Title: Exploring the perspectives of potential consumers and healthcare professionals on the readability of a package insert: the case study of an over-the-counter medicine

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Abstract

Purpose To explore and compare the opinions of physicians, pharmacists and potential users on the readability of a package insert of an over-the-counter medicine.

Methods Exploratory study based on the administration of a semi-open questionnaire. This instrument was developed according to the readability guideline of the European Medicine Agency (EMA) and used to evaluate participants' accessibility to, and comprehensibility of, the package insert for diclofenac 12.5 mg tablets. Sixty-three participants were recruited from the Lisbon region and enrolled in three groups: 21 physicians (Dg), 22 pharmacists (Pg) and 20 potential consumers (PCg).

Results Almost all (85%) of the PCg participants were educated above the 9th grade, although the majority of them (95%) referred at least one package insert interpretation issue, mainly related to the comprehension of technical terms. Amongst other differences between groups, the Pg participants obtained a significantly less score regarding the opinion on the layout of the titles. Furthermore, the Pg and Dg participants proposed technical enhancements, such as the use of a table to explain the posology, precautions in case of renal failure, or the recommendation to take the tablets with meals.

Conclusions Differences in the way of using the diclofenac tablets are expected, considering the comprehension dissimilarities between health professionals and potential consumers. The package insert of diclofenac 12.5 mg could be enhanced. Regarding the readability assessment of this package insert, the method proposed in the EMA guideline might not be as effective as expected. Future research is advisable.

Keywords Package Inserts • Regulatory Issues • Drug information • Communication• OTC Drugs • Drug Safety

Introduction

The labelling and package inserts (PIs) are components of medicinal products that must be developed regarding the clarity of information [1]. All medicine PIs approved in the European Union (EU) must be conceived in accordance with the directive 2004/27/EC (Article 59) to ensure the clarity of the PIs, therefore contributing to the proper and safe use of medicinal products [2]. One of the missions of the European Medicines Agency (EMA) is the scientific evaluation of applications for EU marketing authorization, including the approval of the labelling and PIs of medicinal products. In addition, the EMA have developed legal requisites such as the "Guideline on the readability of the labelling and package leaflet of medicinal products for human use", with the intention of harmonizing the European procedures on this issue [1].

With regards to the fact that medicines are one of the greatest current resources for the prevention and treatment of many diseases, access to safe and effective medicines is considered a basic human right [3, 4]. Self-medication is an important issue in the prevention and control of minor health problems, (avoiding the saturation of the healthcare services), and is defined as the use in a responsible manner of non-prescription medicines (over-the-counter or OTC drugs), with the optional advice from a healthcare professional. Similarly to other medicinal products, OTC drugs are not hazard-free, with risks of interactions, drug abuse and poisoning associated with the use of OTC drugs, which can be considered a public health problem [4,5]. In Portugal, 2914 pharmacies and 838 shops (other than pharmacies) are authorized to sell OTC drugs (2009 data) [6]. The sales of these drugs represent 16% (in units) and 6% (in value) of the global national market, with the group of analgesics and antipyretics (e.g. non-steroid anti-inflammatory drugs, or NSAIDs) representing the highest market share [7].

Taking into account the relatively high sales of these medicines at a national level, the readability of the PIs of NSAIDs (particularly, OTC drugs) is an important issue. In this context, the aim of the present work was to explore and compare the opinions of physicians, pharmacists and potential users on the readability of a package insert of an NSAID (of an OTC).

Methods

This was an exploratory study, based on the administration of a semi-open questionnaire (Table 1), that was developed according to the readability guideline published by the European Commission (EC) [1]. The PI of the diclofenac 12.5 mg tablets was selected because of the following reasons:

1) The recent approval of this medicine as an OTC in Portugal [6];

2) The high consumption of anti-inflammatory medicines in Portugal (26% share of the total OTC market) [6] and;

3) The potential risk of arterial thromboembolic events associated with diclofenac intake, particularly if used in high doses. The Pharmacovigilance Risk Assessment Committee of EMA has recently confirmed the cardiovascular risk associated with diclofenac intake [8].

Furthermore the last approval date of the PI of the diclofenac 12.5 mg tablets was February 2008, being the legibility proof of the package inserts a legal requirement [2].

