New Font Size Requirements in Package Inserts of Medicines

Advantages and disadvantages

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Abstract

The readability guideline, updated in January 2009, contains various changes particular to package inserts, such as the use of a minimum 9 pt font size. Readability test study results using two package inserts, printed in different font sizes between 7 and 16 pt, clearly illustrate that the new minimum font size will improve readability and usability of this important patient information; particularly so, given that the newly recommended minimum falls into the optimal font size range of between 9 to 11 pt.

Zusammenfassung

Neue Bestimmungen zur Schriftgröße bei Packungsbeilagen
Die im Januar 2009 aktualisierte Readability Guideline enthält verschiedene Änderungen, die besonders die Packungsbeilagen betreffen, wie der Gebrauch der Mindestschriftgröße von 9 pt. Eine Lesbarkeitsteststudie mit zwei Packungsbeilagen, gedruckt in Schriftgrößen von 7 bis 16 pt, zeigte deutlich, dass die neue Mindestschriftgröße die Lesbarkeit und Benutzerfreundlichkeit dieser Patienteninformationen verbessern wird, da sie im Bereich des Optimums zwischen 9 und 11 pt liegt.

Introduction

The new "Guideline on the readability of the labelling and package leaflet of medicinal products for human use", short "readability guideline", was published by the European Commission on 12th of January 2009 [1]. It is valid in each European Union Member State and replaced the old version from September 1998, terminating the extensive discussion surrounding the draft readability guideline published in September 2006 [2, 3]. The main aim of this guideline is to assist pharmaceutical companies to better write and design package inserts and to improve labelling and packaging of medicines, so that they are more easily comprehensible and user friendly. However, the readability guideline is a recommendation according to the Community contract of the European Union, article 249 [4], and therefore not binding.

One of the most important changes concerns the 9 pt minimum font size measured in Times New Roman. For marketing authorisation applications up until 1st of February 2011, a transitional period shall apply during which the old minimum font size of 8 pt continues to be acceptable [1, 2]. With the newly-required 9 pt minimum font size, the European Commission puts PAINT-Consult's recommendation, published in Pharm. Ind. of May 2008 [5], into practise while distancing itself from its 2006 draft guideline requiring minimum font sizes in package inserts of between 12 and 20 pt [3].

PAINT-Consult's 9 pt minimum font size recommendation is based on the company's own font size study [5]. An additional analysis of this study illustrates further advantages and disadvantages of the new font size demands.

Method

The font size study was performed in 2007 at different locations in Thuringia (Germany). Each participant evaluated one of two telmisartan package inserts. The first was available on the German medicine market (the original version, n = 1359 words). The second was a model version (n = 579 words), the original package insert optimized using a set of 104 quality criteria. Both versions were printed in every Arial font size from 7 to 16 pt – except 15 pt – using a single spacing [5]. The layout, content, wording, number and print types per line were identical in each original.

The only differences were font size and format size. The same applied to the model package insert.

A minimum of 5 adolescents aged 13 to 19 years and 5 people aged 50 years plus were recruited for each package insert and font size, as according to the PAINT1 survey, both groups have slightly more difficulty locating and understanding the information provided in package inserts [6]. It is important to note that visually impaired people were not excluded from this study.

The written readability test method, as validated in the PAINT1 survey [6], was used here as it is an accepted test procedure across the European Union [1, 7] and avoids negative influences on the results – such as due an interviewer's facial expressions or gestures – in comparison to verbal interview test methods.

The questionnaire used requested demographic data, followed by 15 questions relating to the package insert's key content and, afterwards, to 17 statements concerning participants' personal opinions about the package insert. The following three categories were used to evaluate the answers relating to all 15 content questions:

A) percentage of information not located
B) percentage of information not comprehended
C) time needed to answer all 15 content questions

A fourth category concerns the section which addressed the participants' opinions about the package insert. Each participant used a scale with five categories to assess different aspects of the comprehensibility, legibility, complexity of information, clarity and structure, as well as their confidence in the described medicine. The answers were coded as follows: "yes" = 1 (best mark) up to "no" = 5 (worst mark). Medians were calculated for each of the 17 statements, before the means per package insert and font size were determined.

The final step involved applying ranges to each of the four categories, for both the original package insert group and for the model package insert group. The font size of the original package insert with the lowest percentage of "not found" information was ranked "1"; as shown in Table 1; while the font size version with the highest percentage was awarded the worst rank mark of "9".

Table 1

Percentage of requested information which was not located (averages), the time needed to answer all 15 content questions (calculated medians), percentage of information not comprehended of the located contents (averages) and the participants' personal opinions (mean of the calculated medians from the 17 statements), itemized for each original and model package insert and respective font size [5].

