosmetic and household chemicals by the Pharmacy Board of Sierra Leone.
- To help facilitate the processes and procedures involved in the registration of cosmetics and household chemicals.
- Promote effective and efficient processes for the evaluation of these applications and the subsequent issuance of Marketing Authorization.

## 3.0 SCOPE

In pursuance of Section 44 of the Pharmacy and Drugs Act 2001 these Guidelines are hereby made to provide guidance to applicants on the procedures and requirements for the registration of cosmetics and household chemical substances.

Applicants are encouraged to familiarize themselves with this document and the law before completing the application form.

## 5.0 SPECIFIC REQUIREMENTS

### *5.1 General Requirements*

#### 5.1.1. New Registration

(i) All applications and supporting documents shall be in English and legible. Where material is not originally in English, a copy in the original language and a full translation should be submitted, the accuracy of the translation is the responsibility of the applicant. Authentication of the translation has to be done at the nearest Sierra Leone Embassy or by an authorized issuing authority in the country from where the document originates. Reports submitted only in a language other than English will not be accepted.

(ii) An application for the registration of a cosmetic or household chemical substance either locally manufactured or imported shall be made in writing.

(iii) An application form shall be completed in accordance with the sequence of appendices and shall be dated, signed and stamped by the applicant/licence holder.

(iv) Dossiers should be securely bound and arranged sequentially and should be submitted in separate bound volumes. Certificates of analysis attached to dossiers should clearly state key ingredients used in the formulation of products.

(v) If the applicant is a foreign company, it shall appoint a local agent through whom the application shall be submitted.

(vi) The local agent shall be a registered company or an accredited manufacturer's representative registered in Sierra Leone.

(vii) 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 the Authority's sample Schedule.

d) All supporting documents as specified on the application form

e) Non-refundable application fee as specified in the Authority's fee schedule.

(viii) The Authority shall approve the application before any importation of the products shall be made into the country other than those used as samples for the purpose of this application.

### 5.1.2. Registration Variation

(i) An application for a variation of the registration of a product prior to its re- registration becoming due may be made to the Authority.

(ii) 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 the Authority's sample Schedule.

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

(iii) This variation shall be approved by the Authority before any importation of the varied product shall be made into the country, other than those used as sample for the purpose of this application.

### 5.1.3. Re-Registration

(i) An application for the re-registration of a cosmetic or household chemical substance shall be made (three) months before expiration of the last registration.

(ii) 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 product in the final package as specified in the Authority's sample Schedule.

d) Non-refundable application fee as specified in the Authority's fee Schedule.

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

### *5.2. SPECIFIC REQUIREMENTS*

The presentation of the product shall not have any resemblance in spelling, pronunciation of name and packaging to another product previously registered by the Authority.

Samples submitted for registration shall be in the final package proposed for marketing of the product in Sierra Leone and shall have 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.

If a product is manufactured on contract, evidence of the contract shall be produced in the documentation submitted. This shall be clearly stated on the label of the product.

All documentation submitted shall be in English, and must be legibly printed and not hand written.

All samples of products submitted shall conform to current labeling regulations.

For locally manufactured products, the original certificate of analysis issued by a recognized public analyst shall be submitted.

For imported products, an appropriate certificate of analysis of the finished product shall be submitted.

Supporting evidence shall be submitted for any special labeling claims.

In addition to stating the specific enzymes used in the formulation of powder detergents, adequate documentation should be submitted to justify the mode of culturing and/or synthesis of enzymes used in the formulation of washing powder detergents

The Authority, in considering an application shall,

(i) require the applicant to provide such other information, as may be necessary, to enable it reach a decision.

(ii) Satisfy itself that there is need to have the product registered.

(iii) Consult, when necessary, with other bodies and experts with knowledge of the product.

(iv) Request the local agent to satisfy the Authority that it has the resources and facilities to execute an effective recall of the product if the need arises.

Where the Authority is satisfied that there is the need to register the product and all certificate of registration, subject to such conditions as may be prescribed by the Authority from time to time.

