	Title: GUIDELINES FOR PACKAGING & LABELLING OF PHARMACEUTICAL PRODUCTS	
Rev No: 01	**Doc No: PBSL/GL/038**	Version no. 02
Issue date: 15 Feb 2021	**Effective date: 17 Feb 2021**	Approved by: Registrar

	Title: GUIDELINES FOR PACKAGING & LABELLING OF PHARMACEUTICAL PRODUCTS	
Rev No: 01	**Doc No: PBSL/GL/038**	Version no. 02
Issue date: 15 Feb 2021	**Effective date: 17 Feb 2021**	Approved by: Registrar

TABLE OF CONTENTS **PAGE NO.**

	Title: GUIDELINES FOR PACKAGING & LABELLING OF PHARMACEUTICAL PRODUCTS	
Rev No: 01	**Doc No: PBSL/GL/038**	Version no. 02
Issue date: 15 Feb 2021	**Effective date: 17 Feb 2021**	Approved by: Registrar

1.0 INTRODUCTION

This reviewed guidelines on packaging and labelling of pharmaceuticals and related products is aimed at ensuring that all such products get into the hands of the patients/consumers for whom they are prescribed. In the manufacture of pharmaceutical products, quality assurance is defined as "the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use". In addition, the system of quality assurance for the manufacture of pharmaceutical products should ensure that "arrangements are made for the manufacture, supply and use of the correct starting and packaging materials". Public opinion sometimes considers packaging to be superfluous. However, it must be emphasized that packaging preserves the stability and quality of medicinal products and protects them against all forms of spoilage and tampering. All medicinal products need to be protected and "consequently need to be packaged in containers that conform to prescribed standards, particularly with respect to the exclusion of moisture and light and the prevention of leaching of extractable substances into the contents and of chemical interaction with the contents.

2.0 OBJECTIVES

This guideline has been designed to achieve the following;

- Protect pharmaceutical products against all adverse external influences that can alter the properties of the product, e.g. moisture, light, oxygen and temperature variations;
- Protect pharmaceutical products against biological contamination and physical damage;
- Carry the correct information and identification of the product.

Note that the kind of packaging and the materials used must be chosen in such a way that:

- The packaging itself does not have an adverse effect on the product (e.g. through chemical reactions, leaching of packaging materials or absorption);
- The product does not have an adverse effect on the packaging, changing its properties or affecting its protective function.

3.0 SCOPE

The complexity of packaging materials and the highly technological nature of medicinal products are such that manufacturers are confronted with significant problems. Interaction between packaging and such products is possible due to the combination of a multiplicity of container components and active pharmaceutical ingredients, excipients and solvents used in a variety of dosage forms. Therefore, the quality of the packaging of pharmaceutical products plays a very important role in the quality of such products.

The purpose of this guideline is to describe how the requirements for packaging and labelling apply for the issuance of a marketing authorisation by the Pharmacy Board of Sierra Leone. This guideline shall assist applicants and marketing authorisation holders when drawing up product labels.

4.0 GLOSSARY

- Ampoule: A container sealed by fusion and to be opened exclusively by breaking. The contents are intended for use on one occasion only.

- Bag: A container consisting of surfaces, whether or not with a flat bottom, made of flexible material, closed at the bottom and at the sides by sealing; the top may be closed by fusion of the material, depending on the intended use.
- Blister: A multi-dose container consisting of two layers, of which one is shaped to contain the individual doses. Strips are excluded.
- Bottle: A container with a more or less pronounced neck and usually a flat bottom.
- Cartridge: A container, usually cylindrical, suitable for liquid or solid pharmaceutical dosage forms; generally for use in a specially designed apparatus (e.g. a prefilled syringe).
- Containers: A container for pharmaceutical use is an article which holds or is intended to contain and protect a drug and is or may be in direct contact with it. The closure is a part of the container. The container and its closure must not interact physically or chemically with the substance within in any way that would alter its quality. The following terms include general requirements for the permeability of containers:

  • Hermetically closed containers must protect the contents from extraneous matter and from loss of the substance, and be impervious to air or any other gas under normal conditions of handling, shipment or storage.

  • Tightly closed containers must protect the contents from extraneous matter, from loss of the substance, and from efflorescence, deliquescence or evaporation under normal conditions of handling, shipment or storage. If the container is intended to be opened on several occasions, it must be designed to be airtight after reclosure.

• Well-closed containers must protect the contents from extraneous matter or from loss of the substance under normal conditions of handling, shipment or storage.

