Original Research

Consumer medication information: legislative gap and challenges of practice

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Abstract

Objectives: To assess and evaluate OTC package inserts in terms of availability of key medical information and patient understanding of such information, as well as package insert user satisfaction and perceptions. **Methods:** This study used two quantitative methods: Evaluation of the Over-the-Counter Package Inserts and assessing package inserts user's satisfaction and perspectives using a cross-sectional survey. Descriptive analysis was used to calculate the response proportion of each group of respondents. **Results:** A total of 60 package inserts of Over-the-Counter drugs were evaluated. Less than one-third (30%) of the medication under investigation was found to have information about the unit of measurement of the active ingredient. Less than half (44.5%) of respondents reported they usually use the package inserts for information about their medication, and 42.2% rarely use or read package inserts. Difficulty reading or finding information in the package inserts was reported by 37.3 % of respondents. **Conclusion:** This research identified several factors associated with the proper use of package inserts among the general population in the United Arab Emirates and potential opportunities. Also, due to the lack of binding legislative texts, consumers are dissatisfied with the packaging inserts regarding their appearance and content. A mandatory guideline should be enacted by the competent authorities to ensure the comprehensiveness and readability of pharmacological information.

Keywords: consumer medication; package leaflet; consumer information; over-the-counter drugs; patient education; drug regulatory legislation

BACKGROUND

The Package Insert (PI) provides written information that follows a standard format about the effective and safe use of prescription and over the counter (OTC) medications. To empower patients to act appropriately, the PI is meant to be clear, readable, and understandable to laypeople.[1,2] Some research papers reported that PI is the second source of information about medicines after medical prescription. This importance still exists even with all technological advances in the media, internet, and social media.[3] Evidence shows that OTC or non-prescribed medicines are easily accessible by consumers, and they are available in all community pharmacies.[4] A study conducted in Australia found that more than 80% of adults and 40% of children used OTC each month.[3] It is also reported that patients still have poor knowledge when using them.

Recently, consumers have become more health-conscious and want to know more about their medications and are empowered enough to make choices about their health.[5] Providing such written information now has a broader role as it becomes accepted that people need to be more involved in decisions about their medications.[6] Among the barriers to the effective use of drugs is the busy schedule of physicians and the short time they spend with patients, which in turn compromise the quality and amount of information provided to each patient. Most patients may not be able to retain the verbal information given by the physicians for a long time. Various studies have suggested that PI may act as a valuable tool and can be helpful for patients, particularly as they improve their recall of what was said during the consultation.[5,7] Well-written PIs and providing the necessary information allow physicians to focus more on strategies for diagnosis and treatment of disease.[5]

As the health care delivery orientation continues to move from inpatient to outpatient settings and from cure to care, the responsibility is becoming more of the patient and less of the provider. The understandability, comprehensibility, and readability of the PIs are significant factors influencing patient adherence.[1] Previous studies have found that many patients are not getting oral or written instructions from their healthcare providers on using and managing their prescription medication safely and effectively.[7] Therefore, the information provided in the PIs is of great importance as it can help improve patients' quality of life, reduce anxiety and help patients recognize adverse effects early enough.[1]

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On the other hand, Lack of information, misinterpretation, or inadequate provision of information has been identified as significant factors among many reasons why patients do not take their medicines as the prescriber intends.[8] For example, different studies have demonstrated misunderstanding dosage instructions is common and is associated with medication errors. Misunderstanding of information in PIs is common among patients with limited literacy. This is further worsened when the information is written in a bad, complicated, or confusing style.[9]

Across all clinical situations, PI has a significant impact on patients' knowledge. This impact on knowledge is improved when the PI is concise but precise sufficiently detailed, include graphical presentations, are written in the active voice, and solicit reflection on the part of the patient by posing questions.[7] A well-designed and clearly written, easily readable PIs can significantly influence the delivery and effectiveness of the information provided.[6] Legal experts agree that transparency is sufficient to protect the consumer when dealing with market transactions.[10] Therefore, it is essential to evaluate different OTC Package Inserts in terms of use patterns, information availability, understandability by the patient, and user satisfaction and perspectives as requirements in assessing the transparency of pharmaceutical product information provided in national markets.

