

grenze
der
Lesbarkeit



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Readability Guideline

A brief guideline for a
patient-friendly realization



Readability Guideline – What You Need to Know

The main objective of the readability guideline is to assist pharmaceutical companies in how to present the drug information on labels and package leaflets in an easy-to-understand and patient-friendly way. However, under Art. 249 of the treaty establishing the

European Community, the guideline is not binding. This document serves to introduce and evaluate the readability guideline and simultaneously addresses the impact on those concerned – patients, the pharmaceutical industry and regulatory authorities.

Any recommendations in the guideline regarded as helpful by Edelmann Leaflet Solutions are highlighted in bold.

Fonts

For easy readability, it is important to choose a font in which similar characters, such as “i”, “l” and “1” can be easily distinguished from each other. Although “Times New Roman” is mentioned as an example, and the new guideline also recommends avoiding “narrow” fonts, there are no further requirements with regard to the type of font or preference for typefaces with or without serifs. Based on published studies and the experience of readability tests, these specifications regarding font types are considered sufficient. The font size used to be as large as possible, with 9 pt recommended as a minimum. Alternatively, a minimum height of 1.4 mm for the lower case “x” is also acceptable. The increase of the minimum font size to 9 pt from 8 pt (1998 readability guide-

line) does not necessarily mean larger dimensions of leaflets or packaging materials. There are sufficient options available to compress the information on the current leaflets without loss of information while also improving readability.

A new and very useful recommendation is for the use of different font sizes to make key information, such as headings, stand out and to facilitate navigation in the text.

As in the 1998 guideline, the updated version also specifies a space between the lines of at least 3 mm. Wherever possible, 1.5 line spacing should be used. The use of underlining or italics or capitalised words should be avoided. This makes sense, since the contours of the words in capitals form one line at the bottom and one at the top; they are

more difficult to read than words with letters in upper and lower case. This makes it difficult to recognise the difference in height for the letter “g”, for example. The same applies to underlined words, where it is difficult to recognise the lower contour of words. Any loan words or medical terms should be avoided. With clear and easy-to-understand explanations, Latin terms provide no additional information. According to a study, a large number of medical terms can even lead to the patients losing confidence in the medication.

In this context, the updated guideline also recommends avoiding negative statements and only using standard abbreviations such as IV, IM and SC.

Type table

Arial 9 pt	10 drops in 1 liter of water! This dummy text is being caught by 130 billion receptors of your retina.
Cambria 9 pt	10 drops in 1 liter of water! This dummy text is being caught by 130 billion receptors of your retina.
Futura 9 pt	10 drops in 1 liter of water! This dummy text is being caught by 130 billion receptors of your retina.
Helvetica 9 pt	10 drops in 1 liter of water! This dummy text is being caught by 130 billion receptors of your retina.
Meta 9 pt	10 drops in 1 liter of water! This dummy text is being caught by 130 billion receptors of your retina.
PMN Caecilia 9 pt	10 drops in 1 liter of water! This dummy text is being caught by 130 billion receptors of your retina.
Times New Roman 9 pt	10 drops in 1 liter of water! This dummy text is being caught by 130 billion receptors of your retina.
Verdana 9 pt	10 drops in 1 liter of water! This dummy text is being caught by 130 billion receptors of your retina.

Design and Layout

To ensure **sufficient contrast**, a **dark font colour** on a **light background** should be chosen and background graphics are to be avoided.

The 1998 guideline specified a paper weight of at least 40 g/m². This has now been changed to “sufficiently thick”. Among the newly added sections is that

the use of glossy paper should be avoided and when the leaflet is folded, to ensure the creases do not interfere with the readability of the information. While the 1998 guideline still recommended the A5 to A4 format for the leaflet, this has now been dropped. The emphasis is now on the actual presenta-

tion in column format, where the margins between the columns should be large enough to adequately separate the text and with a recommendation for the use of landscape format, as this may be helpful to patients.

Headings

In addition to the recommendation to use a different font size for headings and for the main text, the updated readability guideline follows the previous version in giving only general recommendations for headlines such as:

- the use of bold print face or different font colour to make the information stand out
- only use two levels of headings, however for more complex information multiple levels may be used
- use lines to separate sections
- consistent design of headers of one level, for example with regard to numbering or spacing before and after headings
- the guideline explicitly recommends including only text and sub-headings that are relevant

Syntax

Side effects are to be listed by frequency of occurrence, starting with the highest frequency. This form of presenting side effects has already proven successful in a study and in readability tests in recent years. It is more appropriate for patients and easier to understand than the currently used MedDRA (Medical Dictionary

for Regulatory Activities) classification, which is organised by system organ class.

Frequency terms should be explained in a way patients can understand.

According to the updated readability guideline, serious side effects requiring immediate urgent action should be

given greater prominence and appear at the start of the section.

Writing Style and the Use of Pictograms

Here the new readability guideline follows the previous version by recommending an active style instead of passive. Sentences should start with a verb. At the same time, the guideline advises giving instructions before giving their reasons. Abbreviations, acronyms, and symbols that are not commonly known are to be avoided. If their use cannot be avoided, their meaning should be

spelled out in full when first used in the text. The guideline recommends that terms like “Your medicine, this medicine, etc.” should be used rather than repeating the name of the product, as long as it does not affect the information. In addition to the information on medical terms in the previous section, it is recommended that one term be used throughout the leaflet to ensure

consistency. Where medical terms cannot be avoided, they should be put in text brackets after the explanation. The use of pictograms and symbols can be helpful, but the guideline advises using them with caution. They should not replace explanatory text.

Additional Information

As a rule, there should be a separate leaflet for each dosage form of a product, which is very useful to patients. However, in individual cases, the competent authorities may agree to allow the use of combined package leaflets. As in the previous version, it is still possible to refer to different strengths and

dosage forms of the same medicinal product in the leaflet. The three pages with information for blind and partially-sighted people added to the new guideline, are identical to the "Guidance concerning the Braille requirements for labelling and the package leaflet" from 2005, which means there are no changes.

The Solution

It can be assumed that the amount of **space needed** to set the text along the lines of the readability guidelines will increase by **at least 30 – 40 %**.

Edelmann Leaflet Solutions GmbH offers the following solutions: Open formats of up to 980 mm length and 680 mm width can e.g. be pre-folded to the commonly used format DIN A5 to fit your assembling machines. Should your folding units, which are integrated into the packing line, be overstrained by these extremely

pre-folded products, then it is possible to use end folded products. These are: **Inserts, outserts, wired, adhesive-bound** as well as **glued booklets**, or different special solutions. These products can be sealed with a perforated adhesive label or glue dot to ensure a safe processing.

Practical example (you formats can also be realized):

open format: 210 mm x 890 mm, closed format: 210 mm x 297 mm
open format: 888 mm x 150 mm, closed format: 28 mm x 150 mm
open format: 530 mm x 980 mm, closed format: 132,5 mm x 75,4 mm
open format: 500 mm x 850 mm, closed format: 50 mm x 65 mm
open format: 252 mm x 702 mm, closed format: 28 mm x 54 mm

These examples correspond to current orders. Further variations are possible. Send us your inquiry.

Send us your requirements, we will find a solution!

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