- Gas cylinder: A container, usually cylindrical, suitable for compressed, liquefied or dissolved gas, fitted with a device to regulate the spontaneous outflow of gas at atmospheric pressure and room temperature.
- Injection needle: A hollow needle with a locking device intended for the administration of liquid pharmaceutical dosage forms.
- Injection syringe: A cylindrical device with a cannula-like nozzle, with or without a fixed needle and a movable piston, used for the administration, usually parenteral, of an accurately measured quantity of a liquid pharmaceutical form. The syringe may be prefilled, and can be for single-dose or multi-dose use.
- Labels: All finished drug products should be identified by labelling, as required by the national legislation, bearing at least the following information:

  (a) the name of the drug product;

  (b) a list of the active ingredients (if applicable, with the International Nonproprietary Names (INNs)), showing the amount of each present, and a statement of the net contents, e.g. number of dosage units, mass or volume;

  (c) the batch number assigned by the manufacturer;

  (d) the expiry date in an uncoded form;

  (e) any special storage conditions or handling precautions that may be necessary;

  (f) the directions for use, and any warnings and precautions that may be necessary;

(g) the name and address of the manufacturer or the company or person responsible for placing the product on the market.

- Marketing authorization (product licence, registration certificate): A legal document issued by the competent drug regulatory authority that establishes the detailed composition and formulation of the product and the pharmacopoeial or other recognized specifications of its ingredients and of the final product itself, and includes details of packaging, information given on the label, product information and shelf-life.
- Materials: A term used to denote starting materials, process aids, intermediates, active pharmaceutical ingredients, packaging and labelling materials.
- Packaging material: Any material, including printed material, employed in the packaging of a pharmaceutical product, excluding any outer packaging used for transportation or shipment. Primary packaging materials are those that are in direct contact with the product.
- Packaging process: All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished product.
- Production: All operations involved in the preparation of a pharmaceutical product, from receipt of the starting materials, through processing and packaging, to completion of the finished product.
- Quarantine: The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

- Strip: A multi-dose container consisting of two layers, usually provided with perforations, suitable for containing single doses of solid or semi-solid preparations.
- Vial: A small container for parenteral medicinal products, with a stopper and overseal; the contents are removed after piercing the stopper. Both single-dose and multi-dose types exist.

5.0 REQUIREMENTS

- ✓ Labelling shall be informative and accurate.
- ✓ Product labels shall be printed. The print shall be in a clear font and legible. The print shall be indelible and not fade when exposed to sunlight.
- ✓ The information on a label shall include, but not be limited to, the following:

(a) The name of the product, and the generic or INN/INCI

(b) A list of the active ingredients using INN/INCI or IUPAC system, where applicable, showing the amount of each present in a dosage unit.

(c) Amount of each Active Pharmaceutical Ingredient present in a dosage unit

(d) The net content of the container

(e) The batch number

(f) Date of manufacture and best before/expiry date

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

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

(i) List of excipients known to be a safety concern for some patients, e.g. lactose, gluten, metabisulfites, parabens, ethanol, or tartrazine. For parenterals and topical preparations, all excipients should be listed.

(j) Pharmaceutical form and contents of the container, e.g. number of dosage units, weight or volume.

(k) Method and route(s) of administration and the statement "Read the patient information leaflet before use."

(l) Indications, frequency, route and conditions of use where applicable

(m) The names of any excipients known to be a safety concern

(n) Name, postal address and premises address of the manufacturer and Distributor

(o) Country of origin.

- ✓ The product name, package or label shall not bear close resemblance to a previously registered product.
- ✓ If the original label is in a local or foreign language, the product information shall be in English or a translation thereof.
- ✓ All products that are not recommended for use in or by children, the statement "not to be taken/used by children" shall be included.
- ✓ All products shall bear the statement "keep out of the reach of children"
- ✓ Products meant for external use shall bear the statement "for external use only"
- ✓ Special storage conditions, if applicable
- ✓ Special precautions for disposal of unused medicinal products or waste material derived from such medicinal products, if appropriate.

