GUIDELINES ON LABELING AND PACKING OF PHARMACEUTICAL AND BIOLOGICAL DRUGS

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Drug Regulatory Authority of Pakistan
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1. HISTORY

This is the first edition of this document.

2. APPLICATION - Guideline for Marketing Authorization Holders

This guideline will be applicable to all registered drug products as per section 7 of Drug Act, 1976 and rules framed thereunder.

3. PURPOSE

The purpose of this guideline is to provide guidance on how to ensure that the information as required under Drug Labeling & Packing Rules 1976 shall be provided on the label on primary and secondary packaging.

This guideline is written to assist applicants and marketing authorization holders when drawing up the label for primary and secondary packaging.

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4. INTRODUCTION

This guideline is developed in line with Drugs (Labeling and Packing) Rules 1986. One of the most possible outcomes of inappropriate product label and package has been associated with prescription and medication errors which may occur partly due to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error prone labeling and packaging designs.

5. DEFINITION AND ACRONYMS

Applicant: The person or company who applies for registration/ marketing authorization of a new drug product or a variation to an existing registration/ marketing authorization.

Application: The information provided by the applicant for evidence-based review and decision as required under Drug (Labeling & Packing) Rules, 1986.

Authority: Drug Regulatory Authority of Pakistan (DRAP).

Drug: Drug as defined in Schedule-I of DRAP Act, 2012.

Act: DRAP Act 2012.

Finished Drug Product: A product that has undergone all stages of production, including packaging in its final container and labeling.

Label: Display of written, printed or graphic matter upon the immediate container or the outside container or wrapper of a drug package**.**

Labeling: All labels on the immediate container or the outside container or wrapper of a drug package**.**

Marketing Authorization Holder / Registration Holder: Any person or legal entity having Drug Manufacturing License (DML) or Drug Sale License (DSL) that has received marketing authorization/ registration to manufacture and/or distribute a medicine.

Pharmacopoeia: Publication as mentioned under Drug (Specification) Rules 1976.

Pharmacopoeial name: The name of a drug as mentioned in the pharmacopoeia.

International non-proprietary name: The name of drug as recommended by the World Health Organization or such other name as may be notified by the Federal Government in the official gazette

6. LABELING AND PACKING INFORMATION

The definition of label in the Act is interpreted to include labels on the immediate container or the outside container or wrapper of a drug package **which contains the information as approved for the purpose of registration of drug**.

6.1. Manner of Labeling:

The following particulars shall appear either in print or in writing in inedible ink in a conspicuous manner on a label of the innermost container of drug and also on the in which such container is packed namely:

(a) The registered name of the drug;

(b) If the registered name is a proprietary name, then immediately following the registered name, the international non-proprietary name, and if no such non-proprietary name is known the Pharmacopoeial name or any other name, if any, approved by the registration board for this purpose in conspicuous manner;

(c) The international non-proprietary name of the pharmacopoeial name of the generic name, and if no such name is known the chemical name of each active ingredient of a drug with weight.

(d) The name and principal place of business of the manufacturer

(e) The drug manufacturing license number.

(f) The drug registration number.

(g) The date of expiry.

(h) Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instructions;

(i) The distinctive batch number date of manufacture and the maximum retail price;

Provided that in the case of a drug packed in a strip of paper or blister or foil or contained in an ampoule of a capacity of not more than two milliliter or in an ampoule containing a sterile suture or ligature and such strip foil blister or ampoule is placed in other package and also in the case of printed collapsible tubes it shall be sufficient to give the information on the outer packing containing such strips, foils, blister or ampoule. Provided further that the Registration Board may allow relaxation of any of these conditions.

6.2. Labeling of Drugs for internal use:

The label of container of a drug meant for internal use, except a Drug contained in a strip or foil or blister or collapsible tube shall in additions to the particulars required to be given under rule 3, bear in a conspicuous manner.

(i) If it contains a substance specified in the schedule the words “to be sold on prescription of a registered medical practitioner only” and;

(ii) If it contains not less than three percent by volume and alcohol a statement giving the quantity of alcohol in terms of average percentage by volume of absolute alcohol in the finished product.

6.3. Labeling of parenteral drug:

- The route of administration (e.g., intravenous, subcutaneous);
- If no preservatives are present, wording such as “Single use. Discard unused portion”;

- If preservatives are present, wording such as “multiple use” as well as wording to explain duration, the conditions of use and the storage after first puncture of the multiple use product (e.g., “use within X hours of first puncture when stored at Y- ZEC”);and
- If dilution is required, the directions for performing the dilution.

6.4. Labeling of Drugs of external use only:

The label of a container of ointment, cream, liniment, lotion, antiseptic or any drug for external application shall in addition to the particular required to be given under rule 3, bear in a conspicuous manner :- (i) The words “For external use only “ and;

6.5. Labeling of physician’s sample:

The label of a container of every drug intended for distribution to the medical profession as free sample shall in addition to the particulars required to be given under these rules bear the words “Physician sample not for Sale” which shall be over printed or stamped. Provided that if the drug is packed in a strip of paper or blister or foil or contained in an ampoule of a capacity of not more than three milliliters or in a collapsible tube, it shall be to label the outer packing only with the said words.

6.6. Labeling of Drugs for Government supply:

The label of a container of every drug intended for the supply to any Government agency including an autonomous body or a semi-Government Agency shall. While complying with the other labeling requirements of these rules, bear the words or mark reading “Government supply” or such other words or mark as may be required by the agency concerned.