Law jurists classify these requirements into two main conditions: comprehensiveness and readability.[11] On the one hand, comprehensiveness requires the availability of all information that guides the consumer to decide the proper decision. There is a consensus among law jurists that such a requirement is an objective demand; it is not about users' discretion but must therefore be regulated in national law.[10] Second, readability refers to how clearly and readable information is provided to consumers.[12] Long texts, small font size, ambiguous medical terms, and poorly statistical information cause misjudgment for poor decisions on the medically prescribed treatment.[13] Readability includes both visual and linguistic characteristics. The first refers to the font size, color, highlights, and graphics, while the latter concerns the word length and syllable structure.[13]

Evidence shows a legislative gap in regulating these requirements, so pharmaceutical companies have discretionary powers over them. Although Art. 33 of Law No. 8/2019 for medicinal products demands medicinal information be written in Arabic and English Languages; the MOH is authorized to identify the format and content of the PI. Apparently, the relevant committees in the ministry have not yet undertaken this task; the research team could not find two identical drug leaflets in terms of form and content of information. Also, the provisions of the Consumer Protection Act No. 25/2020 that oblige the seller to list the "explanatory data" for the goods sold (Art. 7) do not provide legislative solutions to identify the standards of such a requirement. Only Article 8 of this Law obliges the seller to set the price of goods offered to consumers. In contrast, Article 26 demands such information be written- at least- in the Arabic Language.

Also, the general rules provided in the Civil Transactions Law No. 5 of 1985 do not offer reliable solutions to protect the user from the lack or lack of clarity of this information. In the opposite direction, some jurisprudence suggests the possibility of relying on the legal texts governing the theory of deception as a defect of will that enables the contractor to avoid the contract and claim compensation if he suffers damage (Article 187).[10,14] Article 186 of this law considers that deliberate silence about a fact or set of circumstances shall be a misrepresentation if it is established that the deceived person would not have contracted if he had known about that fact. This approach was also based on the definition of deception provided in Article 185 of the act. Deception is when one contractor deceives the other using fraudulent means, both verbal and actual, to induce him to consent to what he would not have otherwise agreed to." This interpretation is consistent with the definition of fraud in Article I of federal law No. 19 of 2016 on combating commercial fraud, which follows the exact definition as Article 186.

The authors disagree with this approach and find it pointless to build on these provisions to ensure optimal consumer protection for many reasons. These rules guarantee therapeutic rather than protective protection for the consumer and therefore assume that the consumer is harmed by using the medical product to establish the legal liability of the product. This goal contradicts the preventive protection discussed in this research, especially if the human body and its integrity are the desired goal of protection. In addition, the UAE legislator did not make the defect of cheating a particular defect, as is the case in most comparative legislation, but required the existence of a gross cheat in the contract to prove to the aggrieved the right to avoid the contract (Article 187). This approach narrows the legal protection provided to the consumer, especially since the research team did not find any judicial ruling that refers to the data contained in medical bulletins as one of these influencing elements. Avoidance is also a negative penalty, not enough to compensate for the damage. The consumer does not always want it; the consumer would not have access to the commodity unless he needs it. The consumer of the medical product needs the product because it concerns his public health. Therefore, an annulment will not be a good option for him but maybe damaged by this option because it is often discovered that the medicinal product is not suitable for him after use for a certain period because it is a matter of how the body reacts to the product. Finally, the consumer does not have the right to avoid upon his consent but requires complex judicial procedures and the presentation of evidentiary means that are difficult for the unprofessional person.

METHODS AND MATERIALS

Ethical approval

The University of Sharjah Ethics Committee ethically approved the study (Reference Number: REC-21-05-19-01).

Study design

A cross-sectional survey was conducted for six months (January

2021 to June 2021). This research study used two quantitative methods: Evaluating the OTC Package Inserts and assessing users' satisfaction and perspectives.

Selection of package leaflets

A list of 100 medicines sold 100,000 times or more throughout 2020 in UAE using the same technique described elsewhere.[3,15] Sixty OTC PIs were randomly selected. The PIs were collected from 12 different community pharmacies in three cities of the UAE: Ajman, Dubai, and Sharjah. The selection was performed to ensure that the list includes drugs of different therapeutic indications, namely non-steroidal anti-inflammatory agents, analgesics, respiratory tract agents, gastrointestinal agents, therapeutic nutrients, minerals, and electrolytes. The selected OTC medicines were of different dosage forms (tablets, capsules, syrups, drops, ointments, and creams). Other dosage forms were excluded, such as injections, suppositories, and inhalants. The selected products were anti-inflammatory 14 agents; respiratory tract 18 agents; therapeutic nutrients; minerals and electrolytes 6 agents; analgesic and pain killers 4 agents; anxiolytic 1 agent, gastrointestinal tract 10 agents; ophthalmic products 2 agents; otic preparations 1 agent; dermatological product 1 agent; antifungal product 1 agent; and antiemetic 1 agent.