- ✓ The name and package design of a product shall not be offensive, unethical, socially or traditionally unacceptable, superstitious, magical etc. Similarly, the product's labels shall be devoid of "wording or design" that may be promotional or serve to enhance marketing.
- ✓ The product's indication should not be used as the name of the product.
- ✓ All dosages should be stated in words.
- ✓ For products meant for children, the age ranges shall be specified for each dosage regimen.
- ✓ The list of indications shall correspond to the known activity of active ingredients declared.
- ✓ Advice on general classification for distribution, e.g., Controlled Medicines, Prescription Only Medicines, Pharmacy Only Medicines, Over-the-Counter and General Sales List
- ✓ The product registration number may be included in the product's labels
- ✓ The word "sterile" if the product is sterile

5.1 Specific Requirements

Small containers

For containers of less than or equal to 10 ml capacity that are marketed in an outer pack such as a carton, and the outer pack bears all the required information, the immediate container should contain at least these minimum information (added):-

i. Brand Name of the FPP, INN name, strength, pharmaceutical form, active substance(s) and route(s) of administration

ii. Method of administration

iii. Batch number assigned by the manufacturer

iv. Expiry date

v. Manufacturing date if space is enough

vi. Contents by weight, by volume or by unit

vii. The name and address of the manufacturing site— or a logo that unambiguously identifies the company.

viii. Directions for use, and any warnings or precautions that may be necessary

Blisters and strips

Blisters and strips should include, as a minimum, the following information (printed directly):-

i. Name, strength and pharmaceutical form of the FPP.

ii. Name and physical address of the manufacturing site (the site responsible for release of the finished product)

iii. The batch number assigned by the manufacturer

iv. The expiry date [Note that for co-blistered products, the expiry date is that of the product which expires first.]

v. The manufacturing date, if space is enough

vi. The batch number assigned by the manufacturer

vii. Directions for use, and any warnings or precautions that may be necessary.

Cosmetics

In addition to the clauses above (as applicable), claims on cosmetics shall not imply actions that are normally considered therapeutic in nature.

Household Chemical Substances

In addition to the clauses above (as applicable), household chemical substances shall be required to provide:

(a) Mode or method of dilution

(b) Method of application and protection required

(c) For insecticide aerosols, re-entry periods shall be specified

(d) Precautions and treatment of accidental ingestion and poisoning

(e) Appropriate conditions for disposal of the container

(f) Hazard symbols

6.0 REFERENCES

1. Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/ EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products. Official Journal of the European Communities, 1993, 214:22–30.
2. Good manufacturing practices for pharmaceutical products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second report. Geneva, World Health Organization, 1992, Annex 1 (WHO Technical Report Series, No. 823).
3. Guideline for submitting documentation for packaging for human drugs and biologics. Washington, DC, Center for Drug Evaluation and Research, Food and Drug Administration, 1987.
4. Packaging — child-resistant packaging — requirements and testing procedures for non-reclosable packages for pharmaceutical products. European Protocol prEN862. Brussels, European Committee for Standardization, 2000
5. Specifications for packaging's resistant to opening by children. British Standard BS 6652. London, British Standards Institution, 1985.
6. The international pharmacopoeia, 3rd ed. Vol. 4. Tests, methods, and general requirements. Quality specifications for pharmaceutical substances, excipients, and dosage forms. Geneva, World Health Organization, 1994.
7. USP Subcommittee on Packaging, Storage, and Distribution. Survey on the practice of repackaging solid oral dosage forms in blister packs. Pharmacopeial Forum, 1996, 22(6):3265–3267.
8. WHA41.16. In: Handbook of resolutions and decisions of the World Health Assembly and the Executive Board, Volume III, 3rd ed. (1985–1992). Geneva, World Health Organization, 1993:89.

9. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirtieth report. Geneva, World Health Organization, 1987 (WHO Technical Report Series, No. 748).
10. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-fourth report. Geneva, World Health Organization, 1996 (WHO Technical Report Series, No. 863).

7.0 APPENDICES

APPENDIX I: CHANGES TO THE LABELLING

Any changes to the labelling, which are not connected with the Summary of Product Characteristics, shall be notified to the Authority where the authorization is granted. Therefore, if a Marketing Authorization Holder wishes either to introduce any label text additional to that in the decision or to change any aspect of the labelling he must first notify this change to the Authority, who shall inform the Marketing Authorization Holder whether the proposed change is accepted or not.

APPENDIX II: CONTROL OF LABELLING COMPLIANCE

The labelling of the medicinal product forms part of the authorization and it must, therefore, be approved by the Authority when the authorization is granted.

Prepared by	***Reviewed by***	***Approved by***
Head of DERD Dr Sheku S Mansaray	Head, Quality Assurance Dr Michael Lahai	Registrar Dr James P. Komeh