Font size [pt]	Percentage of information not located				Time needed to answer all 15 content questions				Percentage of information not comprehended				Personal participants opinions concerning all 17 statements*				Number of participants	
	Original		Model		Original		Model		Original		Model		Original		Model		Original	Model
	[%]	Rank	[%]	Rank	[%]	Rank	[%]	Rank	[%]	Rank	[%]	Rank	[%]	Rank	[%]	Rank		
7	9.8	**5**	5.7	**7**	14.5	**6**	12.0	**7**	19.0	**3**	10.8	**4**	2.26	**6**	1.92	**9**	13	14
8	8.5	**2**	6.7	**9**	15.0	**7**	11.0	**6**	27.2	**9**	9.8	**2**	2.12	**3**	1.69	**5**	11	12
9	12.1	**7**	3.4	**4**	13.6	**4**	10.0	**1**	27.0	**8**	10.4	**3**	2.02	**1**	1.61	**4**	11	12
10	9.1	**4**	3.0	**2**	12.7	**2**	10.0	**1**	20.6	**4**	11.3	**6**	2.47	**8**	1.57	**2**	11	11
11	12.2	**8**	2.8	**1**	13.9	**5**	10.6	**4**	15.0	**1**	11.6	**7**	2.10	**2**	1.59	**3**	11	12
12	6.7	**1**	3.0	**2**	13.0	**3**	10.8	**5**	24.3	**7**	11.4	**8**	2.34	**7**	1.53	**1**	11	11
13	10.9	**6**	4.4	**5**	15.0	**7**	12.7	**8**	18.5	**2**	9.2	**1**	2.22	**5**	1.70	**6**	11	12
14	8.7	**3**	6.0	**8**	15.0	**7**	10.5	**3**	21.8	**5**	14.7	**9**	2.19	**4**	1.86	**8**	11	10
16	16.0	**9**	4.8	**6**	11.8	**1**	13.7	**9**	22.9	**6**	10.9	**5**	2.54	**9**	1.85	**7**	10	11
total	10.4	–	4.4	–	13.8	–	11.1	–	21.3	–	11.0	–	2.25	–	1.70	–	100	105

* Ranges of assessment scales for participants' personal opinions of the package inserts: 1.00 to 1.50 = "yes" (best mark), 1.51 to 2.50 = "mostly yes", 2.51 to 3.50 = "other", 3.51 to 4.50 = "mostly no", 4.51 to 5.00 = "no" (worst mark).

Pharm. Ind. 72, Nr. 12, 2032–2036 (2010)

Results

In total, 205 people participated in this study (age: 13 to 88 years; 63.5 % female; 109 adolescents and 96 adults aged 50 years plus).

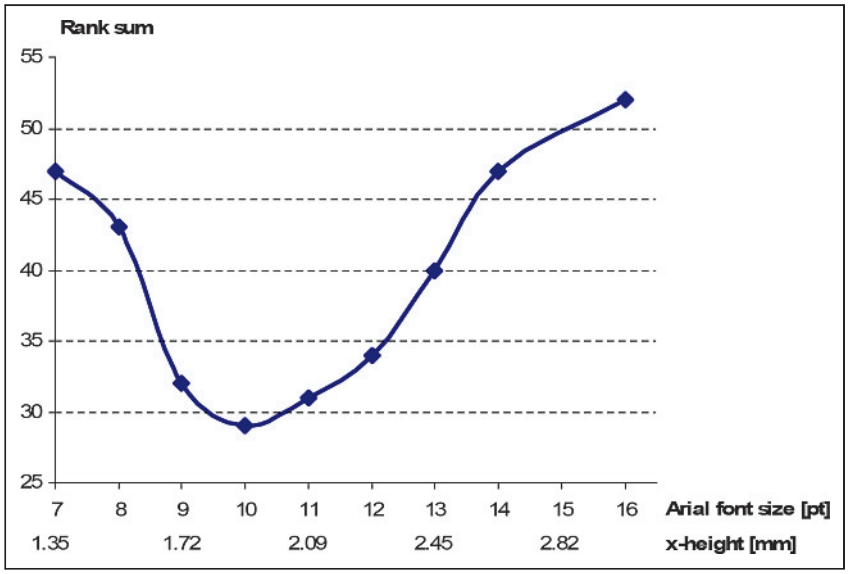
In all four categories, as well per font size, the model package insert group showed better results than the original package insert group (Table 1). Using the Mann-Whitney U-test, the totalled results between the original and model package inserts were always significant. This was often additionally significant in each font size investigated [5].

