Original Article

Evaluation of Medication Package Inserts in Iran

Shahriyar Shahbazi Khamas[1], Atefeh Jafari[2], Morvarid Zarif-Yeganeh[3], Hamidreza Taghvaye-Masoumi[2]

[1]Students' Research Committee, School of Pharmacy, Guilan University of Medical Sciences, Rasht, Gilan, Iran

[2]Department of Clinical Pharmacy, School of Pharmacy, Guilan University of Medical Sciences, Rasht, Gilan, Iran

[3]Hematology-Oncology Research Center and Stem Cell Transplantation, Shariati Hospital, Tehran University of Medical Sciences, Tehran, Iran

Abstract

Objective: Package inserts (PIs) provide information for the safe and effective use of medication. There is no study on the evaluation of PIs in Iran. The purpose of this study was to evaluate the completeness of PIs supplied with the 100 top-selling medications in Iran. **Methods:** This cross-sectional observational study was conducted during 3 weeks in January 2017. One hundred medications were chosen from a list supplied by the Iran Food and Drug Administration (IFDA). The PIs were assessed for the presentation and completeness of quality criteria, which was consisted of two parts. The first part was the criteria required by the IFDA, mentioned in Chapter 16 of the Pharmaceutical Regulations and Instructions provided by the IFDA. The second part of the criteria was defined according to the critical comments of clinical and industrial pharmacists. **Findings:** Thirty-seven out of 100 medications included no PIs. None of the PIs met all the criteria required by the IFDA. The highest score for completeness was 18 out of 21 (85.7%). Medication name, description, and adverse reaction were mentioned in all PIs. Other items such as patient counseling information (98%), warnings (95.2%), precautions (95.2%), pregnancy/lactation (95%), and storage condition (90.5%) have been mentioned in a high percentage of PIs. **Conclusion:** PIs have improved in recent years in Iran, but there is an absolute need for more accurate and up-to-date information. The IFDA should supervise pharmaceutical companies more strictly in this regard and should revise its regulations requiring PIs to conform to the FDA regulations.

Keywords: *Community pharmacy, package insert, patient information, regulations*

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Introduction

Package inserts (PIs) are folded, printed documents accompanying medications, over-the-counter (OTC) or prescribed, and contain information for patients on how to safely use medications. Therefore, they have a substantial impact on patients' compliance.[1] PIs instructions can help safe medication use, successful treatment, and protection from side effects. They are of great importance because self-medication is common in Iran;[2] patients have little knowledge about medicines,[3] and the most available source of information for them is PIs. PIs not only help patients but also give healthcare professionals essential information;[4] therefore, every medication package must include a PI.

Most of the medications have printed information on the original packages and PI accompanied by the medication. The information inside PIs varies between packages, some of them have very accurate and complete information, and some, unfortunately, have incomplete and sometimes false information.

In Iran, during the drug registration process, pharmaceutical companies submit product information and labeling information to the Iran Food and Drug Administration (IFDA). A study in India showed that PIs failed to adhere to the guidelines of the regulatory authorities.[5]

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Address for correspondence:
Dr. Hamidreza Taghvaye-Masoumi,
E-mail: taghvahamidreza@yahoo.com

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To the best of our knowledge, no study has evaluated PIs in Iran. The present study aimed to evaluate adherence to guidelines criteria and the quality and completeness of PIs supplied with 100 top-selling medications in Iran, according to the evaluation criteria in this study.

Methods

This cross-sectional observational study was conducted in January 2017. As the first step in this study, a set of 21 criteria [Table 1] was developed. The evaluation criteria consist of two parts. The first part was the criteria required by the IFDA, mentioned in Chapter 16 of the Pharmaceutical Regulations and Instructions provided by the IFDA.[6] The second part of the criteria was defined according to the critical comments of clinical and industrial pharmacists.

The list of top-selling medications,[7] which was containing the drug and the manufacturer name in Iran, was obtained from the IFDA website. The first 100 medications were chosen from the list. All the 100 top-selling medications in Iran were oral.

The PIs were collected over 3 weeks from the pharmacies located in Rasht, Gilan, Iran, in January 2017. When all required information on an item was present, it was scored as one; otherwise, a score of zero was assigned. Each item has one score, and a total score was 21. The total score (21) was calculated by adding the scores of all 21 items for an individual PI. For each medication, the

Table 1: Package inserts evaluation criteria and comparison with the Food and Drug Administration criteria

