

**Consumer perceptions and satisfaction with medication labelling:
Recommendations to improve its readability and comprehensibility.**

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Consumer perceptions and satisfaction with medication labelling: Recommendations to improve its readability and comprehensibility.

This study explored consumer perceptions and satisfaction with medication labelling, focusing on the readability and comprehensibility of both the packaging box and the package leaflet. Additionally, it examined the participants' stance towards some recommendations to improve the medicines' labels. 257 individuals participated in a questionnaire survey, and most of them appeared to be bothered by the readability and comprehensibility of both the medicine packaging box and the package insert. Therefore, the consumers were roughly moderately satisfied with the medicine labelling, and the majority of them strongly supported most of the proposed recommendations for its improvement. The study results also implied the existence of distinct and measurable market segments that pharmaceutical companies need to consider when designing their products' labelling. Hence, it is recommended that the regulatory authorities and the pharmaceutical industries focus more on the design of comprehensible and legible packaging labels for all market segments.

Keywords: medication labelling; readability; comprehensibility; packaging box; package insert/leaflet; satisfaction

Introduction

Medication labelling plays a crucial role in both the implementation of pharmaceuticals' branding strategy and ensuring their proper use by consumers. Medicines' packaging box and package leaflet aim to display important features of them that patients need to understand, and to provide instructions for their safe and effective consumption (Saif et al. 2024). However, medicine labelling misunderstanding is a rather common issue among patients. Medication misuse, overdose, and subtherapeutic levels are some common errors that may cause adverse events, hospital emergency room visits, hospital admissions, morbidity, and even mortality (King et al. 2011; Pons et al. 2019). Several factors contribute to medicine labelling misunderstanding, inter alia, complex language, unclear instructions, bewildering medical terms, confusing layout, small fonts, and a lack of icons (Pizzol et al. 2019; Tong et al. 2016).

All medicines' packaging distributed in the European Union, including Greece, must conform to the guidelines of Directive 2001/83/EC. Indeed, the specifications set by the regulatory authorities, regarding the information and the way it is presented in the package leaflet, are among the key drivers of the whole research and development process for new medicines. Conforming to these standards is among the most challenging prerequisites to ensuring the marketing authorization of a new medicine (Aronson and Ferner 2017). Despite the European Parliament's guidance for a clear and comprehensible package leaflet (Directive 2001/83/EC), the inclusion of a large amount of required details for the medicine's effective and safe consumption has a negative impact on its readability and comprehensibility. The latter not only results in inappropriate use by patients but also reduces customer satisfaction.

Although customer satisfaction is the fundamental criterion for building and maintaining patient (customer)-centric healthcare systems, prior published research on customer perceptions and satisfaction with medication labelling is rather limited. Most of the relevant research has been conducted in the USA (Andrews et al. 2015; Bix et al. 2016; Harben et al. 2021; King et al. 2011), Brazil (Bernardes et al. 2021; Pizzol et al. 2019; Pons et al. 2019), Sri Lanka (Jayasinghe et al. 2022; Manchanayake, Bandara, and Samaranayake 2018) or Asia (Malhotra et al. 2023; Masumoto et al. 2023), and very few in Europe (Maghroudi et al. 2020; Piñero-López et al. 2019; Spence 2021). Indeed, most of the prior research focused on the readability and/or comprehensibility issues of medication labelling and only a few on customer satisfaction (Pons et al. 2019; Murty and Sansgiry 2007).

To the best of our knowledge, based on a search in Scopus and PubMed, there is a lack of published research focusing explicitly on consumer satisfaction with medicine labelling and how this is influenced by the perceived readability and comprehensibility of the packaging box and package insert, especially from the EU, where Directive 2001/83/EC is applied. Therefore, this study aims to explore consumer perceptions and satisfaction with the

readability and comprehensibility of medication labelling. Moreover, in line with the dominant patient-centred approach of modern healthcare systems, which imposes a shift from product-centred to customer-centred product design, this survey attempts to highlight recommendations to improve the design and layout of medicine labelling.

Background

The interaction that occurs between the medicine and the patient before the medication is administered is of the utmost importance, as this interaction is essential for the patient to fully understand the information presented to him. de la Fuente and Bix (2011) combined the Human Processor Model and the Usability Theory to propose their Comprehensive Interaction Framework, which presumes the human-package interactions as a cyclic information flow, consisting of five stages; (1) exposure, (2) perception, (3) encodation, (4) comprehension, and (5) execution. Therefore, the patient's exposure to the medicine package is fundamental to administering the medicine effectively and safely.

