BS EN ISO 17351:2014

BSI Standards Publication

Packaging — Braille on packaging for medicinal products (ISO 17351:2013)

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National foreword

This British Standard is the UK implementation of EN ISO 17351:2014. It is identical to ISO 17351:2013. It supersedes BS EN 15823:2010 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee PKW/0/-/5, Packaging - Product Identification (Braille).

A list of organizations represented on this committee can be obtained on request to its secretary.

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

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

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Packaging - Braille on packaging for medicinal products (ISO 17351:2013)

Emballage - Braille sur les emballages destinés aux médicaments (ISO 17351:2013)

Verpackung - Blindenschrift auf Arzneimittelverpackungen (ISO 17351:2013)

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Foreword

The text of ISO 17351:2013 has been prepared by Technical Committee ISO/TC 122 “Packaging” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 17351:2014 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of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.

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

This document supersedes EN 15823:2010.

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Endorsement notice

The text of ISO 17351:2013 has been approved by CEN as EN ISO 17351:2014 without any modification.

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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.

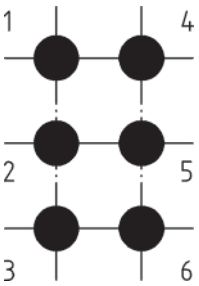
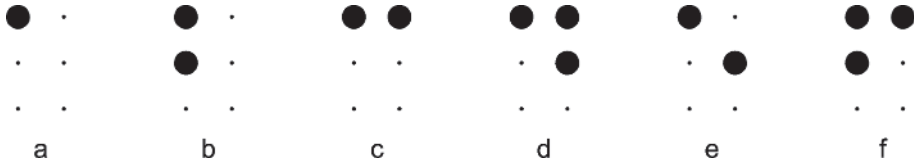


Figure B.1 — The Braille cell

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.

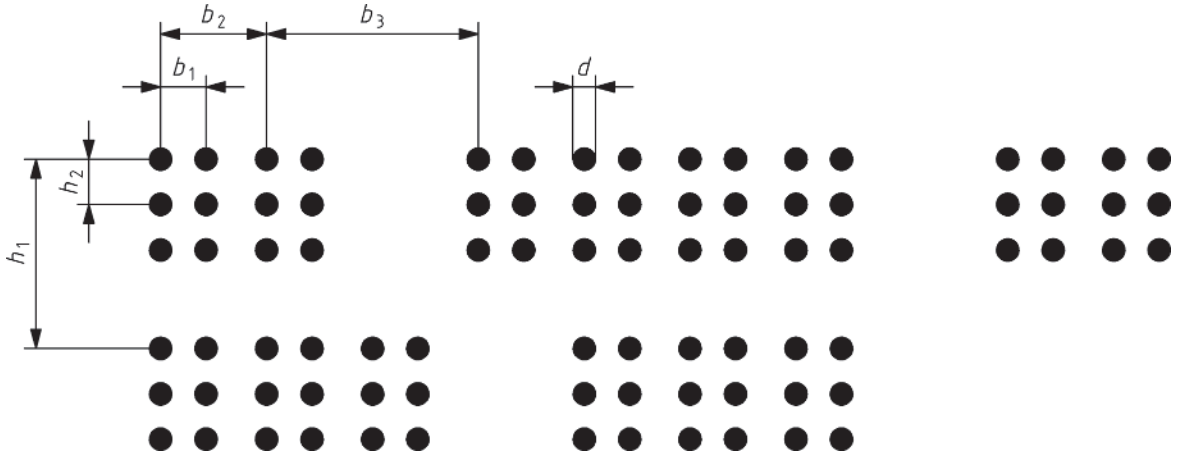


NOTE The large black dots represent the position at which a raised dot will appear in the text. The small black dots indicate that no raised dots will appear in this position. (Some information sources may use other conventions.)

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

B.3 Marburg Medium spacing convention for Braille

The Marburg Medium spacing convention and dimensions for Braille on the female matrix and on the artwork film/artwork file are illustrated in Figure B.3.



Key

Tolerances	± 0,1 mm
b_1	= 2,5 mm horizontal distance between dot centres
b_2	= 6,0 mm between two letters of one word
b_3	= 12,0 mm word spacing
d	= 1,6 mm diameter
h_1	= 10,0 mm line spacing
h_2	= 2,5 mm vertical distance between two dot centres

Figure B.3 — Marburg Medium spacing convention and dimensions for Braille

Given the properties of the substrate and the nature of the production process, it is possible that these dimensional tolerances will not be achieved in the production of the packaging component (for example line-spacing for tractor-fed labels where the upper limit for line-spacing may be exceeded).