FDA criteria	IFDA requirements (inclusion criteria) (Part 1)	Inclusion criteria (Part 2)
Highlight title and limitation statement	Medication name	Pediatric consideration
Product title: Drug name, dosage form, route of administration, and controlled substance symbol	Description	Geriatric consideration
Initial US approval	Indications	Administration with/without regard to meal
Boxed warning	Patient counseling information	Overdosage, toxicity, and management
Recent major changes	Contraindications	G6PD deficiency consideration
Indications and usage	Pregnancy/lactation	Missed dose
Dosage and administration	Dosage and administration	
Dosage forms and strengths	Warnings	
Contraindications	Precautions	
Warnings and precautions: special care precautions, monitoring by laboratory tests, and interference with laboratory test	Drug interactions	
Adverse reactions: categorization of adverse drug reactions, clinical trial experience, and postmarketing experience	Adverse reactions	
Drug interactions	Signs of deterioration	
Use in specific population: Pregnancy, lactation, females and males of reproductive potential, pediatric use, geriatric use	Storage condition	
Drug abuse and dependence: Controlled substance, abuse, dependence	Address, phone number, website	
Overdosage	Date of last revision	
Description		
Clinical pharmacology: Mechanism of action, pharmacodynamics, pharmacokinetics		
Nonclinical toxicology: Carcinogenesis, mutagenesis, impairment of fertility, animal toxicology, and/or pharmacology		
Clinical studies		
References		
How supplied, storage, and handling		
Patient counseling information		
Revision date		

FDA=Food and Drug Administration, IFDA=Iran Food and Drug Administration, G6PD=Glucose-6-phosphate dehydrogenase

presence or absence of the IFDA and FDA criteria and their completeness was expressed as percentages.

Listed medications were categorized based on their indication.

Data were divided into four groups, Group A (OTC medications), Group B (prescribed only medication), Group C (licensed medication), and Group D (local medication).

Group C includes foreign medications produced under the license of the original manufacturers in Iran; Group D contains the same drugs as the Group C, which is produced in Iran without being licensed under any particular foreign manufacturers. Medications in Group A were compared with medications in Group B, while medications in Group C were compared with medications in Group D.

The results of the study were also compared with the studies conducted in other countries to evaluate the quality of Iranian PIs.

The PIs were analyzed twice to reduce the chance of missing information. Descriptive statistical analysis and the Chi-square test were performed using SPSS software (Statistical Package for the Social Sciences, version 24.0; SPSS Inc., Chicago, Illinois, USA). $P < 0.05$ was considered statistically significant.

Results

Thirty-seven out of 100 top-selling medications included no PIs. None of the PIs met all the criteria required by IFDA and quality criteria [Table 2]. The highest score for completeness was 18 out of 21 (85.7%).

As shown in Table 2, items which included in all PIs were medication name, description, and adverse reaction. Other items such as patient counseling information (98%), warnings (95.2%), precautions (95.2%), pregnancy/lactation (95%), and storage condition (90.5%) have been mentioned in a high percentage of PIs.

Pediatric and geriatric considerations were available in 62% and 12.7% of PIs, respectively. Only two medications listed physical signs of deterioration in the dosage form, and 44 PIs listed medication administration with/without regard to the meal. Nine medications on the list were mentioned on the gluten-free list of the IFDA, and three mentioned glucose-6-phosphate dehydrogenase (G6PD) deficiency consideration in their PIs. Fifty-two percent of PIs did not provide any information about overdosage, toxicity, and management.

Table 2: Result of analysis of package inserts (total number=63)

Criteria	Score	Percentage
Medication name	63	100
Description	63	100
Adverse reactions	63	100
Patient counseling information	62	98
Warnings	60	95.2
Precautions	60	95.2
Pregnancy/lactation	60	95
Storage condition	57	90.5
Dosage and administration	50	79
Administration with/without regard to meal	44	70
Indications	42	66.7
Pediatric consideration	39	62
Address, phone number, website	38	60
Missed dose	35	55.5
Drug interactions	33	52.4
Overdosage, toxicity, and management	30	47.6
Contraindications	22	35
Geriatric consideration	8	12.7
Date of last revision	5	8
G6PD deficiency consideration	3	4.7
Signs of deterioration	2	3

G6PD=Glucose-6-phosphate dehydrogenase

Groups A and B consisted of 12 and 51 PIs, respectively. Groups C and D consisted of PIs of the following licensed medications and local medications: fexofenadine 120 mg, metformin 500 mg, sertraline 50 mg, glyceryl trinitrate 2.6 mg (modified release), valproate sodium 200 mg, and atorvastatin 20 mg. Table 3 shows that PIs of licensed medications got a better score on average than local PIs. About 66% of licensed medication PIs had instruction on overdosage, toxicity, and management, but only 16.6% of local PIs mentioned overdosage, toxicity, and management. About 66%and 83.3% of licensed medication PIs provided information on pediatric consideration and dosage/administration, respectively, while 33.3% and 50% of local PIs provided information on these topics. The data indicate that 23% of OTC medications did not have PIs; on average, the PIs of prescribed medication scored better than OTC medications. Nearly half of the PIs pointed out overdosage, toxicity, and management. The missed dose was mentioned: 8.3% in OTC and 65% in prescribed medication. Significant differences between Groups A and B was seen in G6PD deficiency consideration ($P = 0.031$), signs of deterioration ($P = 0.003$), and missed dose ($P = 0.001$). As evident in Table 3, a significant difference between Groups C and D was only seen in the address, phone number, and website items ($P = 0.019$), because of the small sample size.

