



**NSAI**  
Standards

Irish Standard  
S.R. CEN/TR 15753:2008

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

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S.R. CEN/TR 15753:2008

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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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## 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).

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