Unfortunately, a significant portion of people find it difficult to read and understand medicine labelling despite the thorough testing that a medicine undergoes before its market access. Harben et al. (2021) found that the existence of specific information, and the way it is written and presented on a medicine label play a crucial role in patients' comprehension of the most important details, such as its purpose, effect, dosing, precautions, and adverse events. The way certain information is displayed on the medicine packaging box is central to patients' quick and proper decision-making in terms of distinguishing the medicine they intend to consume from other pharmaceutical products and its appropriate administration. Pons et al. (2019) revealed that the design of several medicine labels provoked legibility challenges. Readability and comprehensibility problems emanate from several sources, such as the use of small fonts, the odd/stylized font, the reduced number of icons on how to use the drug, the route of administration and the maximum daily dose, the use of capital letters only, and the

minimal use of bullet points for indications and warnings. Additionally, readability and comprehensibility issues may arise from the lack of graphical elements (e.g., use of colour to highlight the milligrams of active ingredient), the lack of bold writing for critical information, and the expiry date being printed in embossed form instead of black characters. However, highlighting information may prove ineffective when loads of information are displayed on the medicine's exterior packaging (Harben et al. 2021).

The package insert is a leaflet inside the medicine (exterior) packaging box, and it constitutes the fundamental and detailed source of essential information that patients have constantly access concerning the pharmaceutical product. Its main aim is to thoroughly inform patients about the medicine's proper, effective, and safe use, contributing to high levels of patient adherence to therapeutic treatment and preventing erroneous medicine use and adverse events. The leaflet design should ensure that the information is addressed to all people, taking cognizance of their different levels of education and abilities (e.g., low vision). Prior research indicated that patients usually opt to seek for indications, contraindications, side effects, and dosage when opening the medication package. Therefore, this information is considered very critical for the correct use of medicines and must be cited clearly and unambiguously to reduce the risk of erroneous use and adverse events (Pizzol et al. 2019).

Other studies reveal that the most difficult parts of the package insert in terms of understanding are often related to the possible side effects and indications of the drugs. These two sections are probably the most difficult, as they tend to include complex medical terms that are unlikely for the average patient to comprehend. Moreover, it is prevalent to list a multitude of side effects and indications, leading to enormous information collation that the patient is usually unable to efficiently process and understand (Piñero-López et al. 2019). It is also worth mentioning that the abovementioned factors that inhibit the readability of the medicine's exterior packaging play a decisive role in the legibility of the package leaflet.

Methodology and Data Collection

Questionnaire Survey and Data Analysis

This research employed a questionnaire survey to explore the perceptions and satisfaction of the Greek public concerning the readability and comprehensibility of medicine labels. The initial questionnaire design was pretested by 14 individuals in terms of accuracy, content and measurement, and its final version required around 10 minutes for its completion. The questionnaire comprises 5 sections with closed-ended questions. The first two sections explored the participants' perceptions concerning the readability and comprehensibility of the exterior packaging (Pons et al. 2019; Law and Zargarzadeh 2010; Murty and Sansgiry 2007; Harben et al. 2021) and package insert (Pons et al. 2019; Pizzol et al. 2019; Law and Zargarzadeh 2010; Murty and Sansgiry 2007). The third part involved the evaluation of 13 recommendations to improve medicine labelling, both in terms of legibility (7) and understanding (6) (Pons et al. 2019; Pizzol et al. 2019; Law and Zargarzadeh 2010; Murty and Sansgiry 2007; Irungu et al. 2021; Tong et al. 2016; Tong, Raynor, and Aslani 2014; King et al. 2011; Bernardes et al. 2021; Piñero-López et al. 2019).

The next section measured respondents' satisfaction with exterior packaging, package leaflet, and overall medicine labelling (Murty and Sansgiry 2007). The last section of the questionnaire dealt with participants' demographics and medicine intake-related characteristics. A 5-point Likert scale was used for the questions/statements of the first 3 sections, from 1 meaning total disagreement to 5 meaning total agreement. A 7-point scale was also utilised to measure the public's satisfaction with medicine labelling in section 4, from 1 meaning not at all to 7 meaning extremely.

SPSS Version 28.0 was used for data analysis, which included frequencies, some descriptive measures (i.e., mean, standard deviation), and bivariate Spearman's correlations.