Following EC guideline [1], the study participants were recruited using a convenient sampling strategy from the metropolitan Lisbon area (from March to December 2010). The participants were enrolled in three groups: 21 physicians or doctors (Dg), 22 pharmacists (Pg) and 20 potential consumers (PCg). The Dg, Pg and PCg participants were selected, respectively, from medical offices and clinics, community pharmacies, and shopping or residential areas.

Questionnaire

The questionnaire was structured in two parts (Table 1). The first part comprised closed-ended questions based on a 5-point Likert rating scale (1 meaning strongly disagree). The participants used the rating scale to classify their opinion on the clarity, simplicity and comprehensibility of the text, and also on some typographic or printing issues.

The second part of the questionnaire was composed by two semi-open questions about participants' opinion on each one of the six sections of the PI, namely: 1. What X is (or the name of medicinal product) and what it is used for; 2. What you need to know before you <take><use> X; 3. How to <take><use> X; 4. Possible side effects; 5. How to store X; and 6. Package contents and other information [9]. In the first question the participants were invited to describe text comprehension problems (question a), while in the second question the participants were asked to give suggestions on how to improve the clarity of the text (question b). All the study participants had unlimited time to consult the PI. An initial pilot test was performed to validate the appropriateness of the questionnaire [1], using three patients, three physicians and three pharmacists. The questionnaire was self-administered for health-care professionals, while for potential consumers an interview was used to increase response rates and avoid the misinterpretations of the instructions. The interviews were conducted by a pharmacist researcher. No questionnaire usage issues were expressed by participants. All questionnaires were coded into a statistical database and scored. To assure the data entry accuracy, 10% of the questionnaires were randomized and rechecked.

Statistical analyses

The data were analysed with the Statistical Package for the Social Sciences (SPSS v17). Descriptive statistics, and non-parametric tests (Kruskal-Wallis test) were used, with a type I error level of $p < 0.05$.

--- Table 1 to be inserted here ---

Results

Overall, the three groups enrolled 63 participants: 21 Dg, 22 Pg and 20 PCg. The percentage of female participants in each group was, respectively: 33%, 64%, and 60%. Participants' age ranged between 22 and 71 years. The average age was, respectively: 45 (± 13.6), 28 (±4.9), and 26 (± 16.1). Three (15%) of

the PCg participants have not undertaken higher education studies. Physicians were mainly dentists (9 or 43%). All pharmacists worked at community pharmacies. The main results of the study are presented in Appendix 1 and Table 2 for the three groups.

Questionnaire Part A: opinion questions about the design of the PI (question 1 to 6)

The majority of the participants expressed a favourable opinion on the design issues of the PIs (points 1 to 6 of Table 1), excepting the opinion about the layout of the title for each section (point 3 of Table 1) that was significantly less scored by Pg participants (Kruskal-Wallis: $Chi^2 = 8.471$; $p = 0.014$) (Appendix 1).

Questionnaire Part A: opinions about the structure of the text (questions 7 to 13)

The scores of the opinion questions about the length of the paragraphs, the description of the possible side effects, the patients' instructions and the use of abbreviations throughout the text, were not found statistically different between Pg, Dg and PCg. The majority of the participants presented a "neutral", "agree" or "strongly agree" opinion on these issues (Appendix 1). However, the scores about the clarity of the text (Kruskal-Wallis: $Chi^2 = 5.524$; $p = 0.023$), the comprehensibility of the medical terms (Kruskal-Wallis: $Chi^2 = 15.972$; $p < 0.001$) and the repetition of the brand name of the medicine throughout the text (Kruskal-Wallis: $Chi^2 = 7.878$; $p = 0.019$) were statistically different between the three groups. The proportion of PCg participants that "strongly disagree" or "disagree" with the clarity of the text was significantly higher than the equivalent proportion of Dg or Pg participants (Appendix 1). PCg were more likely to prefer the repetition of the brand name throughout the text than pharmacists and physicians (60%, 9.1% and 4.8%, respectively) (Appendix 1).

Questionnaire Part B: a) text not (or insufficiently) understood in each section of the PI

Although no comprehension issues were mentioned by the healthcare professionals, almost all the PCg (95%) mentioned at least one comprehension issue. In the majority of the cases these were associated with the high prevalence of difficult technical terms, such as non-steroidal anti-inflammatory drugs, dyspepsia, melena and hematemesis. Other issues mentioned were the way how the possible side effects were described, and a high prevalence of long sentences in some paragraphs.

