

Landscape Versus Portrait Format in Package Leaflets

Which Format Is More Suitable According to Readability Test Results From the PAINT3 Study?

Jörg Fuchs^{1,2}, Elke Anna Götze¹, Christin Voigt¹

¹PAINT-Consult®, Jena, Germany

²Department of Drug Regulatory Affairs at the Institute of Pharmacy, University of Bonn, Bonn, Germany

Corresponding author: Dr. Jörg Fuchs, PAINT-Consult®, Wenigenjenaer Ufer 12, 07749 Jena, Germany; e-mail: joerg.fuchs@paint-consult.com

■ ABSTRACT

Since 2009, the readability guideline has recommended the use of a landscape layout in package leaflets of medicines. However, no evidence-based research exists to support this specification. The readability test study provided in this article investigated the readability of landscape format in comparison to other formats.

The optimised package leaflets texts of 3 different medicines were each printed using identical layout and design, and in each of the following 4 formats – landscape, portrait (once single-column and once 2 columns per page) and booklet. In addition, 2 package leaflets with similar text available on the German market in 2005 were investigated – whereby one used landscape and the other portrait format. Each package leaflet was investigated using the written readability test method, consisting of a questionnaire containing 25 questions relating to the package leaflets' contents. The 234 participants significantly located and understood more information, required less time to find the 25 requested contents and had better opinions about the optimised package leaflets in comparison to both leaflets available on the German market ($p \leq 0.001$). However, no significant advantage or disadvantage presented for any one of the 4 investigated formats was found.

This finding negates the readability guideline's stated preference for the landscape format. As such, it is requested that the European Commission deletes this unqualified recommendation as soon as possible, as other formats, like portrait format, are similarly appropriate for use in package leaflets.

■ KEY WORDS

- package leaflet
- package insert
- readability test
- landscape format
- portrait format

Pharm. Ind. 78, No. 8, 1178–1184 (2016)

■ ZUSAMMENFASSUNG

Querformat versus Hochformat in Packungsbeilagen – Welches Format ist besser geeignet entsprechend der Lesbarkeitstestergebnisse der PAINT3-Studie?

Seit 2009 empfiehlt die Readability Guideline den Gebrauch des Querformats in Packungsbeilagen von Arzneimitteln. Jedoch existiert keine evidenzbasierte Untersuchung, die diese Vorgabe unterstützt. Die Lesbarkeitsteststudie dieses Artikels untersuchte die Lesbarkeit des Querformats im Vergleich zu anderen Formaten.

Die optimierten Texte der Packungsbeilagen dreier verschiedener Arzneimittel wurden jeweils in identischem Layout und Design und in den folgenden 4 Formaten gedruckt: Querformat, Hochformat (ein- und zweispaltig) und Booklet. Zusätzlich wurden 2 Packungsbeilagen mit ähnlichem Text untersucht, die im Jahr 2005 auf dem deutschen Arzneimittelmarkt verfügbar waren, wobei eine das Querformat und die andere das Hochformat nutzte. Jede Packungsbeilage wurde im schriftlichen Lesbarkeitstest mit einem Fragebogen geprüft, der 25 Fragen zum Inhalt der Packungsbeilagen enthielt. Die 234 Teilnehmer hatten signifikant mehr Informationen gefunden und verstanden, benötigten weniger Zeit die 25 erfragten Inhalte zu finden und hatten eine bessere Meinung bei den optimierten Packungsbeilagen im Vergleich zu beiden Versionen verfügbar auf dem deutschen Arzneimittelmarkt ($p \leq 0,001$). Jedoch bestanden keine signifikanten Vor- oder Nachteile zwischen den 4 untersuchten Formaten.

Dieses Resultat disqualifiziert die in der Readability Guideline aufgeführte Präferenz des Querformats. Deshalb wird die Europäische Kommission gebeten, diese unqualifizierte Empfehlung so zeitnah wie möglich zu entfernen, weil andere Formate wie das Hochformat ähnlich gut für Packungsbeilagen geeignet sind.

