DECISION

No. 12/15.06.2007

on the approval of Guideline on the application of legal provisions concerning the Braille requirements for labelling and package leaflet of a medicinal product

The Scientific Council of the National Medicines Agency,
set up based on Minister of Public Health Order no. 485/09.05.2005, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 15.06.2007, in accord with Article 10 of Government Ordinance no. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law no. 594/2002, as further amended, agrees on the following

DECISION

Single article. – The Guideline on the application of legal provisions concerning the Braille requirements for labelling and package leaflet of a medicinal product is approved, according to the Annex which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Medicines Agency

Acad. Prof. Dr. Victor Voicu

ANNEX

GUIDELINE
on the application of legal provisions concerning the Braille requirements for labelling and package leaflet of a medicinal product

CHAPTER I
Introduction

Art. 1. – (1) This Guideline is meant to offer counseling consiliere to the Marketing Authorisation Applicants and Marketing Authorisation Holders în concerning the requirements relating to the printing of the medicinal product in Braille format and making labelling information in adequate formats available for blind and partially blind persons; it is based on the provisions of the European Commission Guideline „*Guideline concerning the Braille requirements for labelling and package leaflet (Article 56a of Directive 2001/83/EC with further changes and completions)*"[1], but it also covers additional information, such as procedural aspects or information related to the manner in which the National Medicines Agency (NMA) checks compliance with provisions of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, further called „law", which are part of this Guideline.

(2) 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.

(3) 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".

CHAPTER II
Implementation

Art. 2. - (1) According to Art. 863 (f), provisions of Art. 766 (relating to the printing of the medicinal product's name in Braille format for labelling and the package leaflet and making available the information in the prospect in appropriate formats for blind and partially blind people) come into force 1 year after Romania's Accession to the European Union.

(2) Starting with 1 January 2008, these provisions are mandatory for all medicinal products authorised after this date; it will not apply immediately to medicinal products authorised prior to this date.

(3) Nevertheless, companies are encouraged to apply these provisions to all medicinal products as soon as possible.

(4) In term of 5 years from the moment of the coming into force of Art. 766 (thus, 1 January 2013) this provision should be extended to all medicinal products, regardless of the moment of their authorisation.

[1] „*Guidance concerning the Braille requirements for labelling and the package leaflet (Article 56a of Directive 2001/83/EC as amended*)", available online on http://www.sensus.dk/sb4/pharmabraille/european%20commission%20guidance%20pharmabraille.pdf.

(5) When submitting a marketing authorisation for the parallel import of a medicinal product in Romania, it is required to follow the provisions of Art. 766, if the directly distributed original medicinal product already meets this requirement.

CHAPTER III
Braille formatting

Art. 3. - (1) 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.

(2) 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.

(3) The contracted Braille system with letter-combinations should not be used, except in small volume packaging (up to 10 ml volume).

CHAPTER IV
Scope

Art. 4. - (1) "The name of the medicinal product, as referred to in Article 763 (a)" should be interpreted in a way which allows clear identification for blind people.

(2) According to the definition in Article 695 (20) of Directive in the Legislation, "the name given to a medicinal product, 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 authorisation holder", the (invented) name of the medicinal product followed by its strength should be put in Braille on the packaging of the medicinal product.

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

Art. 5. - (1) This interpretation under Art. 4 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.

(2) Also the inclusion of the expiry date in Braille would be welcome, although this may not always be feasible.

Art. 6. - (1) For Herbal Medicinal Products, the Braille requirement will be restricted to the invented name of the medicinal product only.

(2) Where the name consists of the active substance(s), information could be limited to the plant name (plus 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.

Art. 7. - (1) 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.

(2) Particular consideration should be given to medicinal products likely to be used by a high visually impaired target population, eg. certain eye drop preparations.

Art. 8. - (1) In case of multilingual packaging, the name in Braille has to be printed in all the different languages concerned.

(2) Companies are encouraged to use the same invented name for the same medicinal product, in order to avoid confusing the patients.

Art. 9. - (1) 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; other examples include radiopharmaceuticals, infusions or anesthetics.

(2) However, medicinal products based on insulins and solutions for peritoneal dyalisis, are handled by the patient (or by the patient as well) and should be imprinted.

(3) Since free samples are not recommended to be used by patients, but by those who prescribe them in order to get used to the medicinal product, it is generally not necessary to put the name in Braille.

CHAPTER V
Packaging

Art. 10. - (1) 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.

(2) 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.

Art. 11. - On a volunteer basis, companies can put the name in Braille on all packaging components.

