Validation of a new tool to evaluate the readability of Package Leaflets of medicines: LiS-RPL

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Background: Regulations of European Medicine Agency require Package Leaflets of medicines (PLs) to be clear and understandable. However, the number of tools to evaluate the readability of this type of health documents is very limited. Aim: to validate a tool for evaluating subjects' perception and satisfaction on the readability of PLs (LiS-RPL).

Methods: This study was carried out in 2 Portuguese regions (Lisbon and Centre). Overall, 503 participants (53.1% male) were conveniently selected. They were purposively and homogenously distributed per three groups of education: 1 to 6; 7 to 12; and >12 years of schooling. LiS-RPL is a Likert-Scale that was pre-tested in a previous study (Table 1). It was developed in line with the requisites of the *European Guideline on the readability of package leaflets of medicines*. *This tool was initially composed of 14 Items. Participants were required to evaluate 12 randomized PLs with LiS-RPL. An exploratory Factor analysis (EFA) was applied to evaluate dimensionality. Also, a minimum rank Factor analyses (PA-MRFA) was carried out. The adequacy of the matrix for EFA was evaluated with KMO index and Barlett's test of sphericity. The possible existence of a broad second-order Factor was analysed based on an Exploratory Bifactor Analysis (EBA) with Schmid-Leiman Solution. Factor simplicity was checked with Bentler's Simplicity Index (BSI) and Loading Simplicity Index (LSI). Reliability was proved through the application of diverse coefficients.

Conflict of interests: None

* https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf

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Table 1. Descriptive Statistics for the Items of the LiS-RPL (N = 469)† Each item was classified with a 1-5 Likert-scale to level of satisfaction/perception: 1 = Poor; 2 = Not very satisfied; 3 = No opinion; 4 = Satisfied; and 5 = Good

Items of LiS-RPL †	Mean	Standard deviation	Skewness	Kurtosis
Item 1 - Font size	3.47	1.44	-0.55	-1.14
Item 2 - Font type	4.13	1.11	-1.38	1.13
Item 3 - The layout of the title of the sections	4.07	1.02	-1.11	0.62
Item 4 - Colour of the text	4.30	.95	-1.53	2.20
Item 5 - Line spacing	3.85	1.23	-0.86	-0.45
Item 6 - The use of the en-dash throughout the text	4.14	.98	-1.22	1.21
Item 7 - Clarity of the text	3.84	1.16	-0.91	-0.90
Item 8 - Length of the sentences	4.03	1.08	-1.05	0.33
Item 9 - Number of sentences in each paragraph	4.02	1.13	-1.07	0.30
Item 10 - The description of possible side effects	3.90	1.10	-0.87	-0.17
Item 11 - The comprehensibility of medical terms	3.66	1.17	-0.56	-0.74
Item 12 - The clarity of the instructions to the user	3.96	1.07	-0.99	0.24
Item 13 - The use of abbreviations throughout the text	3.45	1.18	-0.31	-0.78
Item 14 - The repetition of the brand name of the medicine throughout the text	4.01	1.01	-0.98	0.46

Findings: A two-Factor and a single-Factor structure was detected with PA-MRFA. EFA with 12 Items showed a two-Factor structure, explaining 69.11% of variance. They were strongly correlated with each other ($r = 0.80$)..

The pattern matrix from exploratory factor analysis of LiS-RPL (N=469) was as follows:

- Factor 1 Clarity and comprehension of text:** Item 12 - The clarity of the instructions to the user ($h^2=.74$); Item 11; The comprehensibility of medical terms 0.9 ($h^2=.62$); Item 7 - Clarity of the text 0.81 ($h^2=.61$); and Item 10 - The description of possible side effects ($h^2 = .66$).
- Factor 2 Format:** Item 2 - Font type ($h^2 =.67$); Item 5 - Line spacing ($h^2 =.61$); Item 4 - Colour of the text ($h^2=.61$); Item 1 - Font size ($h^2 =.34$); Item 3 - The layout of the title of the sections ($h2= .55$); Item 9 - Number of sentences in each paragraph ($h^2 = .68$); Item 8 - Length of the sentences ($h^2 = .62$) and Item 6 - The use of the en-dash throughout the text ($h^2 =.55$).

Schmid-Leiman analysis. all Items seemed to represent the general Factor (loadings above .50). General Factor explained 76.4% of the variance.

Factor simplicity indices: BSI = 0.99 (percentile 99) and LSI= 0.48 (percentile 99). Internal consistency indexes indicated a good reliability. LiS-RPL was considered homogeneous

Discussion and conclusions: LiS-RPL was validated. A new tool thus becomes available to evaluate the satisfaction/perception PLs in the Portuguese market by potential users. LiS-RPL may be useful for the evaluation of PL that already exist or those to be introduced in the Portuguese market.