

Braille is used on pharmaceutical packaging and patient information to meet the needs of blind and partially sighted people, however, legislation has proved to be a minefield. Tony Harper, chairman of the BSI Braille Panel, provides an in-depth look at the problems encountered by the industry and some likely solutions.

TOUCH TO COMMUNICATE



Author

Tony Harper has over 25 years' experience in quality control and quality assurance in the pharmaceutical industry. He was instrumental in setting up the Pharmaceutical Quality Group and was its first chairman, continuing in this role for 15 years. As a trustee and member of the council of the Chartered Quality Institute, Harper plays an active role in institute affairs and is a

member of various national and international standards committees. He is also a member of the Institute of Packaging and actively participates in the Pharmaceutical Packaging Forum and its sub-group on pharmaceutical origination/artwork, and is chairing the project team to write pharmaceutical origination guidelines. For more information, email tonyharper@aol.com.

Blind and partially sighted people have difficulty in identifying their medicines and reading the information provided with medicinal products. While the number of people affected is relatively small (1–2% of the population) and only a small percentage of these can read Braille, the consequences of incorrect product identification and lack of patient information can be serious.

To meet the needs of blind and partially sighted people and enable them to identify their medicines. European legislation was introduced requiring Braille to be added to the packaging of medicinal products. This was included as one of a number of amendments to directives relating to medicinal products for human use, with the amended Directive 2001/83/EC coming into effect in October 2005. In accordance with amended Article 56a, the name of the product in Braille must appear on the packaging, and patient information must be supplied in formats suitable for blind and partially sighted people, as agreed with patients' representative organisations.

European standardisation

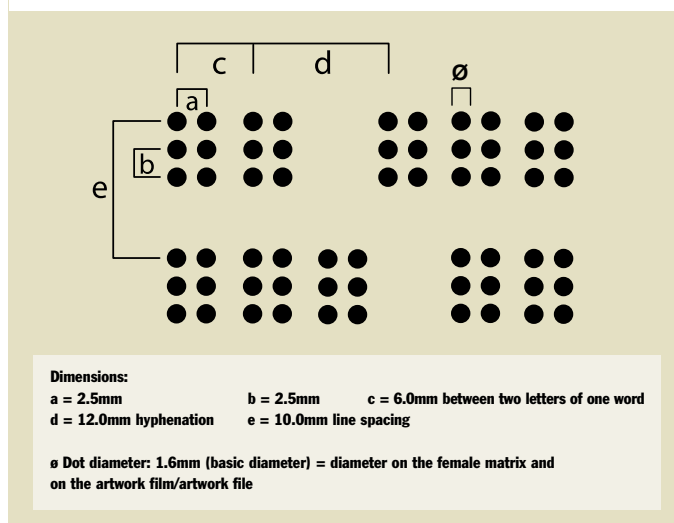
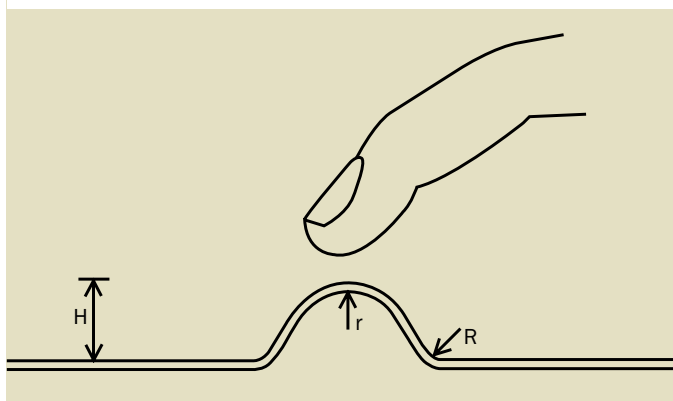
Early in 2005, it became apparent that there was little knowledge of these requirements by various stakeholders and how these should best be implemented. In the UK, discussions were held involving the Association of the British Pharmaceutical Industry and the Proprietary Association of Great Britain, the Medicines and Healthcare products Regulatory Agency and the Royal National Institute for the Blind. As a result of these discussions, it was agreed that a European standard needed to be developed and work has already begun. The key elements are the Braille character sets and the height of the Braille dots on pharmaceutical packaging. Without standardisation there is confusion and the potential for patient injury.

