Guidelines for Mock-up Design of Human Pharmaceutical Products

Version 2.0

Date of Implementation	30/3/2022

Egyptian Drug Authority
Central Administration for Pharmaceutical Products
Administration of Human Pharmaceuticals Regulatory affairs (Hum-Reg-A)
Evaluation Unit of Trade Names and Mock-Up for Human Pharmaceuticals

Please visit EDA's website at
https://www.edaegypt.gov.eg/
For the latest update

For Inquiries *Hdr.naming@edaegypt.gov.eg*

Table of Contents

1. Introduction

1.1. Objective

EDA is issuing this Guidance to explain how Primary and secondary packaging for human medicinal products must be labeled and how it may be designed. These guidelines clarify the specific requirements that must be fulfilled so that requests of mock-up can be approved.

1.2. Scope

This guidance document is applicable to the labeling and design of packaging for human pharmaceutical products

1.3. Purpose

The purpose of reviewing the labeling of human pharmaceutical products is to ensure that the critical information necessary for the safe use of the medicine is legible, easily accessible and that users of medicines are assisted in assimilating this information so that confusion and error are minimized.
The applicants should ensure the following sections are taken into account prior to submission to Egyptian Drug Authority (EDA) as any deviations from this guidance need to be justified.

2. General Consideration

2.1 Submitting mock-ups

- Mock-ups should be in color.
- Where there is a range of pack sizes, only a representative mock-up of the smallest marketed pack size for each strength and dosage form need to be provided.
- There should be no adverse effect on the readability of the text on other pack size labels. The text should be the same on all pack sizes, with the sole exception of a statement regarding pack size/ number of units/ Price of pack or volume.
- In the case of additional product strength, a sample of the label of the existing strength(s) should also be submitted for comparative purposes.
- Label mock-ups are required for all immediate and outer packaging, including, for example, ampoule, vial and blister strip labels.
- Dimensions and color pantone would be useful.
- Omission of some information may be considered for imported products or small volume containers and should be justified.
- In case of presence of a language other than English and Arabic, certified translation may be requested.
- One year grace period is granted for implementation of mock-up change that not related to safety or quality of the product for example (design change, manufacturer name and license holder name)

2.2 Poor design of product labeling

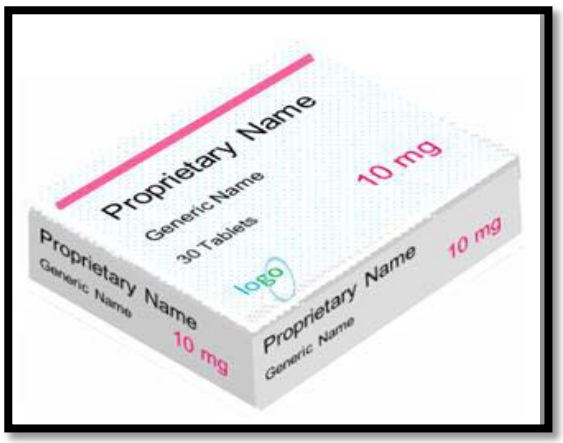
Poor label design contribute to medication error by making it difficult to locate and understand critical safety information so the following should be considered:

- Product name, strength and dosage form should be prominently located and displayed.
- Container label and carton labeling should not look similar across multiple strengths of the same products.
- Abbreviations or symbols should not be used as it will cause serious and fatal errors.
- A design of the label and package should not convey conflicting messages to the users.
- A dark print on a light background should be considered.
- Text should not be difficult to read because of font size or style, insufficient color contrast, or other design elements.
- Capitals and italic type are not recommended to be used.
- Companies should preferably create a container label and carton labeling design that is sufficiently distinct from that of their other products and the products of other companies.

2.3. Information should appear on the principle Display Panel (PDP)

The Principal Display Panel (PDP) is the panel of label that is most likely to be displayed, presented, or examined by the end user. The information below should be the most prominent information on the PDP:

- Trade name of product.
- Name and strength of each active ingredients (in case of products contain more than 3 active ingredients they can be expressed on the side)
- Dosage form and route of administration
- Content (Net weight or volume or number of contents of the container)
- Logo of the company.
- If the dosage form or the product is related to a special population (infant, children, adults, men, women), this should be mentioned.



2.4. Other information should appear on product labels

2.4.1. Outer label

- The active ingredients must be identical to the approved generics and must be typed in two sites:
  - A- Under the trade name: the active ingredients with their quantities (by a font less than 50% of the trade name)
  - B- on the side of the outer label: the active ingredients in their hydrate or salt form with their quantities and their equivalent amounts)
- Storage condition according to the approved stability study.
- Statement (Keep out of reach of children) should be mentioned.