Survey Sample

A convenience sample consisting of 257 individuals was employed in this survey (Table 1). 236 of the respondents completed the questionnaire online and 21 through a face-to-face interview, during March and April 2023. A great effort was made to obtain a sample as representative as possible of the study's target population, namely adults who have used medicines relatively recently, especially in terms of age and education stratification. Female participants (66.9%) were double than male (33.1%), which was, to some extent, expected as women are more likely to do the family shopping. The study sample is, to some extent, more representative of relatively young and well-educated people. However, it is worth noting that around 30% of respondents were 51-65 years old and 10% older than 65, indicating that the sample was somewhat balanced with respect to age distribution. Around 45% of the participants stated that they need to wear glasses or contact lenses when administering their medication, and 10% need help getting a medicine. Finally, around 40% of the respondents were not on medication, and 15% were taking more than 3 medicines at that time. [Table 1 near here]

Results

Evaluation of Medicine Packaging Box and Recommendations for its Improvement

Survey results revealed that most of the participants seem to be bothered by the readability and comprehensibility of medicine's packaging box, as only 11% of them totally agree that they can easily read its information and 9% that they understand its details (Table 2). The mean values for both statements were around 3.0, with one-third of the respondents being neutral, while half of them were split between "2" and "4" on the 5-point scale. Not surprisingly, the individuals' readability and comprehensibility of medicine's packaging box were highly correlated (Table 3). The sample also held a neutral stance that adding more

information on exterior packaging would cause confusion (mean 3.0); however, around 40% of the participants disagreed with this statement, indicating that they would probably prefer to read more details on the packaging box. Finally, 72% of participants totally agreed with the indication of the medicine's purpose of use on the packaging box. [\[Tables 2 & 3 near here\]](#)

The majority of the sample endorsed most of the proposed recommendations to improve the readability and comprehensibility of medicine's packaging box (Table 2). Specifically, individuals were in favour of printing the expire date in black instead of the embossed format, using icons to facilitate understanding of how to administer the drug, utilising the pictograms-symbols for the maximum daily dose, increasing the fonts' size, and highlighting the active ingredient content with colour. The mean values of the answers ranged from 3.9 to 4.4, and more than two-thirds of the participants agreed with the relevant sentences. However, respondents were apparently less convinced that it would be helpful to them to reduce the brand logo's size and the use of colours (mean values around 2.8). Almost all recommendations were negatively correlated with individuals' ability to read and understand packaging box label. This implies that at least a market segment struggles with reading and understanding the medicine packaging box, and appeals for its improvement.

Evaluation of Medicine Package Insert and Recommendations for its Improvement

Public opinion about the medicine package insert's readability and comprehensibility is, to a great extent, similar to the packaging box (Table 4). Particularly, 40% of the sample found it difficult to read the information on the leaflet (mean 3.2), and around two-thirds attributed this difficulty, inter alia, to the small font size usually used. It appears that the comprehensibility of the package insert is somewhat better than its readability, with a mean 2.8. Overall, the public had an almost neutral stance about the impact of the complex medical terms and the information arrangement on the comprehensibility of the package insert. However, it is worth mentioning that a remarkable part of the respondents disagreed that they

faced difficulty in readability and comprehensibility (30% and 43%, respectively). Thus, like the packaging box, a high correlation was found between the readability and comprehensibility of the package insert (Table 5). In general, the standard deviation of answers was rather high (ranging from 1.12 to 1.31 on a 5-point scale), implying that there are probably distinct and measurable market segments. [Tables 4 & 5 near here]

Around 80% of the respondents supported most of the proposed recommendations for the package insert's improvement. Specifically, the participants advocated the use of simple language, short sentences, active voice, and bullet points to describe indications and contraindications, and the display of dosage in tabular format. Half of the individuals also favoured the avoidance of medical jargon, but around 20% expressed the opposite opinion (mean 3.6). Almost all recommendations, except the use of bullet points, were positively correlated with individuals' difficulty in reading and understanding package insert (Table 5).

Satisfaction with Medicine Packaging Box and Package Insert

Participants were roughly moderately satisfied with the overall medicine labelling, as three-quarters of them evaluated their satisfaction between 3 and 5 on the 7-point scale, and the mean was 3.8 (Table 6). They clearly expressed a higher level of satisfaction with the exterior packaging than the package leaflet, as the means of answers were 4.1 and 3.3, respectively. Not surprisingly, overall satisfaction with medicine labelling was highly correlated with the satisfaction of both exterior packaging and package insert (Table 7). Thus, the overall satisfaction with medicine labelling, as expected, was moderately correlated with the perceived ease/difficulty in reading and understanding the information displayed on both the exterior packaging and package insert. [Tables 6 & 7 near here]

