الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

# Guideline on the Braille Requirements for Labeling Information of Medicinal Products for Human Use

**Version 1.0**

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| Date of adoption | 01 June 2023 |
| Date of implementation | Refer to the implementation notice |

# Guideline on the Braille Requirements for Labeling Information of Medicinal Products for Human Use

**Version 1.0**

Saudi Food & Drug Authority

Drug Sector

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**Saudi Food and Drug Authority**

**Vision and Mission**

## Vision

To be a leading international science-based regulator to protect and promote public health

## Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

## Document Control

| Version | Adopted by | Date | Comments |
|---|---|---|---|
| Draft | Executive Directorate of Regulatory Affairs | 5 September 2022 | - |
| 1.0 | Executive Directorate of Regulatory Affairs | 01 June 2023 | Final version |

# Implementation Notice

For new medicinal products seeking marketing authorization, the final version of this document is effective after 3 years following the adoption date of the guideline.

After 5 years of publishing the final version of this document, the implementation is mandatory for all registered products.

Nevertheless, companies are encouraged to submit a variation application to implement the requirement of the guideline as soon as possible.

## Table of Contents

# 1. INTRODUCTION

## 1.1.Purpose

To ensure improved access to information on medicinal products for people with visual impairment, the Saudi Food and Drug Authority (SFDA) has introduced this guideline concerning the Braille requirements for labeling information.

## 1.2.Braille

Braille is the internationally widespread reading and writing system for blind and partially sighted people. The basic Braille symbol is called the Braille cell. Due to the reason that there are differences in Braille in different countries, the type of Braille letter (size of Braille cell) must be made easily readable to the target population.

## 1.3.Scope

This guidance interprets the requirements for Braille on the packaging of human medicinal products to be available in formats for blind and partially sighted people. The Braille requirement does not apply to the packaging of medicinal products solely for hospital use or administered only by health care professionals; for example, it is not required to put the name in Braille for vaccines.

## 1.4.Related guidelines

This document should be read in conjunction with the following guidelines:

- The GCC Guidance for Presenting the Labeling Information, Summary of Product Characteristics (SPC), and Patient Information Leaflet (PIL).
- Templates for Labelling Information, SPC and PIL.
- Guidance for Graphic Design of Medication Packaging.
- Data Requirements for Human Drugs Submission.
- Guidelines for Variation Requirements.

# 2. LABELING

## 2.1.Requirements for Medicinal Products

1. **Name of the medicinal product:**

   It should be expressed in a way that allows clear identification for blind people. The name, which may be either:

   - The invented name; or
   - The generic name or scientific name accompanied by a trademark or the name of the marketing authorization holder.

2. **Strength of medicinal product**:

   The name of the medicinal product followed by its strength should be put in Braille on the packaging of the product.

   **Note**: For medicinal products authorized only in a single strength, it is acceptable that only the name in Braille is put on the packaging.

## 2.2.Small Volume Packages

In the case of small volume packages (up to 10 mL) with limited space capacity, alternative means of providing Braille information may be considered e.g. use of abbreviations or addition of supplementary “tab” label. Particular consideration should be given to medicinal products likely to be used by a high visually impaired target population, e.g. certain eye drop preparations.

## 2.3.Braille printing position:

- The name in Braille must be printed on the outer/secondary packaging, which is normally a carton. In the case where there is no secondary packaging, e.g. large volume bottles (500 mL, 1000 mL, etc.), it is possible to fix an adhesive Braille label around the bottle during the manufacturing process.
- Concerning the location of the Braille on the outer packaging, there is no need to put the Braille dots on an empty space of the packaging, but the underlying printed text has to be easily legible.

- Braille may be extended over more than one face of the package, or oriented differently to the printed text. However, it is the applicant's responsibility to ensure that the readability of the Braille text is not compromised.

## 2.4.Braille printing language:

- The information in Braille must be printed in Arabic and, if possible, in English.
- Companies are encouraged to use the same information that appears in both languages.
- The readability of the multilingual packaging must not be compromised.

## 2.5.General considerations:

- The former requirements do not prevent companies to express further information on a voluntary basis, such as pharmaceutical form, target population, whether it is intended for babies, children or adults, and expiry date.
- An abbreviated pharmaceutical form should be avoided even if the preparation is only available in one form. Either the form should be omitted or the full form added, e.g. 'tablet' where the full pharmaceutical form is 'prolonged release tablet'.
- The name in Braille does not have to be printed on the immediate packaging, on a voluntary basis, companies can put the name in Braille on all packaging components.
- SFDA recommends that the applicants consider the quality of the embossing on the pack in order to ensure the readability of the Braille.

## 3. BRAILLE DECLARATION

A Braille Declaration Form must be provided, signed, and dated by applicants (see appendix 1). SFDA will assess that the wording to be provided in Braille is in line with the requirements of SFDA guidelines. The following approach will be implemented to ensure compliance with the requirements:

- The Braille declaration form must be provided by the applicant for all new applications, at renewal, and for variations.
- The Braille declaration form submitted must include in a text format an exact reflection of information that appears on the pack including units and backslashes.
- SFDA checks that the information provided in Braille on the pack is that which was stated in the Braille declaration, and it is the applicant's responsibility to ensure that the Braille embossing is correctly interpretable and comprehensible.
- In cases where Braille is not included, according to the abovementioned requirements, the justification for such an exclusion should be provided in the declaration form.
- Generally, one Braille declaration form should be provided per product application (although multiple strengths of the same product form, e.g., tablets, could all be listed separately on the same declaration).

### 3.1. Submission of Braille Declaration Form

The declaration form must be submitted at the time of application submission. Applicants should address in Module 1(section 1.3.2) of the application file the proposed implementation of the Braille requirements on the packaging of the medicinal product. In addition, the information that will appear in Braille on the printed outer packaging should be mentioned, if applicable, as normal text), and where applicable and feasible, should be indicated with dots on the mock-ups (Module 1 – section 1.3.4).

## Appendix 1: Braille Declaration Form

Marketing authorization holder's declaration of compliance with SFDA Guideline concerning Braille for Labeling of Medicinal Products for Human Use.

All sections must be completed. Please tick the box if applicable.

<table>
<tr><td colspan="2"><insert applicant company name> , hereby declare:</td></tr>
<tr><td colspan="2"><u>Section 1</u><br>☐ That <insert product name and application number> is in compliance with the requirements as interpreted in SFDA guideline on the Braille Requirements for Labeling of Medicinal Products for Human Use.<br>The following text appears in Braille on the labeling:<br><add, in non-Braille text, the text which appears in Braille><br>The applicant furthermore declares that the text which appears in Braille in Arabic and, if so, English is easily readable, clearly comprehensible and does not affect the legibility of the non-Braille labeling text, and that the Braille used is in a format suitable for blind and partially-sighted people.</td></tr>
<tr><td colspan="2"><u>Section 2</u><br>☐ That no Braille is required on the labeling for <insert product name and application number> as per 'SFDA guideline on the Braille Requirements for Labeling of Medicinal Products for Human Use' because the product is intended for administration by healthcare professionals only.</td></tr>
<tr><td>Signature of applicant:<br>Date:</td><td>E-mail address:</td></tr>
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