Evaluation checklist development

The 35-item evaluation checklist was developed by a literature search of different countries' regulations, mainly European regulations.[6,15] The checklist included four sections that assessed the inclusion of the key characteristics of the PIs; (i) Identification of the medicine, (ii) dosage instructions, (iii) precautions, and (iv) adverse effects.

Patient selection and instructions

The study participants were adults above 18 and were selected from 12 community pharmacies across the UAE. All pharmacists were provided with detailed printed and oral information about the study objectives, and they were asked to invite walk-in patients to participate in the study. Patients were then provided with the participant information sheet to learn more about the research and the voluntary nature of participation. Participant's informed consent was taken and was asked to sign the form with a statement, "by entering the survey, I indicate that I have read the information provided and agree to participate".

Perspectives about the use of PIs

A 27-item web-based questionnaire in Arabic and English Language was shared through email and WhatsApp to the participants, together with a copy of the PI of the dispensed medicine. Participants were asked to read and use the PIs when answering the questionnaire. Participants completed the questionnaire at the pharmacy site. The 10 initial questions were related to identifying the participant's socio-demographic characteristics (age, gender, education level, medical-related educational background, employment status, marital status, and native language), and whether the participant has any health-related issues. The subsequent 9 questions have concentrated on the knowledge, the use of the PIs, and the type of information they look for. The next 5 questions examined the benefits and challenges associated with reading the PIs. The last two questions pertained to the font size and translation language of the PIs.

Data analysis

The IBM Statistical Package for the Social Sciences (SPSS) Statistics for Windows, version 20.0, Armonk, NY, USA, was used for all analyses. Descriptive analysis was used to calculate the proportions of each response for each of the questionnaire's items. When analyzing the data, the responses from specific variables were used to enable more readers; comprehensible confidence intervals (95% CI) were calculated for the relative proportions of some survey questions.

RESULTS

Evaluating the OTC PI

Identification of medicine: All 60 (100%) of the OTC drugs PI evaluated included Arabic and English Language information, both generic and brand names were printed, medication ingredients were listed, clinical uses were described, the number of tablets was mentioned, and the name of the manufacturer was added. However, only 30% of OTC PI under investigation included some information about the active ingredient unit of measurement. More than three quarters 46 (76.7%) of the OTC PIs included in the study used the text size of (9 to 11 pt). None of the OTC products studied included any specific PIs directed to the physicians.

Dosage instructions: The maximum dose allowed or the maximum dose as several tablets, capsules, or volume was included in only one-third of the sample under investigation, 20 (33.3%) and 19 (31.7%), respectively. The duration of the medication use was available in less than half of the evaluated PIs (28; 46.7%). The time during the day, when the medication should be used, was mentioned in only 13 (21.7%) of the evaluated PIs during the study period. Instruction regarding the way to take the medication in an upright position was only reported in 1 (2.9%) of the PIs of the studied OTC medications. Information regarding the patient's action when an overdose was used or he/she forgets to take one dose was reported in 12 (20.0%) and 26 (43.3%), respectively. Only seven OTC PIs under investigation included information regarding the time interval between every two expected doses.

Precautions and adverse effects: Less than three-quarters 43 (71.7%) and 37 (61.7%) of the PIs under investigation included a statement about contraindications and possible drug interactions. However, more than one quarter 16 (26.7%) included information on food or herbal possible interactions. Providing advice on what they should patients do when operating a machine or when he/she should consult a pharmacist or physician was reported in (38; 63.6%) and (47; 78.3%) of the studied OTC PIs respectively. The criteria applied in the OTC package inserts evaluation and the adverse effects information included in the PIs under investigation are summarized in Table 1.