1. Introduction

Within the European Union, package leaflets are the most frequently used resource for patient information concerning medicines – given that they are included with every medicine package. Article 59(3) of Directive 2001/83/EC demands that package leaflets shall be “...legible, clear and

easy to use.” [1]. To ensure this aim, article 65(c) of the quoted directive mandates the European Commission to “...draw up and publish detailed guidance concerning in particular... the legibility of particulars on the labelling and package leaflet” – the so called readability guideline. Section A of the readability guideline, last updated in 2009, provides recommendations for package leaflets; relating particularly to the type size and font, design and layout, headings, print colour, syntax, style of writing, paper, use of symbols and pictograms, but also with regard to the QRD template. In the last paragraph of the layout and design section, the readability guideline recommends: “Consideration should be given to using a landscape layout which can be helpful to patients” [2]. No rationale is provided for this recommendation. In 2005, WIDO – the scientific institute of the German health insurer AOK – proposed the use of the landscape format with its model package leaflet, again without providing any evidence for this decision [3].

Any general favouritism for landscape format can only be acceptable if every package leaflet with a minimum of 1 mm greater width than height outperforms a portrait or quadratic format equivalent. This also includes extremely wide landscape formats, such as 1 m or more and just a few centimetres high. Taking a logical perspective, the benign acceptance of the superiority of the landscape format is unrealistic and impossible to justify – therein calling its virtuous position into serious question.

Beil et al. used a readability test to investigate 2 package leaflets in landscape format and the other in portrait, with 20 participants each. No significant differences in locatability and comprehensibility were found across the 3 investigated leaflets, even though one of the landscape formats used 11pt font size, with both remaining versions presented in 8pt. In response to the question “Which of the leaflets would you prefer?” under simultaneous presentation of all 3 leaflets, 48 of the 60 participants favoured the landscape format; almost mirroring the proportion of both formats used – 2/3 landscape versus 1/3 portrait – which can be additionally explained by the larger font size used in one landscape package leaflet [4]. Thus, this outcome cannot be used as evidence to promote the benefits of landscape over portrait format in package leaflets.

In the year 2000, Hartley and Johnson published their readability test study of the landscape and portrait format involving 20 householders. They found that: “Both of the leaflet designs were equally effective in conveying their information. There was no difference between the accuracy of information retrieval and between the times taken to find the information, and the preferences for the different designs were equally divided” [5].

An intensive search has failed to yield any other reliable published research relating to the question of which package leaflet format – landscape or portrait – is more

appropriate for patients. Regardless of the poor data situation, the prevalence of the use of landscape format has become more and more propagandised – probably as a result of the recommendation in the readability guideline.

This lack of research has prompted the authors to publish the results of their PAINT3 study which, amongst many other areas, deals with the question of which package leaflet format is most appropriate when using package leaflets.

2. Materials and Methods

All 271 package leaflets used in the PAINT2 study – a random selection of all package leaflets available in the year 2005 in the German market [6] – were tested for readability in the PAINT3 study. In addition, 24 model package leaflets of 3 widely used medicines (repaglinide, enalapril, insulin – in total 8 model package leaflets per medicine) were developed for the PAINT3 study using a set of 152 quality criteria [7]. With the aim of assessing the appropriateness of different formats, half of the model package leaflets were printed in the following 4 different formats – each using 9pt font size in non-heading texts:

1. landscape format using 5 columns on each of the 2 pages (width: 297 mm, height: 210 mm)
2. portrait format using 2 columns on each of the 2 pages (width: 173 mm, height: 240–252 mm)
3. portrait format using one column on each of the 2 pages (width: 173 mm, height: 340–403 mm)
4. booklet (width: 95 mm, height: 50 mm, 20 or 24 pages)

Within each group of the 3 medicines, the model package leaflets used identical wording and design (printed in colour on light yellow paper). As a result the only difference in the model package leaflets within each of the 3 medicine groups was the different format used to ensure comparability of the results between the formats (Fig. 1).

All PAINT2 study and model package leaflets (in total: 295) were investigated between September 2008 and May 2009 using the written readability test – also known as ‘self-completion method’ – as this method is accepted within the European Union and eliminates the external negative influences which may occur in the Australian face-to-face interview [8]. The questionnaire from the PAINT1 study was used (one per medicine), in which the number of questions relating to the package leaflets’ key contents was increased from 15 to 25, with 18 additional statements covering participants’ opinions of the package leaflets to extract more data [7].

The participants were recruited in various public facilities – such as community centres – in Jena and Weimar (Germany). Each one tested just one package leaflet in German, using only the written instructions provided in the questionnaire, under one tester’s supervision. In accordance with predefined criteria, a minimum of 15 people must be recruited per package leaflet version, healthcare professionals excluded.