Discussion and Conclusions

This study focused on the readability and comprehensibility of the medicine labelling, namely

the information on the packaging box and the package insert. Prior research revealed that around half of the population of other countries faced difficulties in reading and understanding medicine labels (Law and Zargarzadeh 2010; Pizzol et al. 2019; Pons et al. 2019). Our study results are in line with prior research findings, as the majority of participants seem to be bothered by the readability and comprehensibility of both the medicine's packaging box and the package insert. Law and Zargarzadeh (2010) found that 65% of the US patients requested the medicine's purpose of use to be displayed on the packaging box, which was confirmed by our study, as 72% of the sample was also in favour of this. The main reason that hinders the readability of the package insert is the small font size (62% of the participants answered positively), while the comprehensibility is moderately affected by the unorganized way of information arrangement and the medical jargon used.

This research also explored consumers' opinions of some ways that could contribute to a more patient-centric design of the packaging box and the package insert in terms of improving readability and comprehensibility. The public expressed a high level of agreement with recommendations concerning the packaging box, such as printing the expiry date in black, and using icons, symbols, and a larger font size, in accordance with the findings of prior research (Pons et al. 2019; King et al. 2011; Lee et al. 2019). Moreover, most of the participants strongly supported several of the proposed improvements regarding the package insert, like the use of simple–familiar language, active voice, short sentences, dosage tables, and bullet points for indications and contraindications. This conclusion is similar to the evidence of prior research (Davis et al. 2006; Tong, Raynor, and Aslani 2014). Additionally, almost all of the proposed recommendations were correlated with individuals' difficulty in reading and understanding medicine's label (packaging box and package insert). The standard deviation of respondents' answers concerning the evaluation of readability and comprehensibility of packaging labelling (both exterior and insert) was rather high, signifying

the existence of distinct and measurable market segments that pharmaceutical companies need to consider when designing their products' packaging labels.

To the best of our knowledge, this is the first study in Europe to explicitly measure customer satisfaction with medicine labelling. The respondents were roughly moderately satisfied with the overall medicine labelling, and they appeared to be more satisfied with the packaging box, though moderately, than the package leaflet. The overall satisfaction with medicine labelling, as expected, was significantly correlated with the satisfaction of both the exterior packaging and package insert, as well as with the perceived ease/difficulty in reading and understanding the information displayed on both the exterior packaging and package insert. Therefore, it is expected that the effective adoption of such recommendations would play an important role in increasing the public's satisfaction with medication labelling.

The study results demonstrated that an important part of people have difficulty reading and understanding the information written on medicine packages. Therefore, it is recommended that the regulatory authorities and the pharmaceutical industries focus on the design of more comprehensible and legible packaging labels. To this end, the medicine's label design should be based on readability and comprehensibility tests conducted directly with various segments of patients.

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Table 1. Sample characteristics (N=257).

Variables		N	%	Variables		N	%
Gender	Male	85	33.1%	I need to wear glasses or contact lenses	Yes	113	44.0%
	Female	172	66.9%		No	144	56.0%
Age	<35	90	35.0%	I need help to get a medicine	Yes	27	10.5%
	36-50	67	26.1%		No	230	89.5%
	51-65	74	28.8%	Medicines I am currently taking	None	102	39.7%
	>65	26	10.1%		1-3	118	45.9%
Education	Secondary/High School	54	21.0%	>3	37	14.4%	
	Vocational School	31	12.1%				
	University/ College	131	51.0%				
	MSc/PhD	41	16.0%				

Table 2. Evaluation of medicine's (exterior) packaging box and recommendations for its improvement.

	1	2	3	4	5	Mean	Std. Dev
Evaluation							
I can easily read the information of exterior packaging.	9.3%	25.3%	31.5%	23.0%	10.9%	3.01	1.14
I understand the information of exterior packaging.	8.6%	26.1%	27.6%	28.8%	8.9%	3.04	1.12
Adding more information on exterior packaging would confuse me.	14.0%	23.7%	26.5%	21.0%	14.8%	2.99	1.27
It is useful to indicate the medicine's recommended use on its exterior packaging	1.6%	1.9%	8.9%	15.6%	72.0%	4.54	0.86
Recommendations							
Fonts' size increase.	1.2%	9.3%	17.1%	26.8%	45.5%	4.06	1.05
Highlight milligrams (mg) with colour.	2.7%	8.6%	19.5%	34.2%	35.0%	3.90	1.06
Expiry date printed in black instead of the embossed format.	1.6%	5.4%	8.9%	23.3%	60.7%	4.36	0.96
Less colourful packaging.	16.3%	28.8%	26.1%	20.2%	8.6%	2.76	1.20
Reduce the brand logo's size.	10.1%	27.2%	37.7%	17.1%	7.8%	2.85	1.07
Use of pictograms-symbols for the maximum daily dose.	2.3%	6.6%	16.0%	31.9%	43.2%	4.07	1.03
Use of icons to facilitate understanding of how to administer the drug.	0.8%	5.4%	13.6%	29.2%	51.0%	4.24	0.94

Table 3. Correlations between recommendations and ability to read and understand packaging box label.