Following the initial discussions with the trade associations, conferences and seminars were held to share the knowledge that was developing across Europe. At the UK and European Committee for Standardisation (CEN) meetings, three main issues arose for which separate CEN Task Forces were set up:

- Braille alphabets and character sets
- Braille dot height
- Documentation

The addition of Braille to medicinal products' cartons has been established since 1996, but problems arose concerning the needs of different countries. Guidance documents have been published by the European Carton Makers Association integrating these varying requirements. However, they do not specify a height for the Braille embossing.

The European Blind Union (EBU) published guidelines in support of pharmaceutical Braille requirements in January

Figure 1. Marburg Medium spacing convention for Braille.**Figure 2. Braille dot profile.**

2006. Unfortunately, these specify Braille dot heights that cannot be achieved in practice on pharmaceutical packaging.

Braille alphabets and character sets

While many of the characters in Braille alphabets are standardised across Europe, there are several that differ depending on the country. In some countries, the differences depend on the source of the character set. The pharmaceutical industry has had difficulty identifying character sets in some countries (and which must also be acceptable to pharmaceutical regulatory authorities) and, through the CEN Working Group, has asked the EBU to identify the national character sets and relevant organisations, and to make this information available on the EBU website. As a precursor to this approach, pharmaceutical regulatory authorities in some countries, such as Ireland and the UK, have published character sets that are acceptable for medicinal products distributed in their respective countries.

The main issues are with abbreviations and special characters, such as 'microgram', 'milligram', '%' and '/'. Where practical, and to minimise confusion, these should be standardised across Europe. It is important that the national blind associations and pharmaceutical regulators agree on what

is acceptable. The CEN Task Force is making progress with the main characters and has identified the more critical abbreviations and special characters that must be standardised.

Braille characteristics

Braille is a tactile reading system in which the letters/characters consist of cells containing one to six raised dots. In general, each cell represents one letter or character. The recommended dimensional layout, for example, the distances between the dots and the cells for Braille for incorporation on pharmaceutical packaging, is specified by the Marburg Medium spacing convention. This defines the distance between the dots and cells (see Figure 1).

The shape/profile of the Braille dot is also important for readability (see Figure 2). With lower dot heights, the radius of curvature at the top of the dot (r) should decrease. However, the strength of the dot is determined by the radius at the bottom (R); if it is too large, then the dot may collapse, but if it is too small, the substrate is likely to burst. Tooling manufacturers are developing techniques to optimise the profile for improved Braille dot height and stability.

Braille dot height

The biggest issue that needs to be resolved is the height of the Braille dots. The most common form of incorporating Braille onto the packaging of medicinal products is to emboss the Braille onto the carton. Where the product is not packed into a carton, the label will need to incorporate Braille.

Braille books have been produced for many years using special long-grain paper and an embossing machine. This process and substrate will achieve a Braille height that is nominally 0.4mm, but it is not practical to achieve this height with the cartonboard used for the packaging of medicinal products. When embossing this material, the surface coating and the board will crack. It is important that this cracking does not affect the readability by sighted persons of normal text over which the Braille is subsequently embossed. Ideally, there should be no text underneath the Braille, but due to the size of medicinal packaging and the amount of text (much of which is a legal requirement) that has to be incorporated there is often no spare unprinted space available for Braille – and it is not practical to increase the carton size to accommodate Braille.

