

**DRAFT FOR DEVELOPMENT**

# **Packaging – Braille and other formats for medicinal products**

ICS 11.020; 55.020

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It is being issued in the Draft for Development series of publications and is of a provisional nature. There is no published document that addresses the issues.

A review of this Draft for Development will be carried out not later than 2 years after its publication.

Notification of the start of the review period, with a request for the submission of comments from users of this Draft for Development, will be made in an announcement in the appropriate issue of *Update Standards*.

According to the replies received, the responsible BSI Committee will judge whether the Draft for Development can be converted into a British Standard or what other action should be taken.

Observations which it is felt should receive attention before the official call for comments will be welcomed.

These should be sent to the Secretary of BSI Technical Committee PKW/0 at British Standards House, 389 Chiswick High Road, London W4 4AL.

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## Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 18, an inside back cover and a back cover.

# Foreword

## Publishing information

This Draft for Development was published by BSI and came into effect on 31 July 2007. It was prepared by Technical Committee PKW/0, *Packaging*. A list of organizations represented on this committee can be obtained on request to its secretary.

## Information about this document

Council Directive 2004/27/EC [1] modifies the Community Legislation for medicinal products for human use (Council Directive 2001/83/EC [2]), and by incorporation into national legislation introduces the need to include on the outer packaging of authorized medicinal products their names in Braille as an aid to identification for blind and partially sighted people.

This document is primarily aimed at supporting the implementation of Braille on medicinal products in the European Union (EU) and European Economic Area (EEA) and in particular Part 1 of the associated European Commission Braille Implementation Guidance [3].

In addition to Braille on the labelling of the package, it supports the requirement to provide the package leaflet in formats for blind and partially sighted people.

## Presentational conventions

The provisions of this Draft for Development are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is “shall”.

*Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.*

## Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

**Compliance with a British Standard cannot confer immunity from legal obligations.**

# 1 Scope

This Draft for Development specifies requirements and provides guidance for the application of Braille to the labelling of medicinal products.

The provision of information on medicinal products in alternative formats, suitable for blind and partially-sighted people, is also addressed.

*NOTE 1 The labelling of medicinal products (and associated package information leaflet; see Annexes A and B) placed on the market and incorporating Braille in accordance with this Draft for Development meets the requirements of the UK implementation [4] [5], of the European Directive 2001/83/EC Article 56 (a) as amended by Directive 2004/27/EC [1].*

*NOTE 2 The general principles in this Draft for Development can be applied in other sectors, as appropriate.*

# 2 Terms and definitions

For the purposes of this Draft for Development, the following terms and definitions apply.

## 2.1 audit trail

systematic examination of processes and records to demonstrate compliance with requirements and applicable guidance

## 2.2 Braille

tactile reading and writing system composed of Braille cells

*NOTE Further information and recommendations on Braille and its characteristics can be found in Annex C.*

## 2.3 Braille cell

series of up to six raised dots set out in a domino-type cell

## 2.4 Braille character set(s)

representations for letters, numbers, symbols, punctuation and instructions to the Braille reader

*NOTE See Annex E.*

## 2.5 burst-through

cracking, breaking, pin-holing, etc. of the coating or material surface, visible to the naked eye, caused by the process of embossing Braille

## 2.6 contracted Braille grade 2 Braille

Braille which uses short forms of some commonly used words and contractions of commonly used letter combinations rather than full spelling of all words

## 2.7 job bag

bag containing documentation and samples, specifically for manufacturing particular tooling, die sets or a batch of product

**2.8 line clearance**

removal (line purge) of everything associated with the previous production run

[BS ISO 15378:2006, **3.28**]

**2.9 Marburg medium spacing convention**

defined system of dimensional controls within and between the Braille cells

*NOTE The Marburg medium spacing convention is the Braille recommended in the European Commission Guidance [3] as suitable for use for medicinal product labelling.*

**2.10 marketing authorization holder (MAH)**

organization responsible for placing the packaged medicinal product on the market

**2.11 package leaflet (PL)**

**patient information leaflet (PIL)**

text approved by a relevant competent authority for inclusion with the product

**2.12 quality assurance (QA)**

part of quality management focussed on providing confidence that quality requirements will be fulfilled

[BS EN ISO 9000:2005, **3.2.11**]

**2.13 quality control (QC)**

part of quality management focused on fulfilling quality requirements

[BS EN ISO 9000:2005, **3.2.10**]

**2.14 uncontracted Braille**

**grade 1 Braille**

Braille where normally one cell represents a single letter, number, symbol, punctuation mark or an instruction to the Braille reader (full spelling of words is used)

## **3 General requirements for medicinal product packaging**

**3.1 Braille spacing convention**

The MAH shall specify the Braille spacing convention to be used.

*NOTE 1 The Marburg medium spacing convention [6] is the Braille recommended in the European Commission Guidance [3] as suitable for use for medicinal product labelling.*

*NOTE 2 Annex D contains suggested critical control points to be considered when incorporating Braille onto pharmaceutical packaging.*

### 3.2 Braille character sets

The MAH shall identify the Braille character set appropriate to the market in which the product is to be supplied and specify its use for that market.

*NOTE See Annex E for recommendations regarding Braille character sets.*

### 3.3 Braille dot height

In order to ensure that the name of the medicinal product can be identified by the Braille reader, the minimum dot height shall be as follows.

- a) For embossed materials the minimum dot height shall be no less than 0.12 mm in accordance with **F.1**.
- b) For other Braille production methods the minimum dot height shall be no less than 0.20 mm in accordance with **F.1**.

*NOTE 1 The minimum dot height for embossing Braille on medicinal product cartons has been derived from samples produced by several carton manufacturers in Europe since 1996. Some of these samples have been tested at different times by organizations representing blind and partially sighted people and deemed to be acceptable.*

*More recently, doubts have been expressed on the acceptability of this minimum height by some organizations representing blind and partially sighted people with a request for a higher Braille dot height.*

*Research protocols have been derived to determine the minimum Braille dot height necessary for product identification. When further validated information is available, this Draft for Development will be revised, if necessary.*

*Comments on the acceptability of the minimum Braille dot height are particularly sought.*

*NOTE 2 Burst-through occurs when the substrate or any surface coating fractures causing damage to print and/or surface finish. Burst-through is not recommended, but might be accepted in or required by certain markets.*

*NOTE 3 There are physical limitations in the Braille dot height that is achievable when manufacturing embossed cartons and applying Braille to labels.*

## 4 Product identification and legibility of labelling

### 4.1 Product identification

The approved Braille text on the labelling shall include the information required in the country in which the product is to be supplied, for example:

- a) trade mark or generic name of the product, as appropriate;
- b) the strength of the product (where more than one is available);
- c) the dosage form of the product, e.g. tablet, capsule, solution, where more than one dosage form is available.

*NOTE It might be necessary to include Braille text on more than one carton panel in order to accommodate the legally required information.*

### 4.2 Braille text legibility

The Braille text shall enable Braille readers to identify the medicinal product. If the MAH does not specify compliance with the Braille dot requirements (**3.3**) legibility testing shall be carried out in accordance with **F.2**.

*NOTE Compliance with the Braille dot height requirement (3.3) is evidence of compliance with this requirement.*

### 4.3 Printed text legibility

The placement of Braille text shall not reduce the legibility of printed text for sighted people.