Annex C
(informative)

Technology for the application of Braille to packaging for medicinal products

C.1 General

Different technologies can be used to apply Braille text to the packaging used for medicinal products.

These include, but are not limited to:

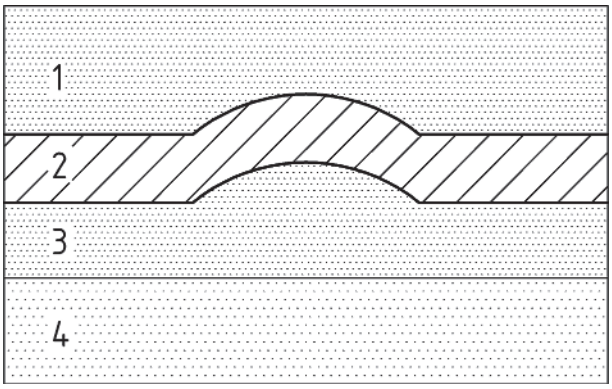
a) embossing;

b) screen-printing;

c) inkjet.

C.2 Embossing

Embossing involves the use of a male die and a female die. The substrate for the carton or label is placed between the two dies and force is applied to create the Braille text; see Figure C.1.



Key
1 female die
2 substrate
3 male die
4 support for male die

Figure C.1 — Principle of embossing

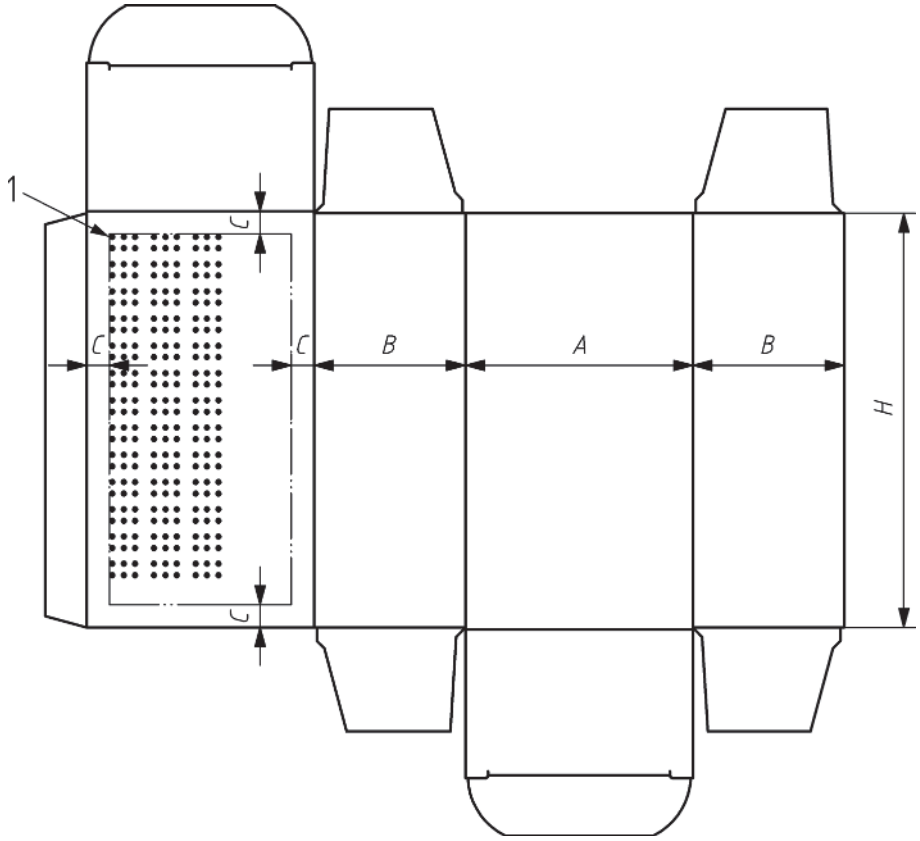
During the production process it is common and economical to use tooling which both embosses the Braille and cuts/creases the substrate for the pack. This is single pass Braille. It is also possible to apply the Braille and cut/crease the substrate in separate operations using separate cut/crease and Braille tooling (two pass Braille).

The Braille male dies are always product-specific; the female dies may be dedicated to a specific product or for universal application, as this is more flexible and economical.

It is necessary for the MAH and the packaging supplier to agree the Braille text to be applied, and its placement on the packaging material.

The positioning of the Braille needs to be defined in relation to the edges of the panel on which the information will appear. It is important to clearly establish the "Braille register point"; see Figure C.2.

