SLOVENSKI STANDARD
SIST-TP CEN/TR 15753:2008

01-oktober-2008

Embalaža - Navodila za uporabo zdravil - Braillova pisava in drugi formati za slabovidne

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

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

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

Ta slovenski standard je istoveten z: **CEN/TR 15753:2008**

ICS:

11.120.10	Zdravila	Medicaments
11.180.30	Pripomočki in prilagoditve za branje	Aids and adaptations for reading

SIST-TP CEN/TR 15753:2008 **en,fr,de**

TECHNICAL REPORT

RAPPORT TECHNIQUE

TECHNISCHER BERICHT

CEN/TR 15753

June 2008

ICS 11.120.99; 11.180.30

English Version

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

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This Technical Report was approved by CEN on 11 April 2008. It has been drawn up by the Technical Committee CEN/TC 261.

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Ref. No. CEN/TR 15753:2008: E

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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.

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.

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

2.10
line clearance
removal (line purge) of everything associated with the previous production run

[ISO 15378:2006, 3.28]

NOTE Typically, line clearance is carried out previous to production to prevent any error and/or cross-contamination. [abbreviated from ISO 15378:2006]

3 Package leaflet alternative formats

3.1 Legislated requirement

The package leaflet (PL/PIL) is required to be available in a suitable format or formats for visually impaired people on request by their representative organizations.

The choice of the appropriate media should be agreed by the MAH in consultation with representatives of organizations of visually impaired people. The choice of format from those available is with the patient / end user.

In many instances, it is likely that the leaflet is required to be available in the following formats:

a) Braille

b) Large print

c) Audio

d) Electronic text

Digital master files can be created from MAH-approved text using validated and controlled processes. These master files should be verified and approved. From these digital master files, alternative formats of the patient information can be produced and distributed, without undue delay, in accordance with specified procedures. The European Commission Guidance [2] does not specify particular alternative formats that should be available or their distribution mechanisms.

3.2 General issues

All package leaflets are required to be prepared for reformatting to suit the media type(s) and to make them meaningful and comprehensively understood by the patient. It is recommended that an expert in this field and/or appropriate organisations representing visually impaired people completes this work.

Any adaptations to diagrams or tables should be carried out by the MAH in conjunction with an expert in this field. The MAH is advised to set up and maintain protocols that ensure that these resources are updated and maintained in accordance with the local markets' regulatory requirements with respect to change control, etc. Close co-operation is advised between MAH and organizations representing visually impaired people as to the exact requirements of each market.

3.3 Local Requirements

The Braille character set, spacing and dot height should be in accordance with local requirements.

NOTE For examples of local requirements, see [4]

4 Alternative package leaflet formats, critical control points

Table 1 contains suggested critical control points, which should be considered when supplying alternative format package leaflets. Where the MAH is outsourcing this activity, agreements should be in place to ensure the critical control points are incorporated. This should not be considered as a checklist for auditors.

Table 1 — Alternative package leaflet formats - critical control points

Stage	Process	Critical control points
General	Media considered: Braille; Large print; Audio and electronic formats e.g.: — synthesized voice over computer/ web; — cassette tape; — CD; — telephone – synthesized voice; — telephone – person; — other formats.	— Whole system process validation/assurance is recommended. — Quality Assurance is preferable, but if not possible the appropriate Quality Control procedures should be in place. — An audit trail is essential.
Origination	Approved text issued by MAH.	Standard Operating Procedures (SOPs) / Work instructions in place to ensure up-to-date text is used.
'Translation' into preferred medium	— Whole process validation / assurance is recommended. Quality Assurance is preferable, but if not possible the appropriate Quality Control procedures should be in place. — 'Translation' into an appropriate computer file format, e.g. .txt or .xml might precede translation into preferred medium for some formats. — There are 'good practice' design documents available for many media. This includes layout. Some examples of these documents are given in the bibliography.	— Example – Braille translation software might not be fully capable of validation to Good Automated Manufacturing Practice (GAMP) [5] standard, so use of QA checks is more appropriate. — For audio output media, checking of pronunciation of unusual / technical words is vital. — For human-read audio output, training SOPs / work instructions are highly recommended. — If contracted Braille is used, care should be taken to avoid confusion/potential safety issues with abbreviations.