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.

The registration of product under these regulations, unless otherwise revoked, shall be valid for a period of 3 years and may be renewed.

The Authority shall publish annually a notice in the Gazette notifying the registration of the product under these regulations.

An appeal for the review of an application can be made in writing not later than 21 (twenty one) days to the Minister and this shall be accompanied with an appropriate fee.

## 5.0 GLOSSARY

In these Guidelines, unless the context otherwise requires,

a) "Product" means a cosmetic, household chemical substance,

b) "Household Chemical Substance" means a substance or mixture of substances packaged for use in a domestic or office setting as a germicide, an antiseptic, disinfectant, pesticide, insecticide, vermicide, rodenticide, detergent or any other substance or mixture of substances declared by the Minister, after consultation with the Authority, to be a chemical substance.

c) "Cosmetic" includes a substance or mixture of substances manufactured, sold, or represented for use in cleansing, improving or altering the complexion, skin, hair, eyes or teeth and includes deodorants and perfumes.

d) "Authority" means the Pharmacy Board of Sierra Leone

e) "Claim" means any message or representation including pictorial, graphic, symbolic or any form of representation, which states, suggests or implies that a cosmetic or household chemical substance has particular characteristics relating to its origin, function, nature, composition or any other characteristics

f) 'Container' means a bottle, jar, box, packet, sachet or other receptacle which contains or is to contain a cosmetic

g) "Flavour" means a substance used as an ingredient of cosmetic solely to impart taste to the product

h) "Fragrance" means a substance used as an ingredient of cosmetic solely to impart odour to the product

i) "Ingredient of a cosmetic or household chemical substance" means any substance which is a component of a cosmetic or household chemical substance and includes colouring agents, botanicals, fragrance and flavour;

j) "Label of a cosmetic or household chemical substance" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of any cosmetic or household chemical substance

k) "Manufacture of cosmetic or household chemical substance"" means and includes all operations involved in the production, processing, compounding,

formulating, filling, refining, transforming, packing, packaging, repackaging and labelling of cosmetics or household chemical substances

l) "Manufacturer" means a Registrant (Market Authorization Holder) engaged in the manufacture of cosmetics or household chemical substances

m) "Package" means any box, packet or any other article in which one or more containers of cosmetics are to be enclosed in one or more other boxes, packets or article in question, the collective number thereof;

n) "Variation" means a change in the indication(s), recommendation(s), classification, colour scheme, product features for a previously registered cosmetic or household chemical substance 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 list of ingredients.

o) "Product variants" means a range of cosmetics or household chemical substance produced by the same manufacturer in the same site, similar in composition and intended for the same use but available in different colours, fragrances, flavours and container shapes

p) "Banned Ingredient" means a substance which is forbidden to be a component of a cosmetic or household chemical substance

q) "Applicant/Licence Holder" Means any person who may either be the trademark owner or person authorized by him, who has rights to sell a

product and is responsible for placing the product on the Sierra Leonean market. Representatives of licence holders may not hold themselves as applicants unless they own the product.

r) "Locally manufactured products" The manufacturing carried out by the local firm in the country of origin to whose order and specifications the product is manufactured and distributed.

s) "Local agent" The local firm who is authorized in writing by a foreign manufacturer or applicant to be the holder of the registration certificate and be responsible for all matters pertaining to the registration of the product.

## 6.0 REFERENCES


1. Subchapter G Cosmetics in Code of Federal Regulations. National Archives and Records Administration, USA. 1995; Part 700: 175 - 203

2. Cosmetics Act 1992 Ministry of Health, Thailand

3. Cosmetic Claims Guidelines. National Coordinating Committee on Therapeutic Goods, Therapeutic goods Administration. Australia

4. Cosmetic Registration Scheme, Malaysia httpp:/www.serve.com/bpfk/html/cosmetic/registration products guidelines.htm

## 7.0 ANNEXES

NONE

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