NOTE It is necessary to leave sufficient space between the cutting and creasing lines and the Braille register point to avoid damage to the dies and to the Braille text. Typically this is between 5 mm and 10 mm.



Key

1 example of a Braille register point
A length
B width
H height
C distance is normally 8 mm but may vary between 5 mm and 10 mm

Figure C.2 — Example of Braille positioning on a carton

Braille text is read from left to right and can be oriented in portrait or landscape mode.

C.3 Screen-printing

The incorporation of Braille using screen-printing is a well-established process. This process can be used on different substrates, e.g. paper, carton board and polymers.

The integration of Braille dots onto packaging components is normally treated as a "colour" and printed using screen technology. The dots are usually transparent. The applied dots should not affect the legibility of the graphics and text underneath.

C.4 Other production methods

C.4.1 General

Other production methods, e.g. inkjet, may be developed and should meet the appropriate requirements for Braille cell dot height and quality (see 4.2).

C.4.2 Containers with integral Braille

Braille can be incorporated onto various containers. These can be produced by a variety of processes and should meet the specification for Braille cell dot height and quality (see 4.2).

Care should be taken not to position the Braille on complex curved surfaces, e.g. shoulder of a cylinder, as this might affect readability (see 4.1). It is advisable during the development process to consult organizations representing blind and partially sighted people or other suitable organizations to confirm that the integral Braille is legible (see A.2).

It is recommended that, where possible, the Braille be positioned to read along the long axis.

C.4.3 Containers with adhesive labels

Braille can be incorporated onto adhesive labels which are subsequently applied to packaging during the manufacture of the medicinal product. These can be produced by a variety of processes and should meet the specification for Braille cell dot height and quality (see 4.2).

It is recommended that, where possible, the Braille be positioned to read along the long axis.

It is recommended that the Braille not be placed on the closure of a container.

C.5 Packaging supplier controls

C.5.1 Identification of Braille tooling

All Braille tooling components should be identified uniquely to enable correct usage. Their permanent identification (e.g. engravement, bar-code or 2D matrix-code) is strongly recommended.

C.5.2 In-process controls

Braille quality and content should be checked as agreed between the customer and supplier (see A.1) and following any change/repair to the tooling.

Records and samples should be retained by the packaging supplier.

C.6 MAH incoming control checks

The MAH should ensure the quality of materials incorporating Braille is maintained. The criteria that could be applied include:

a) accuracy of the Braille translation and application, i.e. conformance to specification and artwork requirements;

b) the position/location of the Braille on the pack/label (see 3.1.2 and Figure C.2);

c) ensuring that all printed text remains legible for sighted people (see 3.1.2);

d) the quality of the Braille text should be to specification (see 4.2 and Annex A).

The frequency of checking these factors can be adjusted in accordance with the experience with the supplier(s) concerned.

Annex D
(informative)

Guidance on Braille specifications and artwork generation

It is important that the print artwork and the Braille content be clearly communicated on the packaging artwork. This needs to be agreed between the MAH (or their contractor) and the packaging supplier. Once approved the artwork should not be amended unless agreed by all parties. Formats for submission of artwork containing Braille can vary in each regulatory authority.

There might be several layers of artwork to define the packaging (e.g. text and graphics, Braille, die-line, varnish, anti-counterfeiting measures). For clarity and verification, the colour used to represent the Braille text should not be used in any other place in the artwork.

The approval of the proof should confirm the Braille characters are correct. A translation of the Braille text may be reproduced outside the die-line for quality assurance purposes; see Figure D.1.

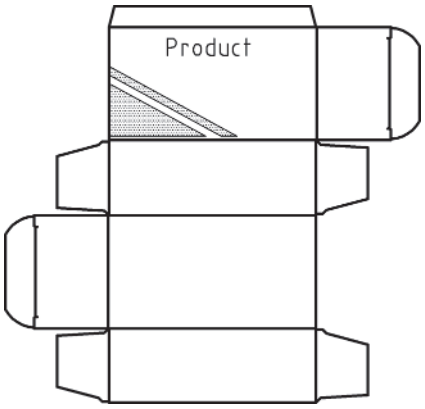
It is recommended that digital approved artwork for Braille packaging be established with separate layers, in particular for separating the Braille text from the printed graphics and text.

It is recommended that a printed hardcopy for Braille packaging be established with separate pages, in particular for separating the Braille text from the printed graphics and text.