- Special precautions for handling (if any, as shaking, dilution,) should be mentioned.
- Special warning according to the leaflet and the technical committee decisions must be mentioned by a color which differs from the color of the pack's data.
- A brief indication or a therapeutic class can be mentioned in a scientific and approved terms.
- Manufacturer and its address.
- The name, address, phone and Fax of the marketing Authorization Holder (MAH) or license holder should be mentioned.
- Registration number of Egyptian Drug Authority / year of registration should be mentioned, solvent registration number should be mentioned in case of a different one.
- The batch number should be mentioned on the outer pack.
- The manufacturing and expiry dates should be mentioned on the outer pack.
- The Approved price of the approved unit and whole pack must be mentioned.
- Other content of the pack should be mentioned on the outer label (if any, as measuring cup, applicator, dropper, syringe, calibrating dropper, others).
- Statement (For more information, see enclosed leaflet) or other equivalent statements must be mentioned.
- All previous data should be written in both English and Arabic on the outer label.

2.4.2. Inner Label

- Product name, strength and dosage form
- License Holder Name and / or Logo
- Manufacturing date
- Expiry date
- Batch number
- Warning / presence of some ingredients (e.g. Benzalkonium chloride) should be mentioned
- Special precautions for handling (if any, as shaking, dilution,) should be mentioned.
- Data should be mentioned in both English and Arabic language.

2.4.3. Blister strip labeling

Due to a range of factors, blister strips may be broken or cut into individual units. In these instances it is recommended that each dose is labeled with, at a minimum, the product name, the active ingredient name, the amount of active ingredient, batch number and expiry.

3. Special Considerations and recommendations

3.1. Type style and size

- Companies should maximize the readability of proprietary names and strength on the container label and carton labeling.
- EDA recommends capitalizing only the first letter of the proprietary name because words written in all capital letters are less legible than words written in mixed case letters.
- Choose a type style with adequate spacing between letters (to enhance legibility) and between words (to enhance readability)
- Using of italic type of font and all capital letters can reduce legibility and adversely affect readability
- Use a type size that can be read easily by a variety of users.
- The largest type size possible is recommended
- To enhance legibility when using small type sizes (on small containers) consider using a background color that is significantly different from the type color.
- The type of the proper or common name should be at a minimum half the size used for the trade name.

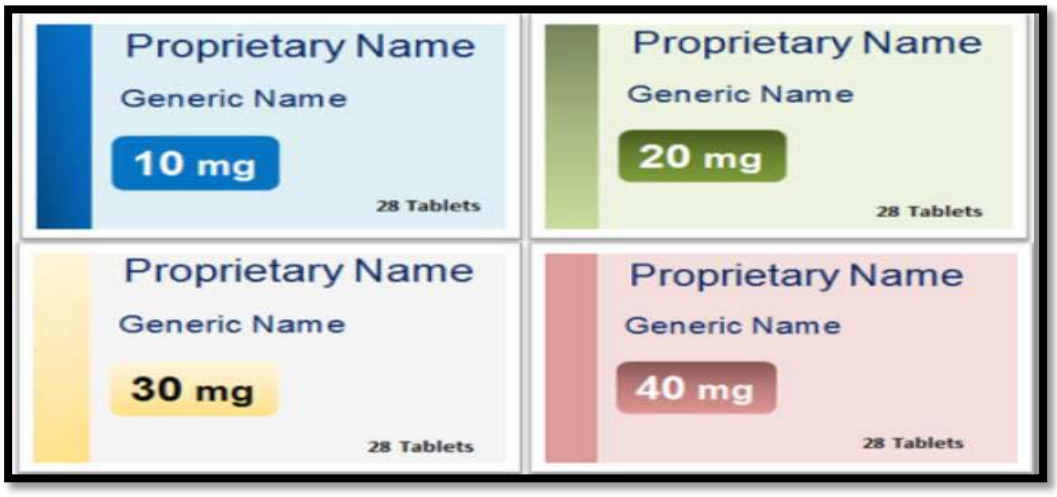
3.2. Proximity and computability of information on the principal display panel

- Consider how the various elements of the label are presented as a whole. In addition to grouping closely related information together on the principal display panel for example if the number of tablets in a package is presented in the same color as the product strength but has more prominent appearance (in bold type or larger type size) the number of tablets may be misinterpreted as the strength or dose .
- List the net quantity in the package separately from and less prominently than the products strength.
- When possible avoid placing unrelated information (include graphics) between the products name and its strength.

3.3. Color and Contrast

- The application of color is just one of many factors to be taken into account in the design of product label
- Use the color for the following purposes :
  - To draw attention to important label information such as name of a product and its strength.
  - To bring attention to or enhance the prominence of warning statements.

- To differentiate one product form another or to differentiate between strengths within a product line.



- Maximize the legibility of text by ensuring good contrast between text and background (e.g. Apply dark text on a pale background). Avoid the use of type and background color combinations that are known be very difficult to read (e.g. Black or yellow type on a red background)

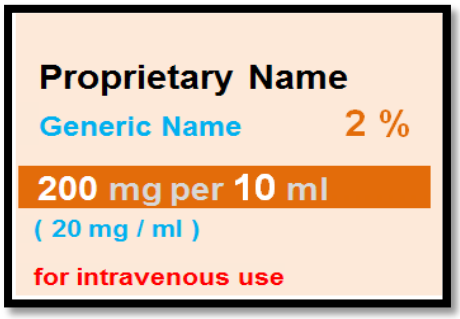
3.4. Use of abbreviations, symbols, Drawings and dose designation.

