nhra BAHRAIN

الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Guideline for Labeling &Package leaflet Information

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Table of contents

Item	Page
1. Introduction	4
2. Scope	4
3. General consideration	4
4. Labelling	5
5. Leaflet	7

1. Introduction

Guideline documents are meant to provide assistance to industry and professionals on how to comply with regulations. Guideline documents also provide assistance to staff on how NHRA mandates and objectives should be implemented in a manner that is fair, consistent and effective.

All medicines must be licensed before marketing in Bahrain, part of licensing a medicine is approving the packaging information which provides a set of comprehensive information enabling the use of the medicine safely and appropriately. Medicine packaging information is represented in labelling and package leaflet.

2. Scope

This guidance document is applicable to the labelling and package leaflet for human medicines. The purpose of this document is to guide applicants on how to present the medicine information on labelling and package leaflet.

3. General consideration

3.1. Text

The used text must be clear and easy to read .The font type, size, color, contrast &spaces for the displayed information must be taken into consideration.

3.2. Language

English and Arabic languages are the acceptable languages in Bahrain. The quality and accuracy of translation must be reviewed by the applicant to assure the translated information is identical and correct.

3.3. Content

The information included on the labelling and package leaflet must be in accordance to the approved medicine information (summary of product characteristics).

3.4. Bar Code

Barcoding is an important tool for ensuring correct identification and selection of medicines and reducing medication errors, currently there is no specific requirement for medicines bar codes.

4. Labelling

The way the information presented on the labelling is designed to maximise the safe & effective use of the medicine. Labelling covers both outer packaging and inner packaging.

4.1. General notes for Labelling

- Labelling for Medicine which is available in different strengths must be designed in way to make it easy to differentiate between labels for different strengths & the information must be expressed in the same manner. However similarity which may contribute to medication error must be avoided.
- Some recommended labelling statements can be found in the GCC guidance for SPC, PIL &Labeling Information.
- Abbreviations in general are not recommended for medicine labelling. However abbreviations are used sometimes for small containers to describe the route of administration for example.
- Approved medicine labelling must hold any identification code, version or reference number based on each company policy.

4.2. Label content

- **The following information must be available on the outer label:**

A. Medicine Name (Trade name, Active ingredient & strength).
B. Statement of active substance
C. Pharmaceutical form &Pack size
D. Method &route of administration
E. Warnings & Precautions
F. Manufacturing and expiry date
G. Storage conditions
H. Batch number
I. Pharmaceutical Company name and address

- The inner label varies based on the dosage form, it can be very small or blister accordingly inner label evaluation is individual and based on the container and medicine type. Exemption from one or more of the below labelling requirement can be given case by case.

- **In general the following information must be included on the inner label :**

1. Medicine Trade Name
2. Active ingredient and strength
3. Contents by weight, by volume or by unit
4. Manufacturing and Expiry dates
5. Batch number
6. Pharmaceutical Company name
7. Storage conditions (**where applicable**)
8. Pharmaceutical form (**where applicable**)
9. Route of administration (**where applicable**)
10. Special warning /precautions /Statements (**where applicable**)

- The information presented on small packs will need careful consideration so the text is presented in a relatively large font size to reduce any possibilities of medication error.

- Example of special additional statements which must be mentioned on the outer or inner label for certain medicines are:

1. The labelling of injectable if no preservative is included wording such as Single use, discard unused portion must be included.
2. If dilution is required, the directions for performing the dilution.

4.3. Label changes

Any change to the approved label information must be prone to NHRA approval through variation applications.

5. Leaflet

Insert leaflet in all medicine packages is mandatory. Medicine leaflet provides essential information for safe & effective use of medicine and must be complying with the approved medicine information (summary of product characteristics/product information).

Where the medicine is available in different strengths or different pack size combined leaflet is accepted however if the different strengths have different indication separate leaflet is required.

5.1. Leaflet design

The leaflet design &content varies between Health authorities. The country of origin (reference country for registration) layout and design for the leaflet is accepted by NHRA & will be evaluated for each application.

Some leaflets are patient oriented leaflets and the information is simplified / reduced such leaflets are accepted specially for pharmacy only (OTC)medicines however if the medicine is for hospital use or must be administered by healthcare professional the leaflet information must be comprehensive to assure all the required information for administration is presented.

5.2. Leaflet for new medicine application

The latest up to date leaflet must be submitted with new medicine applications. Upon licensing a medicine the leaflet revision date is included in the medicine license and NHRA records.

5.3. Leaflet content

The information listed in the leaflet must reflect the approved summery of product characteristics/approved product information and includes the following:

A. **Full description of the Medicine** (Name, the active substance, excipients, the pharmaceutical form, strength & pack size).
B. **Approved indications.**
C. **Important information before using the medicine.**

D. **Dosage information including**: Instruction for proper use, route and method of administration, frequency of administration, duration of treatment, missed doses & overdose).
E. **Description of side effects.**
F. **Warning & precautions**
G. **Additional information**
H. **Storage information.**
I. **Revision date**
J. **Pharmaceutical company name and address.**