Table 1. OTC package inserts evaluation (n=60)	
Criteria	**n (%)**
Identification of the medicine	
Regulations available in Arabic & English languages	60 (100%)
Generic name	60 (100%)
Brand name	60 (100%)
Manufacture name	60 (100%)
Medication ingredients list	60 (100%)
Type & quantity of the ingredients in measuring units	18 (30%)
Clinical uses	60 (100%)
Number of tablets	41 (100%)
Text size (9-11 pt)	46 (76.7%)
Export country	60 (100%)
Another leaflet special for doctors contains detailed drug interactions and rare side effects possibilities and contraindication	0 (0%)
Dosage instructions	
The maximum dose is included	20 (33.3%)
The maximum dose is given as number of tablets or capsules or as volume	19 (31.7%)
Hints on the duration of use are available	28 (46.7%)
Hints on time of the day when the medication should be used	13 (21.7%)
Information such as take the medication before, after, or independent of a meal available in case of orally taken drugs [a]	27 (56.3%)
The type of solution to use is given for orally taken drugs with a solid application form [b]	16 (42.1%)
The amount of solution to use is given by orally taken drugs with a solid application form [b]	15 (39.5%)
Hints that tablets and capsules should be taken in upright position [c]	1 (2.9%)
Provides information on what to do in case of overdose of the medication	12 (20%)
Provides information on what the patient should do if doses are missed	26 (43.3%)
Time interval between 2 doses	7 (11.7%)
Precautions	
Statement of contraindications	43 (71.7%)
Statement of drug interactions	37 (61.7%)
Information on laboratory, food, or herbal interactions	16 (26.7%)
Information on capability to drive a car or operate a machine	38 (63.3%)
Provides advice on when to consult a physician/pharmacist	47 (78.3%)
Adverse effects	
Provides qualitative statements on the frequency of side effects (rare or common)	31 (51.7%)
Verbal frequency terms are explained in the form of natural frequencies (e.g., very common "more than 1 in 10 patients")	26 (43.3%)
Describes severity of every possible adverse reaction	11 (18.3%)
Setting out the side effects by frequency of occurrence, starting with the highest 2	1 (1.7%)
Setting side effects by organ/system/class	46 (76.7%)
Statement on possible influence of the medication on reaction time	4 (6.7%)
Describes suitable measures in case of adverse reactions	2 (3.3%)
Possible side effects if medication is stopped or the dose is changed without doctor's advice	5 (8.3%)
[a] Number of PIs evaluated with orally taken drugs= 41 [b] Number of PIs evaluated with tables, capsules, and effervescent tablets dosage forms= 38 [c] Number of PIs evaluated with tables or capsules= 34	

Patient perspectives on the use of PIs

Socio-demographic characteristics of the participants: Among the 388 respondents in the study (272; 70.1%) were female, and less than a quarter of the sample under investigation were 40 to more than 60 years. Of the 386 participants, 221 (57.2%) and 60 (15.5%) reported that they hold bachelor and postgraduate degrees, respectively. Less than one quarter, 78 (20%) of the sample were from a medical background, and more than half (201; 53.3%) reported that they were unemployed/retired or a housewife during the study period. Although 268 (70.7%) of the respondents reported that they are not complaining of any diseases, still we have 111 (29.3%) of the participants who have reported some acute and chronic diseases. The socio-demographic characteristics of the participants are summarized in Table 2.

OTC medication PIs use: Participants were asked about whom they usually seek for information in case they have any questions or doubts about how they should use their medications; interestingly, 241 (62.1%) of the participants

Languages spoken fluently (388 Respondents)	
Arabic	373 (96%)
English	229 (59%)
Spanish	1 (0.25%)
French	12 (3.09%)
Other	19 (4.89%)
Health problems (379 Respondents)	
Acute disease	14 (3.69%)
Chronic disease	43 (11.3%)
Genetic disease	13 (3.4%)
Allergy	62 (16.3%)
No diseases	268 (70.7%)
Other	1 (0.26%)

mentioned that they usually ask a pharmacist. Only 151 (38.9%) still need to check with their physician or they use the internet 196 (50.5%). However, less than half (176; 44.58%) reported using or reading the PIs to answer their concerns. On the other hand, 164 (42.2%) of the sample, unfortunately, reported that they check and read PIs only "sometimes", "rarely", or "never". Still, interestingly, more than half 224 (57.7%) reported that they read the PIs on "always" or "often" base and the majority (368; 95.8%) of the studied sample reported that the PIs has a great impact on their correct use of medication and see PIs as a beneficial document. Also, (278; 71.6%) reported that they read the PIs before taking their new medicines. Information is often looked at or read in PIs, the participants read the PIs and other medication PIs use information summarized in Table 3.

