SLOVENSKI STANDARD
SIST EN 15823:2010

01-november-2010

Embalaža - Braillova pisava na embalaži za zdravila

Packaging - Braille on packaging for medicinal products

Verpackung - Blindenschrift auf Arzneimittel-Verpackungen

Emballage - Csur les emballages destinés aux médicaments

Ta slovenski standard je istoveten z: **EN 15823:2010**

ICS:

11.180.30	Pripomočki in prilagoditve za branje	Aids and adaptations for reading
55.020	Pakiranje in distribucija blaga na splošno	Packaging and distribution of goods in general

SIST EN 15823:2010 **en,fr,de**

EUROPEAN STANDARD

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EUROPÄISCHE NORM

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English Version

Packaging - Braille on packaging for medicinal products

Emballage - Braille sur les emballages destinés aux médicaments

Verpackung - Blindenschrift auf Arzneimittelverpackungen

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Contents

Page

Foreword

This document (EN 15823:2010) has been prepared by Technical Committee CEN/TC 261 “Packaging”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2010, and conflicting national standards shall be withdrawn at the latest by December 2010.

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Introduction

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

This European Standard 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, Chapter 2 of the associated European Commission Braille Implementation Guidelines [3].

1 Scope

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

NOTE 1 The labelling of medicinal products placed on the market and incorporating Braille in accordance with this European Standard meets the requirements of European Directive 2001/83/EC, Article 56, (a) as amended by Directive 2004/27/EC [1].

NOTE 2 The principles in this European Standard can be applied in other sectors, as appropriate.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
Braille
tactile reading and writing system composed of Braille cells

2.2
Braille cell
series of up to six raised dots set out in a domino-type cell

2.3
burst-through
cracking, breaking, pin-holing of the coating or material surface, visible to the naked eye, caused by the process of embossing Braille

2.4
labelling
information on the immediate or outer packaging

2.5
Marburg Medium spacing convention
defined system of dimensions within and between the Braille cells

NOTE The Marburg Medium spacing convention for Braille [4] is recommended in the European Commission Guidance [3] for use for medicinal product labelling.

2.6
marketing authorization holder
MAH
natural or legal person or entity responsible for placing the medicinal product on the market

3 General requirements for medicinal product packaging

3.1 Product identification

3.1.1 Information in Braille

The approved Braille text on the labelling shall include the information as required in the country in which the product is to be supplied.

NOTE 1 Guidance on the information to be labelled in Braille is given in the European Commission Guidance [3].

NOTE 2 It might be necessary to include Braille text on more than one panel in order to accommodate the legally required information ensuring that Braille cell dots do not compromise any printed text.

3.1.2 Braille text placement

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

NOTE 1 This is indicated when, for example, the application of Braille corrupts printed text and graphics.

NOTE 2 The MAH is encouraged to place the Braille away from printed text and graphics, where possible.

3.2 Braille spacing convention

The MAH shall specify the Braille spacing convention to be used. The use of Marburg Medium spacing convention is highly recommended unless there is a specific national requirement.

3.3 Braille character sets

The MAH shall identify and specify the Braille character set appropriate to the market in which the product is to be supplied, see Annex E.

4 Determination of Braille legibility

4.1 Principles of Braille legibility compliance

The Braille text shall enable Braille readers to identify the medicinal product.

Compliance with the Braille cell dot height limits (see 4.2) is evidence of compliance with the text legibility requirement.

If the MAH does not specify compliance with the Braille cell dot height requirements (see 4.2 and A.1) then legibility testing shall be carried out in accordance with A.2.

4.2 Braille cell dot height

In order to ensure that Braille readers can identify the name of the medicinal product, the Braille cell dot height of production samples when measured in accordance with A.1 at the packaging (e.g. carton or label) manufacturer's site shall be:

a) for embossed materials the target Braille cell dot height shall be 0,20 mm with not more than 5 % of Braille cell dot height measurements lower than 0,12 mm and not more than 1 % of Braille cell dot height measurements lower than 0,10 mm;

b) for other Braille production methods, e.g. screen-printed labels, the target Braille cell dot height shall be 0,20 mm, with not more than 5 % of Braille cell dot height measurements lower than 0,16 mm.

NOTE 1 The MAH and packaging manufacturer are encouraged to aim for a higher cell dot height in line with the packaging manufacturer's processes. Cardboard is not an engineering material and considerations relating to Braille cell dot formation contained within Annex C should be taken into account in order to achieve Braille cell dot height requirements.

NOTE 2 Burst-through can occur 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 by certain markets, however the presence of burst-through should not in itself constitute a valid reason for batch rejection.

NOTE 3 Braille dots should not compromise any printed text whether the dots are intact or are formed with a burst-through.

NOTE 4 The Braille cell dot height limits included above reflect technical issues associated with the production of pharmaceutical packaging – they do not necessarily represent a Braille cell dot height that can be achieved with other media.

4.3 Altered Braille labelling

Braille shall not be obscured by labels or any other adhesive devices, with only one exception: where Braille needs to be altered, the new Braille text should cause the original Braille text to be totally obscured.

Annex A
(normative)

Methods of verification

A.1 Braille cell dot height measurement

The number of samples and the method of measurement shall be agreed between the customer and supplier. The Braille cell dot height shall be measured along the Braille text in at least three places.

The Braille cell dot height can be measured using a calibrated, spring-loaded (spring-force not less than 0,5 N) micrometer with an anvil that covers at least three Braille dots in a cell, see [5]. Measurement of the Braille cell dot height shall use cells containing at least three dots. Alternative methods may be used provided that they are of at least equivalent precision and accuracy.

Measurements can be performed with two decimal places and results shall be reported to two decimal places.

NOTE It is recommended that random checks are carried out across all stations, see C.5.2. Checks should also be made to ensure the readability of underlying printed text.

A.2 Product identification by Braille legibility testing

It is not necessary to undertake legibility testing for each batch provided that the Braille specification applied has been adequately validated.

If the Braille cell dot height requirement (see 4.2) cannot be verified then samples can be tested for Braille legibility by organisations representing blind and partially sighted people or other suitable organisations.

NOTE Testing should be carried out on an agreed protocol taking into account the following factors:

a) The qualification and number of the blind Braille readers used in the test;

b) Separate testing of embossed cartons and labels if it is necessary to test the two types of packaging;

c) Establishing the minimum Braille cell dot height that results in product identification.

Annex B
(informative)

Braille characteristics and recommendations

B.1 Braille character sets

Braille character sets consist of letters, numbers, punctuation, symbols and special characters. Some parts of character sets are common between countries whereas other parts differ, e.g. Latin versus other alphabets and accented letters.

In the artwork creation process, the Braille character set to be used should be verified as appropriate for the country in which the medicinal product is to be supplied. The MAH and packaging supplier should check all Braille artwork for current accuracy and relevance.

If multi-market, multilingual packs are being produced with Braille text, the correct character sets should be included and clearly identified in the artwork.

Capitalization should be avoided other than where required for trademark purposes. Trademark symbols, e.g. ® ™, should be omitted unless required for legal purposes.

B.2 The Braille cell

Each Braille cell consists of up to six predefined dots (see Figure B.1), set out in two columns of three.

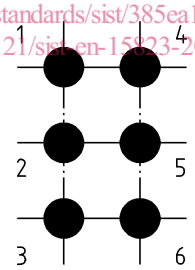

Figure B.1 — The Braille cell

The pattern of dots for a given character is defined in the national character set.

For Braille text visualisation, it is recommended that the dot positions that are raised in the Braille text are indicated by larger filled circles and the positions that are not used are shown as smaller dots.