- The use of certain abbreviation (e.g. µ) and dose designations (e.g. 1.0) to convey health product-related information has been identified as underline cause of fatal errors.
  an abbreviation may have more than one meaning and may therefore be susceptible to misinterpretation
- Minimize Use of abbreviations, symbols and dose designation in product packaging and labeling
- Use international standards for abbreviations (e.g. abbreviate milliliter as ml)
- The proper or common names of products and medicinal ingredients of the products should not be abbreviated.
- Use of drawings or pictograms must comply with the leaflet and must not include any promotional information and should be unambiguous and the meaning should not be misleading or confusing.
- Drawings should be justified and must not go against the norms of good taste and decency.
- Ideally, illustrations of plant or fruit (for example for clarification of the taste) are not accepted. The indication of the taste, written in full, (for example strawberry taste) is sufficient for the correct identification of the medicinal product.

3.5. Expression of strength.

- For liquids intended for oral administration declare the quantity of each medicinal ingredient per ml or per usual volume to be taken e.g. 5ml. products that are intended to be used by different ages may be best labeled per ml.
- For small volume parenteral products declare the quantity of each medicinal ingredient per total volume e.g. 20mg /4ml.
- Avoid using percentage to express concentration or strength when usual dosing is based on weight or volume calculation of the amount to be administered.
- The following list presents examples of labeling practices that may introduce confusion because of the way in which the strength of products is expressed.
    - Presenting strength in more one form (e.g. as both concentrations and percentage)
    - Use different units for volumes (e.g. per ml , per cc)
    - Placing the drug strength and unit pack size in close proximity.
    - Use trailing zeros (e.g. 2.0 or 2.50) or naked decimal (e.g. .2)
    - Superimposing information on other information.

X



√

3.6. Critical Warning

Ideally, a critical warning should have the following features:

- It should appear on the principal display panel on both the outer and inner label.
- It should be located in an area where users will have to interact with in the course of using the product.
- Use wide space around a critical warning to help emphasize the information.
- Use color to bring attention to warnings and to differentiate warnings from other text.

3.7. Mobile scanning technology

The QR code may be added to the packaging to clarify certain information that must be compatible with the leaflet and to be under full control of EDA Authority.

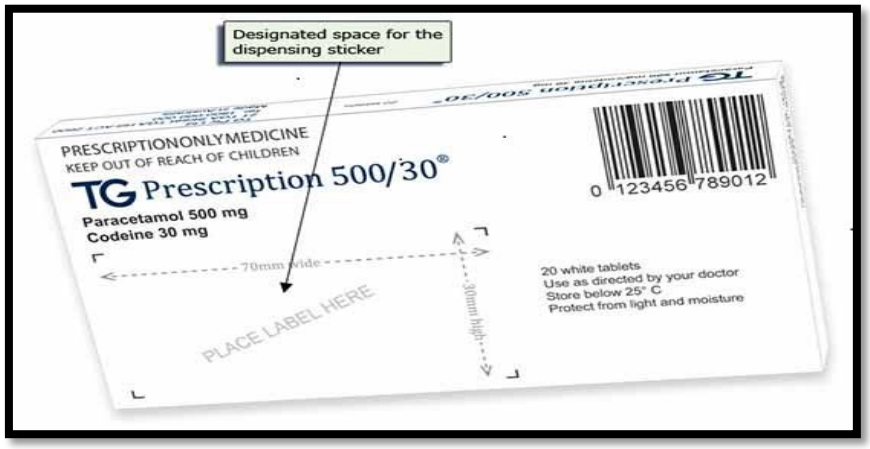
3.8. Recommendations

- Match the styles of primary and secondary packaging

A product's primary and secondary packaging should have an identical or linked visual style.

- Allocate white space for the dispensing label

Have a clearly designated white space for the dispensing label if possible. Label dimensions vary but a minimum of 70 x 35 mm is suggested, as this is the most common size for dispensing.
The white space should not interfere or cover the legibility of the critical information on either side.



- Information in Braille

  - The medicinal product´s name may be mentioned on the outer packaging in braille. It is acceptable to add dosage and pharmaceutical form only if multiple dosages and / or pharmaceutical forms of the medicinal products are available.

  - A declaration by an certified entity which show exactly what information appears on the carton should be submitted

6. References

1- FDA Draft Guidance, “Safety Considerations for Container Labels and Carton Labeling to Minimize Medication Errors”

2- Best practice guidance on the labeling and packaging of medicines (MHRA).

3- Guideline on the regulation of therapeutic products in New Zealand, Part 5:- Labeling of medicines and related products . Edition 1.6 2018

4- Guidance document packaging for human medicinal products HMV (Swiss medic).

5- HPRA Guide to labels and leaflets of human medicines.

6- Good label and package practices guide for prescription drugs June 21, 2019 (Canada).

7- Labeling of medicinal products – famhp (Belgium).