Table 2. Sociodemographic characteristics of the participants	
Sociodemographic characteristics	**N (%)**
Age (388 Respondents)	
18-29	220 (56.7%)
30-39	79 (20.3%)
40-49	58 (14.9%)
50-59	24 (6.18%)
60 and above	7 (1.8%)
Gender (388 Respondents)	
Male	116 (29.9%)
Female	272 (70.1%)
Education level (386 Respondents)	
Less than high school	3 (0.77%)
High school	90 (23.3%)
Bachelor's degree	221 (57.2%)
Postgraduate degree	60 (15.5%)
Other	12 (3.1%)
Participants with medical background (387 Respondents)	78 (20.15%)
Employment status (376 Respondents)	
Employed full-time	135 (35.9%)
Employed part-time	40 (10.6%)
Unemployed	139 (36.9%)
Retired	13 (3.45%)
Housewife	49 (13%)
Ethnicity (386 Respondents)	
Arabic	361 (93.5%)
African	9 (2.3%)
Asian	13 (3.36%)
European	3 (0.77%)
American	0 (0%)
Other	0 (0%)
Relationship status (386 Respondents)	
Single	218 (56.47%)
Married	157 (40.6%)
Divorced	8 (2.07%)
Other	3 (0.77%)
Number of children (386 Respondents)	
None	229 (59.3%)
One	16 (4.1%)
Two to four	79 (20.46%)
More than four	62 (16.06%)

Table 3. OTC medication PIs use	
Criteria	**N (%)**
Last time for taking OTC medication (386 Respondents)	
Before one week	96 (24.87%)
Before two weeks	43 (11.1%)
Before one month	53 (13.7%)
Before two months	33 (8.5%)
When questions or doubts arise (388 Respondents)	
Seek the pharmacist advice	241 (62.1%)
Seek the physician medical advice	151 (38.9%)
Ask a relative/friend who used the same medication	48 (12.37%)
Ask a relative/ friend who has a medical background	59 (15.2%)
Search on the internet	196 (50.5%)
Read the package insert	173 (44.58%)
Know what is the PIs (387 Respondents)	350 (90.4%)
What package inserts do you usually read? (387 Respondents)	
Prescription medications	53 (13.7%)
OTC medications	42 (10.85%)
Both	250 (64.6%)
None	42 (10.85%)
Participants who find PIs beneficial (384 Respondents)	368 (95.8%)
Frequency of reading the PIs (388 Respondents)	
Always	104 (26.8%)
Often	120 (30.9%)
Sometimes	101 (26%)
Rarely	55 (14.17%)
Never	8 (2.06%)
The need for reading the PIs (388 Respondents)	
Before starting to take the medication	278 (71.6%)
With the first dose of the medication	90 (23.19%)
When expecting side effects caused by the medications	91 (23.45%)
When curious about the medication	188 (48.45%)
Others	2 (0.5%)

Information often looked for when reading the PI (386 Respondents)	
Name of the ingredients	119 (30.8%)
Reasons of taking the medication	276 (71.5%)
How the medication should be taken	275 (71.2%)
How many times the medication should be taken	233 (60.3%)
For how long the medication should be taken	187 (48.4%)
Possible side effects	294 (76.16%)
When to seek a medical advice	123 (31.86%)
What to do in case of adverse reaction	168 (43.5%)
What to do if missed a dose or in case of overdose	142 (36.8%)
Medication's storage	159 (41.2%)
Precautions and warnings	187 (48.4%)
Safe method of disposable	62 (16.06%)

Usefulness and understandability of PIs

Although the majority 335 (87.0%) of the participants reported that they were either "very easy" or "easy" to understand OTC PIs, 140 (37.3%) reported that it was difficult for them to find the name of active ingredients in the products. Furthermore, participants reported their concerns about the difficulty they face when they are trying to find some information regarding what they should do (i) in case of adverse drug reaction (21.3%), (ii) in case of missed dose (27.2%), and (iii) precautions and warnings (19.2%). When the participants were asked about the reasons for not reading or using the PIs, of 382 respondents answered this part of the survey, 201 (53.4%) and 160 (41.8%) reported that information provided by the physician during the clinic or pharmacists during the prescription dispensing respectively was enough. An important proportion of our sample reported that the main reasons for not being able or interested in reading or using PIs during the study period were the small font size of PIs 141 (36.3%) and that PIs are too long to read (163; 42.6%). Usefulness and understandability of OTC users are summarized in Table 4.