6.7. Labeling of Drugs for Veterinary use:

The label of a container of drug for veterinary use shall bear in a conspicuous manner the words “For veterinary use only”

6.8. Drugs in Pressurized Containers and Flammability:

Drug products packaged in a disposable metal container designed to release pressurized contents by the use of a manually operated valve must show the cautionary statements, hazard symbols, and signal words.

Drug products packaged in unpressurized containers operated by a manual pump spray device or any other containers that contain flammable ingredients should show a cautionary warning indicating flammable contents and appropriate directions for use (e.g., "Do not use near an open flame").

6.9. Labeling of Special Containers:

Drug products may be packaged in special containers that are too small to accommodate an inner label. This inner label may contain further abbreviated labeling, provided there is an outer label that meets all regulatory requirements. The two types of packages are:

- Multiple-dose packs, such as: blister packs, strips, push-through cards, ampoules, or vials attached by a plastic strip; and
- Single-dose packs, such as: sachets, pouch-type packs, individual dose vials of liquid or pre-packaged syringes.

6.10. Outer transparent wrapper not to require labeling:

The transport cover, wrapper, case, or other covering used solely for the purpose of packing, transport or delivery of a drug shall not require to be labeled.

6.11. Use of letters to indicate specifications:

The letters "P.P", "Ph.I", "Eur.P", "B.P", "B.P.C" and "U.S.N.F". shall be printed or written in indelible ink on the label to indicate so that the drug is manufactured in accordance with the specifications set out in the Pakistan Pharmacopoeia, international Pharmacopoeia, European Pharmacopoeia, United States Pharmacopoeia, British Pharmacopoeia, British Pharmaceuticals Codex or the United States National Formulary.

6.12. Packing of finished drugs:

Each finished drugs ready for use shall be packed in containers intended for retail sale to a hospital dispensary, clinic, or any other such institutions.

6.13. Labeling of Drugs manufactured for export:

The drugs which are registered for export purpose only shall are exempted from the operation of Drug (Labeling & Packing) Rules 1986and can be labeled as per requirements of the exporting country. However the label on the package or container of such drug shall bear the following particulars at a conspicuous place on the innermost container in which the container is packed namely:-

(i) The Name of the drug

(ii) The name and principle place of business of the manufacturer and ;

(iii) Batch number of the drug date of manufacture and the date of expiry.

Provided that in the case of a drug packed in strips of paper or foils or blister or contained in ampoules of a capacity of not more than two milliliters or in printed collapsible tubes, except for expiry date it shall be sufficient if these particulars are given on the outer packing containing such strips, foil, blister, ampoules or tubes.

7. SAFETY CONCERNS AND OTHER PUBLIC HEALTH CONCERNS IN BRAND NAMES

a) The brand name of a medicinal product should not be liable to cause confusion in print, handwriting or speech with the brand name of another medicinal product. When assessing the potential for such confusion, the following aspects are considered:

- The indication(s);
- The patient population(s);
- The pharmaceutical form(s);
- The route(s) of administration;

- The strength(s);
- The setting for prescription, dispensing and use;

b) The brand name of a medicinal product should not convey misleading therapeutic and/or pharmaceutical connotations. This also includes brand names that are similar or allude to the name of pharmaceutical companies if they are thought to be misleading and cause confusion at the level of product information.

c) The brand name of a medicinal product should not be misleading with respect to the composition of the product.

d) The use of qualifiers/abbreviations by letters as part of the brand name should in principle be acceptable on conditions. Qualifiers consisting of a single letter or number(s) are discouraged, because they may be confused with the strength and/or posology of the medicinal product.

e) The brand name should not convey a promotional message with respect to the therapeutic and/or pharmaceutical characteristics and/or the composition of the medicinal product.

f) The brand name should not convey or suggest a spiritual association or be comparative, nor superlative in any way.

g) The brand name should not comprise wholly of initial letters (acronyms) or code numbers nor include punctuation marks.

h) The importance of other elements such as labeling and pack design should be taken into consideration as contributing factors for the safe use of a medicinal product. These aspects should be discussed at the time of the review of mock-ups.

7.1. Safety Evaluation

Proposed proprietary name is evaluated for its potential to inadvertently function as a source of error for reasons that are unrelated to the orthographic and phonological similarity to other product names. These situations could occur, for example, when a proposed proprietary name for a multi-ingredient product represents only one of the active ingredients contained in the product; when names suggest a frequency or route of administration inconsistent with the actual product characteristics; or when names look

or sound like other medical terms or diagnostic tests or use a standard medical abbreviation in the name. Names with these characteristics may be potentially misleading and cause confusion at any point under the proposed prescribing conditions and lead to medication errors.

To fully assess the safety of proposed proprietary names, it is essential that product characteristics be considered in the overall risk assessment. Product characteristics can act together with the orthographic and phonologic attributes of the proposed proprietary name;

(1) to increase the risk of confusion when there is an overlap in product characteristics among two or more products, or

(2) in some instances, to decrease the risk of confusion by helping to differentiate products through dissimilarity.

Typical product characteristics that could lead to confusion with other products, including, but not limited to, the following:

- Established name of the product
- Proposed indication
- Dosage form
- Route of administration
- Strength
- Unit of measure dosage units
- Recommended dose
- Typical quantity or volume
- Frequency of administration
- Product packaging storage conditions
- Patient population
- Prescriber population

Product characteristics are used in the analysis of a proprietary name to anticipate the clinical setting(s) in which the product is likely to be used.

8. REFERENCES:

1. Drugs (Labeling and Packing) Rules. 1986.
2. WHO Guidelines on Packaging of Pharmaceutical Products (TRS 902 Annex9).

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