The primary purpose of Braille text is to enable a Braille reader who is blind or partially sighted to identify their medicine and differentiate one medicine from another. Unlike reading larger volumes of text in Braille, the ability to do this rapidly is not the main issue with medicinal products, so the Braille dot height may not be as critical as for Braille books. As a rule, cartonboard is embossed to a depth where cracking is not visible to the naked eye. On the basis of tests carried out over several years in different countries, using samples produced by several carton makers, it has been established that a minimum dot height of 0.12mm is acceptable for medicinal product identification. This figure has been incorporated into UK Draft for Development Standard DD264:2007. At the CEN Working Group, the 0.12mm Braille dot height has been challenged by some organisations representing the blind, but no validated evidence has been produced to support the need for a higher Braille dot height.

In July 2006, a CEN Task Force was set up to urgently examine the height requirement and develop a protocol for testing and evaluating the minimum Braille dot height. Unfortunately, this Task Force failed to provide a protocol for discussion at the November 2006 CEN meeting and a draft was only provided at the end of December 2006. This draft protocol is extremely complicated and will be excessively time consuming and expensive to carry out. Fundamentally, the proposed research will take a further year to deliver any results.

'The new European Directive was implemented before work has even started on preparing the associated European standard, which will define precisely the requirements such as dot height and required alternative formats for the patient information leaflets,' says Dr John Gill, RNIB, in *Pharmaceutical Technology Europe*. 'This will leave a period of uncertainty, where manufacturers run the risk of implementing systems that subsequently do not meet the specifications in the European Standard, and will, therefore, have to be changed. The EC might want to consider not requiring compliance with the directive until the associated standard is published.'

While the pharmaceutical industry would welcome a moratorium, it is unlikely that the EU will suspend compliance. It is also highly unlikely that the organisations representing blind and partially sighted people would find this approach acceptable. A pragmatic compromise is needed to establish the minimum Braille dot height on packaging.

The minimum Braille dot height requirements could be established using a protocol based on a UK pilot study carried out in 2006. A set of medicinal product cartons with varying Braille dot heights from 0.6mm to 1.8mm were tested by a group of blind Braille readers of different ages and competences, who were asked if they could identify the product. The results demonstrated correct identification of the medicinal product if the Braille dot height was greater than 0.10mm.

As a result, a minimum height specification of 0.12mm is included in the UK Draft for Development standard. This pilot study can easily and quickly be extended to test a larger number of Braille readers, pharmaceutical packaging materials and formats. It should be possible for this work to be done in advance of the next CEN Meeting in Berlin in April 2007.

The results of an extended study, based on the above, can be incorporated into the draft European Standard document to enable this to be circulated for public comment in 2007. Without a Braille dot height specification, the development of the European Standard will have to be delayed or suspended. If there is no consensus on Braille dot height, momentum will be lost and confusion will persist.

Embossed cartons

Braille is normally incorporated onto medicinal product cartons by embossing. In this process, Braille characters are set in a male die, which is matched with a female die. The tooling is either completely product specific with matching male and female dies or universal, where a common female die is used with specific product male dies. This latter approach has considerable advantages in efficiency and, provided appropriate quality checks are made, has no greater risk than

using dedicated tooling. This efficiency is manifested by faster production of tooling, lower costs of tooling, saving of tooling storage space and shorter machine set-up times, leading to considerable cost savings.

Labels

Labels applied to medicinal products are manufactured using a variety of substrates – for example, paper, synthetic vellum, polypropylene and varnished papers. The normal process for incorporating the Braille is by screen-printing where a varnish is forced through a fine mesh screen containing the Braille characters. The minimum height of the Braille dots for labels is specified as 0.20mm in the UK Draft for Development. It is important that the Braille dots are clearly formed (see Figure 3) and adhere well to the substrate. This is usually verified by carrying out a rub-test to verify the adhesion.

Although it is possible to produce higher Braille dot heights on labels, other factors such as reel stability, application to the product, and subsequent packing and transportation have to be considered. The minimum Braille dot height for labels must also be established using a similar protocol to that for cartons. Quality assurance/control and critical control points are elaborated in the UK Draft for Development 264:2007 and the draft CEN Standard.