DISCUSSION

In this study, the PIs were evaluated to assess if OTC PIs contain the key information and details that assist the patient in understanding medication taking and improving treatment outcomes. Providing verbal and written information about medications at multiple stages can help improve patients' understanding and knowledge, therefore leading to safe and accurate medication use.[4] It has also been found that a higher rate of patients used PIs as a source of medications information instead of asking healthcare professionals, the internet, and other sources.[9] As shown in Table 1, the PIs missed many essential elements.

For this reason, pharmaceutical companies ' obligation to information is provided in the Civil Codes of many countries and many provisions provided in special legislation either. For example, the new Civil Code of Quebec provides this obligation in Articles 1468 and 1469 to enshrine the jurisprudential rule of the manufacturer's duty to inform.[16] Many developed and developing countries have stipulated in their national legislation a list of mandatory information to be included with the drug.[17] Proper attention is also considered to the form of that information, requiring specific printing characters in

Table 4. Usefulness, understandability, difficulty to find some information, and reasons for not reading or using the medication PIs

	N (%)
Understandability (385 Respondents)	
Very easy to understand	119 (30.9%)
Easy to understand	216 (56.1%)
Difficult to understand	44 (11.4%)
Very difficult to understand	6 (1.55%)
Usefulness (387 Respondents)	
Completely useful	175 (45.2%)
Useful	201 (51.9%)
Not useful	10 (2.58%)
Completely not useful	2 (0.5%)
Effectiveness of PIs (387 Respondents)	
Completely effective	143 (36.95%)
Effective	212 (54.78%)
Not effective	24 (6.2%)
Completely not effective	8 (2.06%)
The need for seeking healthcare professional advice, after reading the PIs (380 Respondents)	
Very needed	43 (11.3%)
Needed	126 (33.15%)
Slightly needed	152 (40%)
Not needed	59 (15.5%)
Difficult to understand or find in the PIs (375 Respondents)	
Name of the ingredients	140 (37.3%)
Reasons of taking the medication	60 (16%)
The way of taking the medication	71 (18.9%)
Number of times for taking the medication	77 (20.5%)
The duration of taking the medication	56 (14.9%)
Possible side effects	80 (21.3%)
When to seek medical advice	71 (18.9%)
What to do in case of adverse reaction	80 (21.3%)
What to do if missed a dose or in case of overdose	102 (27.2%)
The right way for medications storage	46 (12.2%)
Precautions and warnings	72 (19.2%)
Safe method of disposable	75 (20%)
Others*	8 (2.1%)
Reasons for not reading or using the PIs (382 Respondents)	
Information provided by the physician is enough	204 (53.4%)
Information provided by the pharmacist is enough	160 (41.88%)
Familiar with the medication	69 (18.06%)
The small font size of PIs	141 (36.9%)
The PIs is too long	163 (42.6%)
Information about side effects and/or interactions make the patient stressed/uncomfortable	51 (13.3%)
The PIs information is difficult to understand	55 (14.3%)
The PIs information is confusing	53 (13.87%)
The PIs information is not useful	17 (4.45%)
Others*	9 (2.35%)

terms of size, color, and the use of particular marks for certain necessary information.[12]

Regarding the dosage instructions, less than one-quarter of evaluated PIs lacked information about the preferred time to take medication, taking tablets in an upright position, providing information of what to do if an overdose was taken, the time interval between two doses. In addition, less than half of PIs evaluated didn't provide the amount of maximum dose, the duration of use, type, and amount of solution to use with orally taken medications. Provide information if doses were missed. It was previously presented that people should drink

an amount of 60ml of liquid and be in an upright position at a minimum angle of 45 when orally administered tablets or capsules are taken to achieve the appropriate passage rate; those instructions were missing in most of the evaluated PIs.[21] Two studies that evaluated PIs in Saudi Arabia reported that instructions on medication dosing were limited and lacked critical information.[3,22] The correct way of using medicines is essential to maximize treatment effectiveness and avoid adverse effects. Less than half of PIs justified the type and solution to use while taking capsules, tablets, and effervescent tablets, (16; 42.1%) and (15; 39.5%), respectively. One particular study demonstrated that people should drink an amount of 60ml of liquid and be in an upright position at a minimum angle of 45 degrees when orally administering tablets or capsules to achieve the appropriate passage rate.[21]