	Readability	Comprehensibility
I understand the information of exterior packaging (Comprehensibility).	0.726**	
Fonts' size increase.	-0.170**	-0.174**
Highlight milligrams (mg) with colour.	-0.012	-0.092
Expiry date printed in black instead of the embossed format.	-0.131*	-0.139*
Less colourful packaging.	-0.254**	-0.282**
Reduce the brand logo's size.	-0.095	-0.165**
Use of pictograms-symbols for the maximum daily dose.	-0.160*	-0.134*
Use of icons to facilitate understanding of how to administer the drug.	-0.148*	-0.164**

** . Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Table 4. Evaluation of medicine's package insert/leaflet and recommendations for its improvement.

	1	2	3	4	5	Mean	Std. Dev
Evaluation							
I find it difficult to read the information on the leaflet.	9.3%	20.2%	30.4%	23.0%	17.1%	3.18	1.21
The difficulty in reading stems from the small font size that is usually used.	7.4%	12.5%	17.9%	32.3%	30.0%	3.65	1.24
It is difficult for me to understand the information written in the leaflet.	16.0%	27.2%	26.8%	23.7%	6.2%	2.77	1.16
The difficulty in understanding stems from the complex medical terms involved.	8.6%	21.4%	33.9%	24.5%	11.7%	3.09	1.12
The difficulty in understanding stems from the disorganized way the information is presented.	17.1%	20.2%	23.0%	25.3%	14.4%	3.00	1.31
Recommendations							
Simple – familiar language.	0.0%	3.1%	11.7%	25.3%	59.9%	4.42	0.82
Short sentences.	0.8%	2.3%	16.7%	30.4%	49.8%	4.26	0.87
Use of active voice.	1.6%	9.3%	17.9%	27.6%	43.6%	4.02	1.06
Avoid medical jargon.	1.9%	16.3%	32.3%	23.3%	26.1%	3.55	1.10
Display dosage in tabular format.	1.2%	2.3%	15.6%	31.9%	49.0%	4.25	0.89
Use bullet points to describe indications & contraindications.	0.8%	4.7%	16.3%	33.1%	45.1%	4.17	0.92

Table 5. Correlations between recommendations and ability to read and understand package insert.

	Readability	Comprehensibility
It is difficult for me to understand the information written in the leaflet (Comprehensibility).	0.583**	
Simple – familiar language.	0.238**	0.189**
Short sentences.	0.180**	0.148*
Use of active voice.	0.127*	0.137*
Avoid medical jargon.	0.190**	0.191**
Display dosage in tabular format.	0.143*	0.057
Use bullet points (list format) to describe indications and contraindications.	0.046	0.084

** . Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Table 6. Public's satisfaction with medicine labelling.

	1	2	3	4	5	6	7	Mean	Std. Dev
Satisfaction with exterior packaging.	1.6%	7.4%	26.8%	28.8%	23.3%	8.6%	3.5%	4.05	1.26
Satisfaction with package leaflet.	8.9%	18.7%	31.5%	19.5%	17.1%	3.5%	0.8%	3.31	1.33
Overall satisfaction with medicine labelling.	0.8%	12.8%	31.9%	26.1%	17.9%	8.6%	1.9%	3.81	1.25

Table 7. Correlations between satisfaction, and readability and comprehensibility of medicine labelling.

	Overall satisfaction with medicine labelling.	Satisfaction with exterior packaging.	Satisfaction with package leaflet.
Satisfaction with exterior packaging.	0.800**		
Satisfaction with package leaflet.	0.798**	0.657**	
I can easily read the information of exterior packaging.	0.494**	0.453**	
I understand the information of exterior packaging.	0.476**	0.449**	
I find it difficult to read the information on the leaflet.	-0.379**		-0.382**
It is difficult for me to understand the information written in the leaflet.	-0.465**		-0.439**

** . Correlation is significant at the 0.01 level (2-tailed).