In the category "time needed to answer all 15 content questions" advantages were found in font sizes between 9 and 12 pt for both package inserts. This also applied to the model package insert in the categories "percentage of information not located" and "participants' opinions" (Table 1). However, differences in the results between the nine font sizes investigated in each of the four categories, itemized per package insert, were not significant (H-test after Kruskal-Wallis).

The rankings presented in Table 1 were added for each font size tested. The results clearly depict font sizes between 9 and 11 pt printed in Arial as the optimal range for package inserts (Fig. 1). The improvement caused through use of these medium font sizes becomes more apparent through an overall view of the package insert. Increasing or decreasing font sizes outside the optimal 9 to 11 pt range serves only to reduce the usability of package inserts.

Further to this, simply calculating the rank sum once for the adolescents and once for the adults aged 50 years plus, illustrates that for both participant groups these medium font sizes are the most appropriate for use in package inserts. Again, use of smaller or larger font sizes only led to a decrease in the package inserts' usability, regardless of the participant's age group.

■ **Figure 1**



Rank sum of the percentage of information not located, the time needed to answer the 15 content questions, the percentage of information not comprehended and the mean of the personal opinions (Table 1) from the original, as well as the model package insert, itemized for each Arial font size / x height.

Arial font size [pt]	Rank sum	Arial font size [pt]	Rank sum
7	47	12	34
8	43	13	40
9	32	14	47
10	29	16	52
11	31		

Discussion

The summarized results provided in Fig. 1 clearly demonstrate that using minimum 9 pt font size leads to an improvement of package inserts in comparison to the 8 pt font size of the old readability guideline. Using font sizes of between 12 and 20 pt, as stated in the readability guideline draft from December 2006 [3], would reduce the usability of package inserts and, therefore, it is deemed a good decision to withdraw these large fonts.

Additionally, the 9 pt font size can be more readily introduced, requiring fewer adaptations to packaging than larger fonts. It must also be noted that using the 9 pt font size allows for more words per line than larger fonts, thereby avoiding hyphenation [5]. As well as this, the 9 pt font size package insert format will be more patient friendly than would be the case with the revoked readability guideline draft font size. For example, the original package insert used for this study – which contained 1 359 words – required a paper format of around A4 printed on both sides, using the 9 pt font size. Increasing the font size to 12 pt led to a much larger and ungainly A3 format [5].

This is of particular importance, as the volume of texts used in package inserts increases inexorably; in the year 2000 German package inserts contained on average 1 496 words [11], this had increased to an average of 2005 words within five years – an increase of 34 % [12]. The use of more condensed wording and greater optimisation of text volume during readability tests will avoid format increases when the font size changes from 8 to 9 pt [8]. However, it must be acknowledged, if using larger font sizes, such as those of the readability guideline draft, number of words

compressions cannot fully compensate.

We must point out that Table 1 offers evidence of the existence of further important possibilities for improving package inserts than are possible through the use of larger font sizes. For example, using the set of quality criteria which was applied to the model package insert, the total percentage of "not located" information was reduced to 42.3 % and the percentage of "not comprehended" contents to 51.6 % of the original package insert.

Other available publications recommend the use of larger font sizes, similar to the readability guideline draft [3]. However, these suggestions largely investigate a maximum of two different font sizes between 12 and 18 pt [13, 14], or result from studies which have tested labels or texts with fewer than 500 words [15–17]. Therefore, these findings cannot fully apply to package inserts, which usually have a much larger volume of text.

In contrast, studies in which a wider range of font size was tested, using larger volumes of text, have led to findings similar to those of this study, because readers require fewer eye fixations with this font size.

The new readability guideline recommendation: "A type size of 9 points, as measured in font 'Times New Roman'…" also merits critical analysis, as 9 pt Times New Roman font has an x-height of just 1.46 mm or a cap height of 2.13 mm [1]. This is much smaller than the x-height of 9 pt Arial font (1.72 mm) or its cap height of 2.94 mm; and similar to 8 pt Arial font (x-height: 1.53 mm, cap height: 2.05 mm), therefore both may be used according to the new readability guideline.

However, the figure clearly shows that 8 pt Arial font size is not included in the range of optimal font sizes. Indications exist to suggest the readability of texts is more likely to depend on a letter's height [22]. Therefore, the finding that optimal font sizes for package inserts of between 9 to 11 pt applies to Arial and may be transferred to similar large fonts, but not in generally to Times New Roman.

Conclusion

Using a minimum 9 pt font size in package inserts will especially improve the locatability of the medicine information provided and can be more readily put into practise than larger font sizes. This will also exert a positive influence on readability, thereby furthering the patient's motivation to read package inserts and increase the user's trust in the medicine. Therefore, it becomes apparent that, while noting the existence of a transitional period until 1st of February 2011, pharmaceutical companies should implement this recommendation as soon as possible.

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