Art. 12. - Affixing an adhesive Braille label at the point of sale/dispensing of the medicinal product is not recommended, due to the risk of affixing the wrong Braille label and confusion.

Art. 13. - (1) 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.

(2) 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 of the member state of destination and that the original Braille text will not cause confusion.

CHAPTER VI
Package information leaflet for blind and partially sighted

Art. 14. - (1) 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).

(2) 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.

(3) Choice of the appropriate medium should be made by the Marketing Authorisation Holder in consultation with representatives of organisations for the blind and partially sighted.

(4) It is the responsibility of the marketing authorisation holder to provide the package leaflet on request from patients organisations in an appropriate format and to ensure that the current version is supplied.

(5) The Braille format or other alternative formats of the prospect must not necessarily be separately approved by the NMA; however, as far as the NMA is seen by

the users, it may require from the holder the change of the format in order to make it more adequate.

Art. 15. - These requirements concerning the package leaflet for blind and partially sighted persons also fully apply to parallel importers/distributors.

CHAPTER VII
Procedure

Art. 16. – The inclusion of the Braille format can be done at the same time with the marketing authorisation's renewal or calling to the procedure mentioned in the Minister of Public Health Order No. 1205/02.10.2006 on the approval of the management of applications for proposed changes in design and wording of the package of medicinal products for human use, as well as changes in leaflet and Summary of Product Characteristics, other than caused by Type IA, IB and II variations (further called Order No. 1205/02.10.2006) or at the same time with a variation which implies a change in the patient's prospectus.

Art. 17. - (1) In order to include the Braille formatting, the applicant should submit a „compliance declaration" (according to the annex) for all new authorisation applications, as well as, for the applications submitted in accordance with Order No. 1205/02.10.2006, as required, in order to update the patient information according to provisions of Art. 766 of the law, to a variation which implies a change in the prospect, also used to ensure compliance with provisions of Art. 766 of the law and in view of the renewal for the updating of the labelling and package leaflet in accordance with provisions of Art. 766.

(2) Section 1a or 1b and 2 must be filled in, and the declaration must be signed and dated by a competent person in order to represent the applicant.

(3) The declaration must precisely indicate what information is show non the package.

(4) At the time being, the provision of models labeled in Braille is not necessary (however if the applicant finds a way of providing those, they are welcome), nevertheless, common models (non-Braille) should be provided, together with the indication pointing from which version of the labelling shall the declaration on the Braille formatting come into force; the model should also contain the place where the Braille formatting shall be printed.

(5) A declaration is needed for each dose or strength.

(6) If a change occurs in the naming of the product (according to Art. 4-6 of this Guideline) the declaration's update shall be needed.

(7) In case of a notification mentioned in Art. 771 (3), the Marketing Authorisation Holder should make sure that this will not affect the readability of any text undergoing Braille formatting, in order to maintain compliance with the declaration on the Braille formatting.

(8) The quality of this mechanism and environment of the Braille formatting should be cautiously evaluated in order to grant the inscription's readibility throughout the entire availability period of the medicinal product.

Art. 18. - (1) Via its competent structures, the NMA checks the complaince with provisions of Art. 766 of the law.

(2) To this extent, the Pharmaceutical inspection Department may draw samples of the marketed medicinal products to be checked and may also carry out, if needed, inspections in order to check compliance with provisions of Art. 766 of the law and the submitted declaration.

ANNEX 1

DECLARATION ON BRAILLE INSCRIPTION

Check one of the sections 1a or 1b, as well as section 2, if needed.

<*Name and surname*>, representing <*Marketing Authorisation Holder*>, I hereby declare that:

Section 1a

☐ The medicinal product <*name, No. APP* > is compliant with provisions of Art. 766 of Law No. 95/2006 on healthcare reform, as interpreted by the European Commission Guideline „*Guidance concerning the Braille requirements for labelling and the package leaflet (Article 56a of Directive 2001/83/EC as amended*)"
The label shall contain the next text in Braille: <*insert the (non-Braille) text in Braille* >:
I also declare that:

- The text in Braille is easily readable, intelligible and does not affect the readability of the text in Braille.
- The Braille specification used is suitable for Romanian patients.

Section 1b

☐ The Braille inscription on the medicinal product's label is not necessary, <*product's name, MA No.*>, in compliance with the European Commission Guideline „*Guidance concerning the Braille requirements for labelling and the package leaflet (Article 56a of Directive 2001/83/EC as amended*)", since the medicinal product may only be administered by healthcare professionals.

Section 2

☐ The prospect is available on request of the patients' organisations in adequate formats for blind and partially-sighted people.

<*Signature, date and status*>