Packaging - Braille on packaging for medicinal products

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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 15823:2010 sisaldab Euroopa standardi EN 15823:2010 ingliskeelset teksti.	This Estonian standard EVS-EN 15823:2010 consists of the English text of the European standard EN 15823:2010.
Standard on kinnitatud Eesti Standardikeskuse 30.09.2010 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.09.2010 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 23.06.2010.	Date of Availability of the European standard text 23.06.2010.
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English Version

Packaging - Braille on packaging for medicinal products

Emballage - Braille sur les emballages destinés aux médicaments

Verpackung - Blindenschrift auf Arzneimittelverpackungen

This European Standard was approved by CEN on 26 May 2010.

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Foreword

This document (EN 15823:2010) has been prepared by Technical Committee CEN/TC 261 “Packaging”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2010, and conflicting national standards shall be withdrawn at the latest by December 2010.

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Introduction

Council Directive 2004/27/EC [1] modifies the Community Legislation for medicinal products for human use (Directive 2001/83/EC [2]) and by subsequent incorporation into national legislation, introduces the need to include on the packaging of authorized medicinal products their names and, where appropriate, the form and strength in Braille as an aid to identification for blind and partially sighted people.

This European Standard is primarily aimed at supporting the implementation of Braille on medicinal products in the European Union (EU) and European Economic Area (EEA) and in particular, Chapter 2 of the associated European Commission Braille Implementation Guidelines [3].

1 Scope

This European Standard specifies requirements and provides guidance for the application of Braille to the labelling of medicinal products.

NOTE 1 The labelling of medicinal products placed on the market and incorporating Braille in accordance with this European Standard meets the requirements of European Directive 2001/83/EC, Article 56, (a) as amended by Directive 2004/27/EC [1].

NOTE 2 The principles in this European Standard can be applied in other sectors, as appropriate.

2 Terms and definitions

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

2.1
Braille
tactile reading and writing system composed of Braille cells

2.2
Braille cell
series of up to six raised dots set out in a domino-type cell

2.3
burst-through
cracking, breaking, pin-holing of the coating or material surface, visible to the naked eye, caused by the process of embossing Braille

2.4
labelling
information on the immediate or outer packaging

2.5
Marburg Medium spacing convention
defined system of dimensions within and between the Braille cells

NOTE The Marburg Medium spacing convention for Braille [4] is recommended in the European Commission Guidance [3] for use for medicinal product labelling.

2.6
marketing authorization holder
MAH
natural or legal person or entity responsible for placing the medicinal product on the market

3 General requirements for medicinal product packaging

3.1 Product identification

3.1.1 Information in Braille

The approved Braille text on the labelling shall include the information as required in the country in which the product is to be supplied.

NOTE 1 Guidance on the information to be labelled in Braille is given in the European Commission Guidance [3].