All data retrieved was coded and inserted into a SPSS 16.0 statistic program table via double data input for checking. Percentages of information found and correctly comprehended, as well as medians of the time required to locate the 25 key messages, were calculated per package leaflet.

The 5 point scale listed in Table 1 was used to calculate medians for each of the 18 participants’ assessments relating to the package leaflets’ comprehensibility, legibility, complexity of information, clarity and structure, as well as their trust in the relevant medicine.

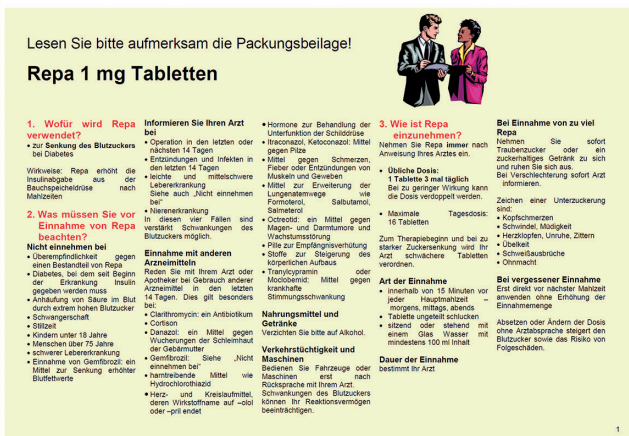


Figure 1: Examples of a model package leaflet investigated in the PAINT3 study, using the portrait format with 2 columns and the landscape format (Source: all figures and tables were made by the authors/PAINT-Consult®).

Table 1

Comparison of the locatability, comprehensibility and participants' opinions, itemised according to the package leaflet format used.

Format	Active substance	Results to 25 content questions			Average of 18 statements seeking participants' opinions*	Average age of participants (years)	Number of participants (n)
		Percentage understood of found information (%)	Percentage of found information (%)	Time to locate 25 pieces of information (calculated median; min)			
Model package leaflets, coloured							
landscape, 5 columns (see Fig. 1)	repaglinide	91.2	92.8	19.0	1.7	39	16
	enalapril	89.4	90.0	20.0	1.9	34	19
	insulin	89.8	91.0	19.3	1.8	33	17
portrait, 2 columns (see Fig. 1)	repaglinide	93.0	95.8	15.4	1.7	33	17
	enalapril	93.4	96.8	18.5	2.0	33	16
	insulin	89.8	92.7	25.0	2.0	39	17
portrait, 1 column	repaglinide	94.5	97.3	19.0	1.7	41	16
	enalapril	87.2	89.3	17.0	2.0	40	16
	insulin	88.1	92.2	19.4	1.8	39	17
booklet	repaglinide	94.2	96.8	15.3	1.7	26	16
	enalapril	91.5	91.5	18.0	1.8	33	17
	insulin	88.9	93.3	20.4	1.7	36	16

Package leaflets available on the German market in 2005, black print on white paper

landscape, 2 columns	sulpiride 50 mg	82.6	87.4	26.8	2.7	31	18
portrait, 1 column	sulpiride 200 mg	79.6	90.5	27.5	2.8	34	16

Word count of package leaflets: repaglinide (682 words), enalapril (849 words), insulin (835 words), sulpiride 50 mg (1 953 words, last updated: January 2001), sulpiride 200 mg (2 060 words, last updated: June 1999).

*Code of participants' opinions: "yes" = 1, "mostly yes" = 2, "other" = 3, "mostly no" = 4 and "no" = 5, whereby "yes" was the preferred answer.

The Kruskal–Wallis H test was used as a global test to calculate significant differences between the 4 formats provided in Table 1 of the model package leaflets, within each group of the 3 medicines. The Mann–Whitney U test was used to assess whether significant differences exist between 2 single package leaflets.

3. Results

In total, 5091 people aged between 11 and 93 years participated in the PAINT3 study (average age: 37 years). The most important result of the PAINT3 study was that the volume of text of package leaflets exerted the highest influence on the usability of this patient information; such that increasing the number of words in package leaflets significantly increases the time to locate information, reduces the comprehensibility, motivation to read the provided contents and trust in using the medicines ($p < 0.001$, Spearman's rank correlation). This major influence of the volume of text and that of other factors inhibits a comparison of readability test results of all package leaflets using landscape format against those in portrait format, as package leaflets using landscape format available on the German market in 2005 were – with an average of 1689 words – significantly shorter than those using portrait format (2125 words, $p = 0.003$ [Mann–Whitney U test]).