Braille artwork

The biggest single cause of medicinal product recalls is due to errors in printed packaging. Despite advances in production methods and controls, the situation has not improved greatly. This is most likely due to the increased complexity and number of items of printed packaging.

The origination of Braille is a critical process that needs to be carefully controlled. Braille is text and needs to be controlled in a similar manner to conventional text. In fact, Braille origination probably requires greater control as it is not easily readable by sighted persons. The introduction of Braille into the original artwork for medicinal products should ensure a high level of control and, ideally, be incorporated as a separate layer. The Braille text should also be printed in normal text on the same layer but outside the profile of the product.

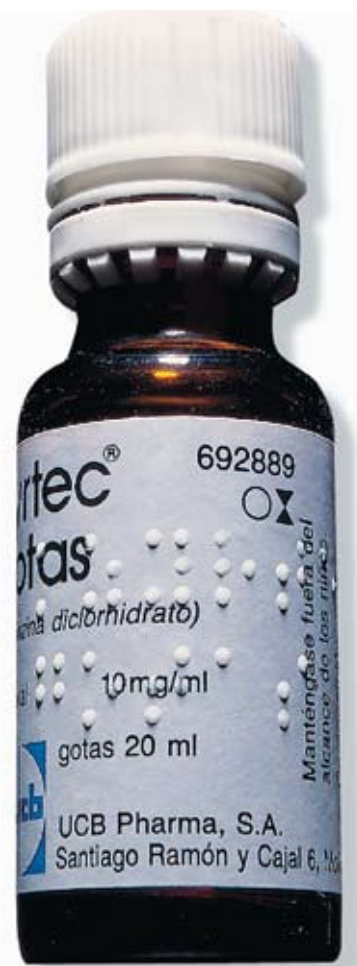


Figure 3. Example of Braille on a bottle.

Kentworth Products, Dublin

Patient information

Directive 2004/27/EC requires patient information to be available in alternative formats. These include:

- Braille
- Large print
- Audio via tape or CD
- Audio via telephone

The appropriate formats will need to be agreed with patients' organisations and organisations representing blind and partially sighted people, and may vary from country to country. Where possible, national telephone numbers should be available to direct the patient or carer to the source of the information.

Whatever formats are made available, it is essential that the patient information is correctly prepared and issued in a timely manner. Controls must be in place to ensure that the correct information is supplied. Special attention must be given to the transposition of diagrams from the printed form of the patient information into Braille so the patient can use the product safely.

It is unlikely that alternative formats of patient information will be distributed directly by the larger medicinal product manufacturer and/or product distributor, but will be supplied by third parties contracted to provide this information directly to the patient. In a number of countries, systems have developed whereby the medicinal product authorisation holder (MAH) contracts with a third party experienced in providing

information in formats suitable for blind and partially sighted people. However, a significant number of MAHs intend to carry out the work internally and produce only large print and audio versions of patient leaflets, as these two formats meet the needs of virtually all blind and partially sighted people.

Whatever process is used, the responsibility for the provision of the correct version of the alternative formats cannot be delegated, but remains with the MAH. Appropriate and validated good practices and quality assurance need to be in place, and audited at regular intervals to ensure requirements are met.

Call for standard

The requirements for Braille on pharmaceutical packaging and the provision of alternative formats of patient information will assist blind and partially sighted people identifying and using their medicines safely. The various stakeholders need to urgently agree on those aspects that need to be standardised and reach a consensus so that that the necessary information can be published and made available to those who need it.

The first requirement is for an authoritative European source of national character sets with standardisation of special characters. The second requirement is to reach agreement on an acceptable minimum Braille dot height. With effective communication and understanding, hopefully these two requirements can be achieved for the benefit of all concerned. **END**

References available from the author on request.

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