Questionnaire Part B: b) participants' suggestions to improve the clarity of the text in each section of the PI

Participants from the three groups suggested at least one change in section 2 of the PI (i.e. Before taking Diclofenac 12.5). As expected, the number of suggestions made by PCg was less than the number made by Pg and Dg participants (Table 2).

--- Table 2 to be inserted here ---

In relation to the content of section 3 (i.e. How to take Diclofenac 12.5), both pharmacists and physicians suggested modifications, such as the simplification of the text, the utilization of a table to explain the posology, and an update of the information about not exceeding the maximum dosage. Pharmacists also referred the absence of other relevant information, such as the recommendation to take the tablets with meals and precautions associated with renal failure. With regards to layout issues, both healthcare professionals and potential consumers suggested the use of various colours, underlining, bold and tables. None of the participants suggested the use of pictograms or warning signs.

Discussion

Medicines PIs are mandatory in most develop countries, but interestingly pharmaceutical regulations on the readability of PIs vary between countries. For instance, according to the regulations from the Food and Drug Administration (FDA), the use of a PI inside all packages of medicines is not mandatory in the United States of America, contrary to what happens in the EU [1,10,11].

According to the EC legibility guideline [1], it is recommended to enrol geriatric and low literacy patients in a legibility test, enhancing the chances of identifying readability issues in the PIs. The fact that the average education of the PCg participants was higher than the average education of the Portuguese population (72% of the Portuguese population were not educated above the 9th grade or the mandatory basic education in Portugal, and only 14% attended a higher education course in 2008) [12], was not considered an advantage to the design of the present study since more interpretation issues would be expected if less educated PCg participants had been enrolled in the study. If this is so, more issues are expected on the proper use of medicines, assuming patients with low literacy are usually less informed about health issues (e.g. asking fewer questions to practitioners). [13-15].

Some studies support the importance of the design of PIs (e.g. manipulation of text colour within PIs sections) [16, 17]. Moreover, previous investigations demonstrated that the use of pictograms and warning signs in the PIs enhanced patients' comprehension [18]. The participants did not consider the absence of figures in the PI unsatisfactory. Consequently, the consumers and health professionals enrolled in this study were not necessarily aware of the potential advantages of using illustrations, particularly in the case of PIs of self-medication drugs.

The predictable cognitive differences between patients and healthcare professionals (about the content of the PI) were considered to be relevant. This mismatch in the interpretation of some medical lexicon adds further responsibility to healthcare professionals in assuring complete patient understanding. Medication errors have been associated with inadequate interpretation of the labelling or PIs of medicinal products [19-24]. In this context, healthcare professionals are responsible for assuring the transmission of information fundamental to the adequate use of medicines, despite what materials might exist, in particular dosage instructions, side effects and strategies for patients' adherence [25-27].

In another study [28], the package insert of the diclofenac 12.5 mg tables was optimized through the use of simple explanations of the technical terms within brackets with the use of the same questionnaire

and an equivalent number of participants, with it being found that simple lexical modifications deeply improved the participants' comprehension of the PI. Therefore the results of this study [28] constituted a measure of comparability with the results of the actual investigation, since the PI of diclofenac 12.5 mg was significantly improved only through the addition of simple lexical explanations.

Finally, professionals uncovered critical information gaps (e.g. not taking the medicine with meals and special care in case of renal insufficiency), which may possibly contribute to compromising the safe use of the medicine by patients.

Study Limitations

Study results cannot be extrapolated to the Portuguese population, since no sample representation was aimed, following the EC guideline [1]. The PCg interviews should have been audio or video-recorded to allow for later analysis and, ideally, the possible negative health outcomes as result of the low clarity of the diclofenac 12.5 mg PI, as well as, the *a priori* expectations (of each participant) about the content of the PI, should have been assessed. Doctors' results should be interpreted with caution since most Dg participants were dentists, even if these physicians are heavy NSAISs prescribers. Although the majority of the participants had a favourable opinion of the PI design issues (e.g. font size, font type, dash use, etc.), the way in which these issues influenced participants' PI comprehension was also not specifically evaluated.