Therefore, the assessment of the PAINT3 study readability test results relating to the appropriateness of the format used focused on the one hand on the 3 quartets of model package leaflets mentioned in the “Materials and Methods” section and Table 1. On the other hand, the group of 271 package leaflets available on the German market in 2005 was investigated in relation to very similar texts – printed once in landscape format and once in portrait format. In the latter case, only one pair could be found which applied to 2 sulpiride package leaflets (Table 1).

Table 2 provides the demographic data of participants in the PAINT3 study who used a model package leaflet with one of the 4 formats mentioned in the Materials and Methods section of this article, or one of both sulpiride package leaflets available on the German market. Both groups showed similar characteristics. However, the group of participants that tested one of the model package leaflets achieved, in each of the following 4 parameters, significantly better results than the group using a sulpiride package leaflet ($p \leq 0.001$, Mann–Whitney U test; Table 1):

- percentage of located information
 - percentage of understood information
 - time required to locate the 25 pieces of information requested
 - participants' opinions of the tested package leaflets
- The testing of the results between the 4 package leaflet formats provided in Table 1, within the group of repagli-

nide model package leaflets, showed no significant differences in the percentages of located and understood information, the time required to find 25 information and participants' opinions of the package leaflets. Also within these parameters, no significant differences were found between the tested formats in the group of enalapril and insulin model package leaflets, as well as between both sulpiride package leaflets.

4. Discussion

The PAINT3 study results show that the format – landscape or portrait – has no significant influence on the readability and usability of package leaflets. This was found to be the case in short package leaflets – according to the results of the investigated model package leaflets – and in longer versions, as illustrated with both sulpiride package leaflets. That landscape and portrait formats are equally effective in short package leaflets is confirmed by the results of Hartley and Johnson, mentioned already in the introductory section of this article. They investigated both formats using the 148×210 mm paper size and approximately 12pt font size [5]. The study of Beil et al., based on a morphine package leaflet text containing 2449 words, confirms the authors' findings concerning longer versions [4].

Within each group of the 3 medicines with a model package leaflet, the readability test results provided in Table 1 are consistent. This applies also to both sulpiride versions. The slightly higher locatability time in the case of the insulin package leaflet with 2 columns and portrait format can be assessed as an outlier, as it did not display any significant disadvantage in comparison to other formats. Such eventualities were factored into the decision taken prior to the study to calculate a median rather than a mean. The median calculation minimises the influence of extreme levels precipitated by test participants who have difficulty using texts. It has been the authors' experience in extensive readability testing that those persons usually require more time.

The booklet showed similarly good results to other investigated formats. However, these cannot be transferred to longer versions and no reliable readability test research on booklets with long texts has been found. Furthermore, when opening a booklet the reader sees only 2 pages; which, in the case of 20 pages, constitutes 10 % of the text – as compared to 50 % in package leaflets with 2 pages. The results suggest that this is not a disadvantage in the case of short texts. However, package leaflets have on average over 2000 words [6, 9] and the percentage of text visible to users on 2 pages reduces concomitantly as more booklet pages are required.

It cannot be excluded that significant differences might occur if the number of participants per package leaflet were greatly increased in comparison to those in-

■ Table 2

Characterisation of participants considered for the format investigations of the package leaflet readability test.

Participants' characteristics		Participants who tested	
		model package leaflets	sulpiride package leaflets
Participants		n = 200	n = 34
Age		13–79 years	17–66 years
Average age		36 years	32 years
Gender	Female	58.5 %	61.8 %
	Male	41.5 %	38.2 %
Residence	Germany	100 %	100 %
Mother language	German	92.4 %	87.5 %
	Other than German	7.6 %	12.5 %
Education	8 th class	10.6 %	8.8 %
	10 th class	29.6 %	32.4 %
	A-level	33.7 %	38.2 %
	Technical college	12.1 %	5.9 %
	University	14.1 %	14.7 %
Number of medicines used daily	No drugs	52.8 %	50.0 %
	1 drug	23.1 %	29.4 %
	2 drugs	13.1 %	11.8 %
	3–4 drugs	8.0 %	2.9 %
	5–7 drugs	2.0 %	2.9 %
	8–10 drugs	1.0 %	-
	more than 10 drugs	-	2.9 %
Use of medicines with indication similar to tested package leaflet	yes	8.7 %	3.0 %
	no	91.3 %	97.0 %
Average time of reading per day	≤ 0.5 hours	19.0 %	18.2 %
	1 hour	33.0 %	30.3 %
	more than 1–2 hours	26.5 %	27.3 %
	3–4 hours	15.5 %	18.2 %
	5–7 hours	5.5 %	-
	more than 7 hours	0.5 %	6.1 %
Frequency of hearing, watching and reading medical reports	none	29.6 %	33.3 %
	1 per week	33.2 %	54.5 %
	2 per week	19.9 %	12.1 %
	3–4 per week	11.2 %	-
	5–7 per week	6.1 %	-