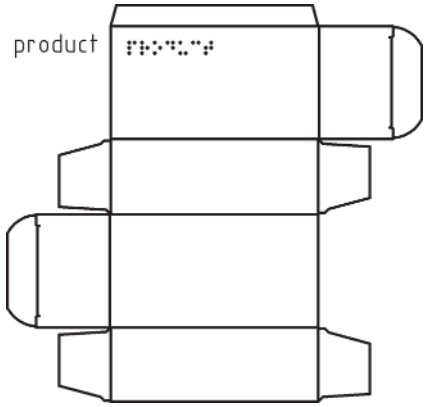
For printed paper proofs, it is recommended that the approved artwork proof be set up as follows:

— on the first page all texts, graphic elements and die-line except for the Braille text should be presented;

— on the second page only the Braille text and the die-line should be presented; see Figure D.1.



a) Page 1



b) Page 2

Figure D.1 — Approved artwork proof

Consideration should be given to potential conflicts between the placement of Braille text and ensuring legibility of printed text; see 3.1.2 and 4.1.

Annex E
(informative)

Braille character sets

Braille character sets consist of representations for letters, numbers, symbols, punctuation instructions and instructions to the Braille reader.

There is general agreement on certain Braille characters, particularly the main Latin alphabet. Examples of Braille symbols for letters that are in common use are given in Figure E.1, but there are certain national deviations from this character set.

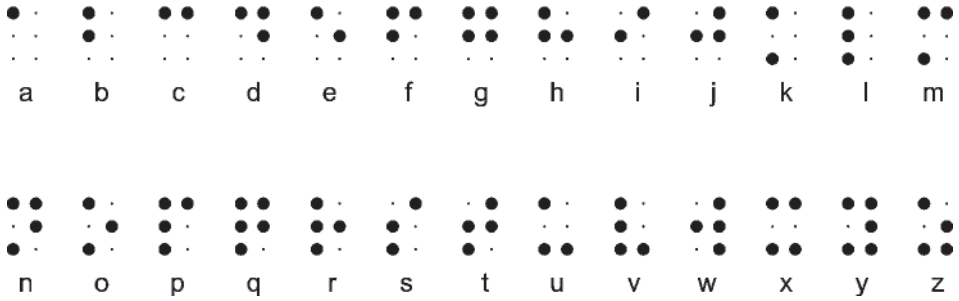


Figure E.1 — Example of Braille transposition of letters in common use

CAUTION — Do not copy; not to scale.

There is not unanimity concerning the Braille symbols for numbers and accented letters and special characters including "/", "%". The character set used for a particular market should be in compliance with local requirements. Information on national character sets is available from http://www.pharmabraille.com (subscription access). The European Blind Union (EBU) is attempting to harmonize Braille alphabets, special characters, symbols and abbreviations.

Bibliography

[1] Directive 2004/27/EC of the European Parliament and the Council on the Community code relating to medicinal products for human use [viewed 2012-08-22]. Available from http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0034:0057:EN:PDF

[2] Directive 2001/83/EC on the Community code relating to medicinal products for human use, amended by Directive 2004/27/EC of the European Parliament and of the Council [viewed 2012-08-22]. Available from http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:EN:PDF

[3] Guideline on the readability of the labelling and package leaflet of medicinal products for human use [viewed 2012-08-22]. Available from http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf

[4] Marburg Medium spacing convention for Braille [viewed 2012-08-22]. Available from http://www.blista.de/download/druckerei/braille-dimensions.pdf

[5] Braille dot height research: Investigation of Braille dot elevation on pharmaceutical products [viewed 2012-08-22]. ISBN: 0704426919/9780704426917. Available from http://www.birmingham.ac.uk/Documents/college-social-sciences/education/victar/braille-dot-height.pdf

Further information

Further information can be obtained from the sources given below. This list is not exhaustive and the information available given should not necessarily be treated as authoritative. Any proposed action taken using such information should be checked against local regulatory requirements.

Association Valentin Haüy. http://www.avh.asso.fr

Braille Authority of the United Kingdom: http://www.bauk.org.uk

UK Association for Accessible Formats (incorporating the former Braille Authority of the United Kingdom): http://www.ukaaf.org/

Deutsche Blindenstudienanstalt V. (blista), Marburg: http://www.blista.de

European Blind Union (EBU) Pharmaceutical Braille code website: http://www.pharmabraille.com

European Blind Union (EBU). http://www.euroblind.org/working-areas/access-to-information/nr/17

Institut National des Jeunes Aveugles. http://www.inja.fr

Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk/index.htm

Organización Nacional de Ciegos Españoles (ONCE). http://www.once.es

Royal National Institute of Blind People. http://www.rnib.org.uk/ and http://www.rnib.org.uk/professionals/solutionsforbusiness/pharmaceutical/Pages/pharmaceutical.aspx

Tiresias: http://www.tiresias.org

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