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Packaging — Braille on packaging for medicinal products

Emballage — Braille sur les emballages destinés aux médicaments

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Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Terms and definitions ... **1**

3 General requirements for medicinal product packaging ... **1**
3.1 Product identification ... 1
3.2 Braille spacing convention ... 2
3.3 Braille character sets ... 2

4 Determination of Braille legibility ... **2**
4.1 Principles of Braille legibility compliance ... 2
4.2 Braille cell dot height ... 2
4.3 Altered Braille labelling ... 3

Annex A (normative) **Methods of verification** ... **4**

Annex B (informative) **Braille characteristics and recommendations** ... **5**

Annex C (informative) **Technology for the application of Braille to packaging for medicinal products** ... **7**

Annex D (informative) **Guidance on Braille specifications and artwork generation** ... **10**

Annex E (informative) **Braille character sets** ... **12**

Bibliography ... **13**

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 17351 was prepared by Technical Committee ISO/TC 122, *Packaging*.

Introduction

This International Standard has been developed to meet various national and regional requirements for Braille on packaging for medicinal products, and technical constraints and user requirements, to harmonize technical standardization and specifications. The knowledge and experience that has been gained in EN 15823:2010 was used for the development of this International Standard.

The background for the creation of an European Standard for Braille on packaging for medicinal products (EN 15823) was a European Directive issued in 2004 by the European Commission (Council Directive 2004/27/EC). This Directive requires Braille labelling on outer packaging for medicinal products within the European Union. In practice it means that basically the name of the medicinal product and, where required, the form and strength has to be in Braille as an aid to identification for blind and partially sighted people.

Braille will continue to be an essential means of communication for blind and visually impaired people around the world. Once other accessible packaging technologies emerge additional standards may be created to complement this International Standard.

Packaging — Braille on packaging for medicinal products

1 Scope

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

NOTE The principles in this International 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 1 to entry: The Marburg Medium spacing convention for Braille [4] is recommended in the European Commission Guidance [3] for use for medicinal product labelling and is explained in B.3.

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 in Braille as required in the country in which the product is to be supplied.

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

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 (see also Annex D).

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 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 can 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 Reference[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 be 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 organizations representing blind and partially sighted people or other suitable organizations.

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.

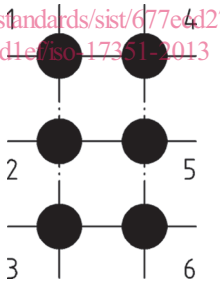
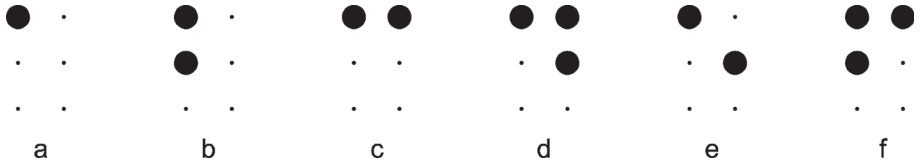


Figure B.1 — The Braille cell

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

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



NOTE The large black dots represent the position at which a raised dot will appear in the text. The small black dots indicate that no raised dots will appear in this position. (Some information sources may use other conventions.)

Figure B.2 — Braille text visualization of characters “a” to “f”