EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

ENTR/F2 D(2005)

Guidance concerning the Braille requirements for labelling and the package leaflet

Article 56a of Directive 2001/83/EC as amended

After finalisation of the revision of the 'GUIDELINE ON THE READABILITY OF THE LABEL AND PACKAGE LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE' the guidance concerning the Braille requirements will be included as part of this readability guideline.

Guidance concerning the Braille requirements for labelling and the package leaflet (Article 56a of Directive 2001/83/EC as amended)

Directive 2004/27/EC – amending Directive 2001/83/EC - includes changes to the label and package leaflet requirements.

This guidance interprets the requirements for Braille on the packaging, and the requirements for the package leaflet to be made available in formats for the blind and partially sighted according to Article 56a.

Legal text:

Directive 2001/83/EC as amended by Directive 2004/27/EC, Article 56 a

> The name of the medicinal product, as referred to in Article 54 a must also be expressed in Braille format on the packaging.
> The marketing authorization holder shall ensure that the package information leaflet is made available on request from patients organisations in formats appropriate for the blind and partially-sighted.

Directive 2001/83/EC as amended by Directive 2004/27/EC, Article54 a

> The name of the medicinal product, followed by its strength and pharmaceutical form, and if appropriate, whether it is intended for babies, children or adults; where the product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name.

Implementation

The provision of Article 56a will apply after the end of the implementation period - 30 Oct 2005 – to all medicinal product approved after this date. It will not apply immediately to products authorized before 30 October 2005.

Nevertheless companies are encouraged to apply the provision to all medicinal products as soon as possible. For specific implementation requirements reference is made to the relevant national legislation and EMEA guidance for Centrally Authorised Products.

Braille

Braille is the internationally widespread reading and writing system for blind and partially sighted people. The system was founded in 1825 by Louis Braille (1809 – 1852), who lived in France and himself was blind.

Braille is not a language, it is just another way to read and write a language.

Braille consists of arrangements of dots which make up the letters of the alphabet, numbers and punctuation marks. The basic Braille symbol is called the Braille cell.

Due to the reason that there are differences in Braille in different countries, the type of Braille letter (size of Braille cell) has to be standardized. The use of Marburg Medium is highly recommended.

The uncontracted Braille system should be used. In this system every Braille character (Braille cell) makes up the letter of the alphabet, punctuation mark, numbers, etc. The contracted Braille system with letter-combinations should not be used, except in small volume packaging (up to 10 ml volume) – see paragraph below under "Scope".

Scope

"The name of the medicinal product, as referred to in Article 54a" should be interpreted in a way which allows clear identification for blind people. According to the definition in Article 1.20 of Directive 2001/83/EC as amended "the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorization holder", the (invented) name of the medicinal product followed by its strength should be put in Braille on the packaging of the product.

For medicinal products authorised only in a single strength, it is acceptable that only the invented name in Braille is put on the packaging.

This interpretation does not prevent companies to express further information (pharmaceutical form, and if appropriate, whether it is intended for babies, children or adults, etc) in Braille on bigger volume packages on a voluntary basis. Also the inclusion of the expiry date in Braille would be welcome, although it is acknowledged that this may not always be feasible.

For Herbal Medicinal Products the Braille requirement will be restricted to the invented name of the Medicinal Product only. Where the name consists of the active substance(s), information could be limited to the plant name (+ plant part in those cases where several parts are available), plus the type of preparation and the strength in those cases where several strengths exist.

In case of small volume packages (up to 10 ml) with limited space capacity, alternative means of providing Braille information may be considered, eg. use of contracted Braille system or certain defined abbreviations or addition of supplementary "tab" label. Particular consideration should be given to medicinal products likely to be used by a high visually impaired target population, eg. certain eye drop preparations.

In case of multilingual packaging, the name in Braille has to be printed in all the different languages concerned. Companies are encouraged to use the same invented name for the same medicinal product.

There is no need to put the name in Braille on the packaging of products which are only intended for administration by health care professionals, for example it is not required to put the name in Braille for vaccines.

Packaging

The name in Braille does not have to be printed on the immediate packaging - such as blisters, ampoules and bottles, it only has to appear on the outer/secondary packaging, which is normally a carton. In case where there is no secondary packaging, eg. large volume bottles (500 ml, 1000 ml, etc.), it is possible to fix an adhesive Braille label around the bottle during the manufacturing process.

On a volunteer basis companies can put the name in Braille on all packaging components.

Affixing an adhesive Braille label at the point of sale/dispensing of the medicinal product on request is not recommended, due to the risk of affixing the wrong Braille label and confusion.

Concerning the location of the Braille on the outer packaging there is no need to put the Braille dots on an empty space of the packaging, but the underlying printed text has to be easily legible.

Where Braille is present on the (outer) packaging of a medicinal product, parallel importer/parallel distributor should ensure that the same Braille text is provided in the language(s) of the member state of destination and that the original Braille text will not cause confusion.

Package information leaflet for blind and partially sighted

On request the package leaflet should be provided for partially sighted people in a suitable print, taking into consideration all aspects determining the readability (eg. Font-size: Sans serif typefaces , 16 - 20 point, contrast: black letters on white paper, word spacing, text alignment, line spacing, layout, paper quality). For blind people the text has to be provided in an appropriate format , it is recommended to provide the text in a format perceptible by hearing (CD-ROM, audiocassette, etc.). In certain cases the appropriate format may be the package leaflet available in Braille.

Choice of the appropriate medium should be made by the MAH in consultation with representatives of organizations for the blind and partially sighted. It is the responsibility of the marketing authorization holder to provide the package leaflet on request from patients organizations in an appropriate format and to ensure that the current version is supplied.

This provision of Article 56a will apply after the end of the implementation period - 30 October 2005 – to all medicinal product marketing authorization applications approved after this date. It will not apply immediately to products authorized before 30 October 2005.

Nevertheless companies are encouraged to apply the provision to all medicinal products as soon as possible. For specific implementation requirements reference is made to the relevant national legislation and EMEA guidance for Centrally Authorised Products.

These requirements concerning the package leaflet for blind and partially sighted persons also fully apply to parallel importers/distributors.