Conclusions

Although understandable discrepancies between potential consumers and health professionals are expected, the content of the diclofenac 12.5 mg PI might be improved in view of adequate usability for non-expert final users. In this PI the use of technical terms was an issue for good comprehension, constituting a risk regarding the safe use of the medicines. Written information given to patients would benefit from systematic contributions provided by local healthcare professionals.

Practice implications

Regarding the assessment of the readability of the PI of the diclofenac 12.5 mg tablets, the method proposed in the EMA readability guideline [1], might not be as effective as expected. The present PI layout might benefit from adjustments to the type of medicine i.e. a non-prescribed or self-medication drug. Additionally, it might be recommended to update the guidelines, considering the enrolment of health professionals in legibility tests of the PIs, as well, there is a need to make critical assessments of the content of the PIs depending on the characteristic of the various populations (e.g. taking into account the different literacy rates amongst member states) [29].Future research on this topic seems important as a way of assuring patients' safe and effective use of the medicines.

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Conflicts of interest None. This work is part of a larger post-interventional study with some available data yet published in: Improving Package Leaflet Information: Potential Users and Physicians Opinions, Abstracts / Research in Social and Administrative Pharmacy 8 (2012) e1–e66.

Contributions to the manuscript CP ─ contributed to the definition of the study design; developed the questionnaire and other necessary materials to support the study; managed the administration of the questionnaires; organized and performed the data treatment and drafted the first version of the article.

AC ─ contributed to the definition of the study design, supervised the entire process, administered some questionnaires to the pharmacists and revised the article making all the necessary amends.

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Table 1 Questionnaire about the content of the package insert of diclofenac 12.5.

QUESTIONNAIRE PART A
Rating Scale: 1 = Strongly disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = Strongly agree
After carefully reading the package insert of the diclofenac, please score some of the characteristics of the content of this package insert according to the following items (by choosing a number 1 to 5):
1. Font size
2. Font type
3. The layout of the title of the sections
4. Colour of the text
5. Line spacing
6. The use of the en-dash throughout the text
7. Clarity of the text
8. Length of the sentences
9. Number of sentences in each paragraph
10. The description of the possible side effects
11. The comprehensibility of the medical terms
12. The clarity of the patients' instructions
13. The use of abbreviations throughout the text
The repetition of the brand name of the medicine throughout the text

QUESTIONNAIRE PART B

For each section of the package insert explain using a few words:

a) What parts of the text do you not understand (or understand insufficiently)?

b) What alterations do you suggest to improve the clarity of the text (or parts of the text)?

What is 12.5 Diclofenac?

a) _____

b) _____

Before taking Diclofenac 12.5

a) _____

b) _____

How to take Diclofenac 12.5

a) _____

b) _____

Possible side effects of Diclofenac 12.5

a) _____

b) _____

How to store Diclofenac 12.5

a) _____

b) _____

Other information

a) _____

b) _____

Table 2 Number of participants: that made at least one suggestion on the improvement of the clarity of the text.

	n	Section 1	Section 2	Section 3	Section 4	Section5	Section 6
	100%	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
PCg	20	5 (25)	20 (100)	4 (20)	17 (85)	1 (5)	7 (35)
Pg	22	10 (45.5)	16 (72.7)	15 (68.2)	16 (72.7)	6 (27.3)	5 (22.7)
Dg	21	10 (47.6)	12 (57.1)	12 (57.1)	8 (38.1)	6 (28.6)	6 (28.6)

PCg, Potential consumers' group; Pg, Pharmacists' group; Dg, Doctors' group; Sections of the Package Insert: Section 1, What X is and what it is used for; Section 2, What you need to know before you <take><use> X; Section 3, How to <take><use> X; Section 4, Possible side effects; Section 5, How to store X and S6, Package contents and other information

Appendix 1 Results of the questionnaire.