Evidence also suggests that the medications errors and the development of adverse effects were highly associated with improper understanding of the instructions in PIs, or with those who practice self-medication, specifically in patients with low health literacy and those with multiple conditions who are using multiple medications.[23] Moreover, most of the important precautions were mentioned in the PIs, although nearly one-quarter only mentioned information about other drugs interactions, such as laboratory, food, and herbal. Furthermore, PIs evaluated were unclear or missed some information about adverse effects, such as the severity of possible adverse effects, what actions should be taken in case of adverse reactions, dose changes, or stoppage of medications. A recent study found that about 20% of participants read PIs when they experienced potential side effects.[3] Besides, it has been described in a systematic review that patients are entitled to have more and better information about their medications to enable and prepare them for what they might experience in response to a drug administration.[4]

Notably, the inadequacy of this information raises the legal liability of manufacturers if they cause damages to users. Case law in the UAE classifies this deficiency as a tortious liability that requires a warranty according to Art. 282 of the Law of Civil Transactions No. 5/1985.[24] This is also the same approach of the French Court of Cassation, which judged in 2018 that the lack of information regarding the drug's side effects makes the product defective, so it demands compensation according to Art. 1245/3C of the French Civil Code.[16] However, it is vital to make sure that even if the company has complied with law demands, this does not mean that it has fulfilled its obligation to inform the consumer from the perspective of contractual relations. Indeed, the statutory obligation to provide information provided in health regulation is not confused with the equivalent obligation of civil law.[16] Health law texts of a criminal nature criminalize a person who does not comply with them and do not compensate the aggravated party.[25] The injured person has the right to claim compensation for any damage he may suffer due to the failure of the manufacturer to comply with the duty of information based on the text of Article 282 of the UAE Civil Transactions Law.[24]

Also, The research results added further support to the findings of other similar studies published elsewhere and to the guideline for testing the comprehension of PIs by users who suggest that 90% of participants are expected to find the information required, and of these, 90% can understand the information (European Medicine Agency, 2009).[3,7] One particular study has demonstrated that given the way PIs are written, a high level of education and literacy were found to be the most relevant predictors for acceptable comprehension rates.[19] In the current study, (278; 71.6%) reported that they read the PIs before taking their new medicines; this might be because most of the participants were educated. The inability to find and understanding instructions might harm patients' safety. Evidence suggests that the medicines errors and development of adverse effects were highly associated with improper understanding of the instructions in PIs or with those who practice self-medication, specifically in patients with low health literacy and those with multiple conditions who are using numerous medications. How the medication should be taken, the reason for taking the medication, possible side effects, precautions, and warnings are among the most information that respondents were interested in PIs throughout the study period.[9]

A study conducted in Sweden found that the information on the risk of drug interactions and contraindications was difficult to comprehend by the patients. It was reported that patients would easily understand PIs content if fewer and better-presented information on interactions and precautions was provided.[15] Furthermore, it has been demonstrated in one particular study that patients poorly comprehended the information in PIs regarding the dosage instructions and side effects.[21] Legibility and comprehensibility of PIs can enhance the safe and effective use of herbal products. They also prevent herbal-drug interactions and potentially harmful adverse effects.[4] For instance, an increase in the number of words in the PIs was associated with a significant decrease in the ability to locate the contents.[21]

Furthermore, several studies have addressed concerns about using a small font size in medication PIs.[2,20] In the current study, of 387 participants, 274 (70.8%) reported that the larger font size is their main preference in the medication PIs. Interestingly, the majority 340 (87.85%) said "Yes" when asked about their opinion on receiving a translation to their native language of any medication PIs. Usefulness, understandability, difficulty in finding some information, and reasons for not reading or using the medication PIs are summarized in Table 4. It also seems that the reason for the high dissatisfaction with the medical bulletin information in this research is that the most significant percentage of respondents of Arab origin (96%) deal with PI written in Arabic. Previous research studies found that dealing with Arabic PI is more problematic than others written in English.[2] A recent study done in Saudi Arabia assessed the readability of two types of medicinal information written in the Arabic Language based on sentence structure and vocabulary used, reported that almost 50% of the applicants misunderstood at least one aspect of the Arabic medication labels of 5 of the commonly prescribed medications,[20] especially in sections related to side effects and precautions.[13] One of the

