TECHNICAL REPORT

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English Version

Packaging - Package leaflets for medicinal products - Braille and other formats for visually impaired people

Emballages - Notices de médicaments - Ecriture en braille ou autres formats pour personnes malvoyantes

Verpackung - Gebrauchsinformation für Arzneimittel - Blindenschrift und andere Formate für sehbehinderte Menschen

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Contents

Page

Foreword

This document (CEN/TR 15753:2008) has been prepared by Technical Committee CEN/TC 261 “Packaging”, the secretariat of which is held by AFNOR.

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Introduction

Community legislation for medicinal products for human use is included in Directive 2001/83/EC [1] as amended by Directive 2004/27/EC. This includes a requirement that on the outer packaging of authorized medicinal products their names are provided in Braille as an identification aid for visually impaired people. It is also a requirement to provide patient information in formats suitable for visually impaired people. European Commission guidance is available [2]. (A draft European Commission guideline on readability of the label and package leaflets of medicinal products for human use is also available [3]).

This European Technical Report provides guidance to support the requirement to provide the package leaflet in alternative formats for blind and partially sighted people for medicinal products in the European Union (EU) and European Economic Area (EEA).

1 Scope

This European Technical Report addresses the provision of information for medicinal products in alternative formats suitable for blind and partially sighted people.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
marketing authorization holder (MAH)
natural or legal person or entity responsible for placing the packaged medicinal product on the market

2.2
Braille
tactile reading and writing system composed of Braille cells

2.3
Braille cell
series of up to six raised dots set out in a domino-type cell

2.4
contracted Braille
Grade 2 Braille
braille that uses short forms of some commonly used words and contractions of commonly used letter combinations rather than full spelling of all words

2.5
uncontracted Braille
Grade 1 Braille
braille where normally one cell represents a single letter, number, symbol, punctuation mark or an instruction to the Braille reader

NOTE There is no abbreviation of letter groups or words and full spelling of words is used.

2.6
package leaflet (PL)
patient information leaflet (PIL)
text approved by a relevant competent authority for inclusion with the product

2.7
quality assurance (QA)
part of quality management focused on providing confidence that quality requirements will be fulfilled

[ISO 9000:2005 3.2.11]

2.8
quality control (QC)
part of quality management focussed on fulfilling quality requirements

[ISO 9000:2005, 3.2.10]

2.9
audit trail
systematic examination of processes and records to demonstrate compliance with requirements and applicable guidance