	Strongly disagree n (%)	Disagree n (%)	Neutral n (%)	Agree n (%)	Strongly agree n (%)
Font size					
PCg	1 (5)	4 (20)	7 (35)	5 (25)	3 (15)
Pg	1 (4.5)	5 (22.7)	1 (4.5)	14 (63.6)	1 (4.5)
Dg	1 (4.8)	2 (9.5)	4 (19)	8 (38.1)	6 (28.6)
Font type					
PCg	0 (0)	1 (5)	2 (10)	11 (55)	6 (30)
Pg	0 (0)	1 (4.5)	2 (9.1)	12 (54.5)	7 (31.8)
Dg	0 (0)	2 (9.5)	1 (4.8)	13 (61.9)	5 (23.8)
The lay out of the titles of the sections					
PCg	0 (0)	1 (5)	2 (10)	9 (45)	8 (40)
Pg	0 (0)	3 (13.6)	4 (18.2)	14 (63.6)	1 (4.5)
Dg	0 (0)	2 (9.5)	1 (4.8)	13 (61.9)	5 (23.8)
Colour of the text					
PCg	0 (0)	1 (5)	2 (10)	6 (30)	11 (55)
Pg	0 (0)	3 (13.6)	7 (31.8)	6 (27.3)	6 (27.3)

Dg	1 (4.8)	2 (9.5)	3 (14.3)	10 (47.6)	5 (23.8)
Line spacing					
PCg	1 (5)	1 (5)	6 (30)	7 (35)	5 (25)
Pg	2 (9.1)	7 (31.8)	3 (13.6)	7 (31.8)	3 (13.6)
Dg	0 (0)	0 (0)	7 (33.3)	10 (47.6)	4 (19)
The use of en-dash throughout the text					
PCg	0 (0)	0 (0)	4 (20)	8 (40)	8 (40)
Pg	0 (0)	4 (18.2)	6 (27.3)	8 (36.4)	4 (18.2)
Dg	0 (0)	0 (0)	7 (33.3)	10 (47.6)	4 (19)
Clarity of the text					
PCg	4 (20)	6 (30)	5 (25)	4 (20)	1 (5)
Pg	0 (0)	9 (40.9)	4 (18.2)	8 (36.4)	1 (4.5)
Dg	1 (4.8)	2 (9.5)	4 (19)	13 (61.9)	1 (0)
Length of the sentences					
PCg	3 (15)	1 (5)	8 (40)	8 (40)	0 (0)
Pg	0 (0)	6 (27.3)	5 (22.7)	10 (45.5)	1 (4.5)
Dg	0 (0)	1 (4.8)	7 (33.3)	11 (52.4)	2 (9.5)
Number of sentences of each paragraph					

PCg	2 (10)	1 (5)	5 (25)	10 (50)	2 (10)
Pg	0 (0)	3 (13.6)	5 (22.7)	13 (59.1)	1 (4.5)
Dg	1 (4.8)	1 (4.8)	10 (47.6)	9 (42.9)	0 (0)
The description of the possible side effects					
PCg	2 (10)	0 (0)	3 (15)	12 (60)	3 (15)
Pg	0 (0)	8 (36.4)	5 (22.7)	8 (36.4)	1 (4.5)
Dg	1 (4.8)	1 (4.8)	6 (28.6)	10 (47.6)	3 (14.3)
The comprehensibility of the medical terms					
PCg	4 (20)	6 (30)	8 (40)	2 (10)	0 (0)
Pg	0 (0)	5 (22.7)	7 (31.8)	9 (40.9)	1 (4.5)
Dg	0 (0)	3 (14.3)	3 (14.3)	14 (66.7)	1 (4.8)
The clarity of the patients´ instructions					
PCg	0 (0)	1 (5)	2 (10)	9 (45)	8 (40)
Pg	0 (0)	4 (18.2)	6 (27.3)	8 (36.4)	4 (18.2)
Dg	0 (0)	2 (19.5)	2 (9.5)	13 (61.9)	4 (19)
The use of abbreviations throughout the text					
PCg	6 (30)	3 (15)	3 (15)	0 (0)	8 (40)
Pg	0 (0)	2 (9.1)	9 (40.9)	11 (50)	0 (0)

Dg	1 (4.8)	4 (19)	6 (28.6)	7 (33.3)	3 (14.3)
The repetition of the brand name of the medicine throughout the text					
PCg	2 (10)	2 (10)	2 (10)	2 (10)	12 (60)
Pg	0 (0)	1 (4.5)	7 (31.8)	12 (54.5)	2 (9.1)
Dg	1 (4.8)	2 (9.5)	10 (47.6)	7 (33.3)	1 (4.8)

PCg, Potential consumers' group; Pg, Pharmacists' group; Dg, Doctors' group