common mistakes is the hybridization of the writing between English and Arabic Languages.[1] This is because all numbers in Arabic documents are always written in English, including the medication's timing, dosage, and duration. Applicants with low education levels usually misunderstand these numbers. For example, they mistakenly read "take 1 tablet…for 38 days" instead of "take 1 tablet…for 30 days".[20] In addition, non-Arabic terms (Latin), which might not be incomprehensible to the reader, are usually written in these leaflets in the Arabic Language, such as (vaccine).

In contrast, a misunderstanding occurs because some medical literature uses Arabic scientific terms that are unknown to the public because they used to use the Latin term. Also, mistakes sometimes happen because of false translations from English to Arabic, especially regarding numbers. The research team noticed many circulations issued by the departments of health declaring a correction of a number error provided in an Arabic leaflet to adopt the English version. For example, the Circulation No. 94 dated September 2020, 14 declared a discrepancy in the Arabic section of the leaflet of Revlimid (lenalidomide) 5mg, 10mg, 15mg, and 25mg Capsules manufactured by Celgene International Sarl, Switzerland, dated April 2018 and the English text is correct. The error was: "the usual dose of Revlimid is 15 mg once a day", while the right statement should be: "the usual dose of Revlimid is 25 mg once a day".[19] These problems reinforce the importance of this research because it draws the decision-maker's attention to the need to intervene to regulate the issuance of medical bulletins written in Arabic.

For the above, many developed and high-income economy communities, like the EU, USA, Canada, Australia, and Brazil, realized this importance and constituted guidelines and standards for the production and delivery of (LPL). Various regulatory efforts have been suggested in those countries to improve the usability and readability of written information provided with drugs.[5] For example, the Directive 2004/27/EC demanded readability and comprehension testing of the used leaflets, so in 2009 the European Commission issued the "Guideline on the readability of the label and package leaflet of medicinal products for human use". Those technical standards and guidelines establish the format and content of PIs to make them more comprehensive, readable, and understandable to the patients. The primary purpose of these guidelines is to provide mandatory provisions on ensuring that the information on the Label and Package Leaflets is accessible and readable for those who receive it to use medicine safely and appropriately. Despite those efforts, the evaluation of the success of these efforts showed various problems, specifically low readability.[13,20]

CONCLUSION

This study identified several factors associated with PI proper use hesitancy among the general population in UAE. The study calls for the development of public health interventions to promote maximum and proper use of OTC medications PI in the community. This study also concluded that leaving the matter of determining the content and form of PIs to the producing companies has a negative impact on their expected results. Although most of the respondents were keen to review this information, the style and format are not clear enough to enhance the Patient's Right to Information. To evade medication errors due to shortage and deficits in the current information, the research recommends improvement in the existing PIs based on field research studies monitoring the level of patient satisfaction with the PIs information. Therefore, the competent authorities are recommended to enact binding national guideline to organize and regulate written information provided in the PIs.

CONFLICTS OF INTEREST DECLARATION

The authors declare no relevant or material financial interests related to the research described in this paper" and declare no conflicts of interest.

AUTHORSHIP CONTRIBUTION

Abduelkarem and Fayyad contributed to the concept and design of the study. Both authors contributed to the data analysis. Hassanein participated in the literature review and the writing of the manuscript and data interpretation. Abduelkarem provided revisions to the scientific content and made a significant contribution to drafting the paper for its intellectual contribution. All authors contributed to critical revision and final approval of the manuscript and agreed to take responsibility for the manuscript's content.

CONSENT FOR PUBLICATION

We, authors give our consent for this manuscript, to be published in the Journal of Pharmaceutical Policy and Practice.

ETHICAL CONSIDERATIONS

The University of Sharjah Ethics Committee ethically approved the study (Reference Number: REC-21-05-19-01).

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DATA AVAILABILITY

The datasets generated during and/or analyzed during the current study will be available upon request from (Prof. Abduelmula R Abduelkarem, email: aabdelkarim@sharjah.ac.ae). Data will be available for 1 year from the date the study has ended by email.

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