cluded in this study and the quoted research. Nonetheless, this would not change the finding that a general preference for landscape format in package leaflets is unfounded.

More notable is the fact that the results point to other factors – particularly using shorter texts and a systematic optimisation – as significantly more important for im-

proving the readability of package leaflets. In this context, line length also merits to be mentioned as an important factor in selecting an appropriate format, as this significantly influences the legibility. The DIN1450 norm recommends a line length of up to 80 characters per line (including spaces), whereby larger font sizes require longer lines than small fonts [10, 11]. Tinker and Paterson

■ Table 3

Comparison of averages of the PAINT2 study package leaflets itemised per format used [14] (The PAINT2 study analysed a representative selection of 271 package leaflets of all versions available in 2005 on the German market [6]. The levels of the single booklet, one multilingual and 4 quadratic package leaflets are not provided in this table due to their low number of cases).

	Portrait format (n = 204)			Landscape format (n = 61)				
	1 column	2 columns	3 columns	1 column	2 columns	3 columns	4 columns	5–14 columns
Number of package leaflets	77	122	5	5	18	14	10	14
Number of characters per package leaflet ^{a)}	10995	17440	19091	4765	7537	12479	12359	18691
Characters per 100 cm ² surface ^{a), b)}	1186	1616	1448	878	1237	1476	1350	1063
Line height (mm)	2.86	2.74	2.95	3.00	2.75	2.84	2.88	3.24
Font size (mm) ^{b)}	2.42	2.33	2.53	2.47	2.39	2.36	2.32	2.67
Line length (mm)	108	68	64	107	88	75	70	61
Characters per line	101	59	49	111	82	73	61	50
Number of hyphenations per 1000 words	12	40	42	6	8	26	20	41
Number of column and page breaks in sections and paragraphs	0.6	2.1	3.4	0.4	2.1	3.3	3.7	7.4

^{a)}The number of characters does not include space. 1000 characters equate to, on average, 141 words.

^{b)}Blank areas at the end of package leaflets were excluded before the calculation.

^{c)}Font size measured from ascender to descender line.

investigated a text in 10pt font size printed in 7 line lengths (59, 80, 97, 114, 152, 168 and 186 mm), with 80 students per length. Participants with 80 mm line length had the highest speed of reading; therefore, both authors recommended a line length between 75 and 90 mm when using 10pt font size [12]. Using 9pt font size printed in 5 different line lengths and testing with 2000 students, both authors recommended a line length between 67 and 101 mm for 9pt font size and 1 to 2pt space between lines. Longer and shorter lines caused lower reading speeds [13].

According to PAINT2 study results already provided in Pharm Ind 10/2015 and again in Table 3, using landscape format does not ensure an optimal line length. In addition, 2005 was a year when 75.3 % of German package leaflets were presented in portrait format rather than landscape (22.5 %) [6]. An evaluation – of 138 package leaflets of all PAINT2 study versions that could be obtained in the year 2015 – showed a similar allocation of format use; 73.2 % portrait and 25.4 % landscape format [15].

Furthermore, the PAINT2 study results showed that:

- package leaflets with portrait format and 2 columns per page are most effective in saving space as they ac-

commodate significantly the highest number of characters per printed area ($p \leq 0.001$), caused by less blank areas compared to landscape package leaflets with more columns per page or formats with single columns that used overly long lines

- increasing the volume of text causes an increase of columns used ($p < 0.001$) – independent of the format
- an increasing number of columns causes an increase in the number of page and column breaks in paragraphs ($p < 0.001$)

According to available research, such breaks reduce the locatability and comprehensibility of provided information [16, 17]:

- increasing the number of columns decreases line length, measured as number of characters per line or in mm ($p < 0.001$)
- with decreasing line length, the number of hyphenations per 1000 words significantly increased ($p < 0.001$)

According to the provided PAINT2 study results, an advantage exists for the portrait format rather than landscape. Particularly, under consideration of the ongoing increase in the volume of text [6, 9], the 2 column portrait format is the most effective space saving format.

5. Conclusion

No reason exists for the general favouritism towards landscape format in package leaflets as published in the readability guideline. Given the evidence presented, the authors earnestly trust that the European Commission share their consideration to delete the relevant landscape recommendation as soon as possible.

REFERENCES

- [1] The European Parliament and the Council of the European Union. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use – as amended by Directive 2002/92/EC, Directive 2004/24/EC, Directive 2004/27/EC. Official Journal of the European Communities. 2007 Nov;50(L311):67–128.
- [2] European Commission. Guideline on the readability of the labelling and package leaflet of medicinal products for human use. [cited 2016 May 17]. Available from: http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf
- [3] Nink K, Schröder H. Zu Risiken und Nebenwirkungen: Lesen Sie die Packungsbeilage? Bonn: Wissenschaftliches Institut der AOK (WiDO), 2005. [cited: 2016 May 17]. Available from: http://wido.de/fileadmin/wido/downloads/pdf_arzneimittel/wido_arz_pub-packbeila2005_0908.pdf
- [4] Beil C, Menges K, Linz B, Dobmeyer T. Lesbarkeitstests von Packungsbeilagen. Pharm Ind. 2008 Nov;70(11):1323–31.
- [5] Hartley J, Johnson M. Portrait or landscape? Typographical layouts for patient information leaflets. Visible language. 2000 Jan;34(3):296–309.
- [6] Fuchs J, Werner S, Scheunpflug C, Götze EA, Elstermann K, Scheffel K, et al. Excessive medical information increase in package leaflets. Int J Clin Pharmacol Ther. 2010 Dec;48(12):781–90.
- [7] Fuchs J. Die Packungsbeilagen als ein Mittel zur gezielten Information und Handlungsanleitung für Patienten – Entwicklung und Testung eines Instrumentes zur Beurteilung und Optimierung der Packungsbeilagen von Arzneimitteln [Package leaflets as medium to convey targeted information and directions for use to patients: Developing and testing a tool to assess and optimise pharmaceutical product package leaflets – dissertation]. Humboldt University Berlin, 2005. [cited 2016 May 20]. Available from: http://www.paint-consult.com/fileadmin/editorial/downloads/publikationen/Pro motionsarbeit_Dr_Fuchs.pdf
- [8] CMD(h). Position paper on user testing of package leaflets – Consultation with target patient groups (Compliance with article 59(3) of Council Directive 2001/83/EC), Doc. Ref.: CMDh/234/2011 – February 2011. [cited 2016 May 22] Available from: http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Consultation_PatientsGroups/CMDh_234_2011.pdf
- [9] Wolf A, Fuchs J, Schweim H. Implementation of the European QRD template in package leaflets of centralized approved medicines. Therapeutic Innovation & Regulatory Science. 2016;50(1):106–14.
- [10] Deutsches Institut für Normung. DIN 1450:2013-04. Lettering – Legibility. [cited 2016 May 20] Available from: <http://www.beuth.de/norm/din-1450/170093157?SearchID=494580178>
- [11] Poulton E. A note on printing to make comprehension easier. Ergonomics, 1960;3(3):245–8.
- [12] Tinker M, Paterson D. Studies of typographical factors influencing speed of reading – III. Length of line. J Appl Psychol. 1929;13(3):205–19.
- [13] Tinker M, Paterson D. Speed of reading nine point type in relation to line width and leading. J Appl Psychol 1949;33:81–2.
- [14] Fuchs J, Kutscha M. Handling des stetigen Textzuwachses in Packungsbeilagen. Pharm Ind. 2015;77(10):1438–45.
- [15] Fuchs J, Kraft S, Vettermann A, Reiche M. Publication in press.
- [16] Azodi K, Himstedt S, Hinrichs A, Krüger M, Schrader S, Schulz M. Testing of the readability of package leaflets as an initial step under the pharmaceutical care initiative towards increasing the safety of medicinal products. Pharm Ind. 2002;64(11):1119–25.
- [17] Fuchs J, Hippus M. Inappropriate dosage instructions in package leaflets. Patient Educ Couns. 2007;67:157–68.