Table 3: Comparison between package inserts of the licensed/local medications and over-the-counter/prescribed only products

Criteria	Licensed medication	Local	*P*	OTC	Prescribed only	*P**
Medication name	6	6	-	12	52	-
Description	6	6	-	12	52	-
Indications	5	2	0.093*	8	35	0.966
Patient counseling information	6	6	-	12	51	0.631
Contraindications	3	2	0.575*	5	18	0.649
Pregnancy/lactation	6	6	-	12	49	0.398
Dosage and administration	5	3	0.241*	11	40	0.256
Address, phone number, website	0	4	0.019*	8	30	0.571
Storage condition	6	5	0.317*	11	47	0.891
Pediatric consideration	4	2	0.269*	5	35	0.101
G6PD deficiency consideration	0	0	-	2	1	0.031
Warnings	6	6	-	11	50	0.511
Precautions	6	6	-	11	50	0.511
Drug interactions	5	3	0.241*	4	30	0.130
Adverse reactions	6	6	1.00*	12	52	-
Signs of deterioration	0	0	-	2	0	0.003
Date of last revision	2	0	0.138*	1	5	0.892
Administration with/without regard to meal	3	3	1.00*	9	35	0.607
Geriatric consideration	1	0	0.317*	0	8	0.150
Overdosage, toxicity, and management	4	1	0.093*	5	26	0.605
Missed dose	4	5	0.523*	1	34	<0.001

*Chi-square test. OTC=Over-the-counter, G6PD=Glucose-6-phosphate dehydrogenase

Table 4: Comparison with other studies from different countries

	India[18]	Pakistan[25]	International[8]	Germany[24]	Saudi Arabia[4]	Palestine[26]	Present study
Adverse reactions (%)	96.3	96.2	81.4±17.8	100	100	99.3	100
Direction for use (%)	-	51.2	71.6±21.1	85.7	46	93.3	70
Overdosage (%)	68.8	63.8	-	-	-	71.1	47.6
Precautions (%)	95	96.2	73.7±22.5	100	100	98.5	95.2
Drug interactions (%)	76.3	70	-	100	-	94.1	52.4
Contraindications (%)	97.5	97.5	81±26.4	100	-	95.6	35
Pregnancy/lactation (%)	86.3	83.8	81±26.4	94.11	97	68.2	95
Storage condition (%)	-	96.2	71.6±21.1	-	-	86.7	90.5

The most commonly used medication categories based on an indication in the list were cardiovascular drugs (21%), analgesics/anti-inflammatory drugs/antipyretics (20%), gastrointestinal drugs (13%), and antidiabetics (11%).

Table 1 shows the differences between the US FDA labeling guidelines and the IFDA criteria. There are certain deficiencies in the IFDA guidelines such as "Boxed warning," "Recent major changes," "Use in a specific population," "Drug abuse and dependence," "Clinical Pharmacology," "Nonclinical toxicology," and "Clinical studies."

Discussion

According to the results of this study, the highest score for PIs completeness was 18 out of 21 (85.7%), and about two-thirds of medications (63%) had PIs. Medication name, description, and adverse reaction were mentioned in all PIs; it is promising because sufficient information on adverse reaction helps patients during treatment. However, information on geriatrics, G6PD deficiency, physical sign of deterioration, and date of last revision were most frequently missing in the reviewed PIs. Further, excipients that could be harmful to some patients were not mentioned in any PIs.

A study that compared patient information leaflets of the United Kingdom, the United States, and Australia showed that the best PI was from Australia. The US PIs lacked sufficient information such as drug interactions and contraindications and did not even get an acceptable score for readability and comprehensibility.[8] Other studies showed that many PIs defected vital information such as adverse reactions and dosage instruction and did not pass safety criteria.[4,9]

PIs play an essential role in patients' health through improving patient's knowledge[10] and helping them in adherence to treatment.[11] This was the reason why many studies were conducted in different countries. A study indicated that most of the patients fail to understand the information on PIs, specifically in contraindications and interactions sections.[12] In this study, about half of the PIs did not refer to drug interactions, and it is undesirable because patients with comorbidities take multiple medications (polypharmacy), and as such, the probability of interactions between OTC or prescription medication increases.[13] Thirty-four percent of the listed medications were OTC. Of these 34%, only 11% had PIs. Patients who buy OTC medications no longer refer to the doctor and do not benefit from their guidance, and most often patients do not receive counseling for their OTC medications in the pharmacy. Therefore, there is a need for correct and complete PIs.

Sticking to medication routines or medication adherence is essential. Missed dose and nonadherence may lead to multiple complications such as hospital admission and ketoacidosis in diabetic patients[14] and failure in controlling blood pressure[15] and may reduce patients' life quality. Appropriate guidance in this matter can reduce many of these problems. One of the most important causes of death in Iranian population is cardiovascular diseases,[16] and it is worth mentioning that most of these patients receive medication therapy. In this study, four out of 21 cardiovascular medications did not have PIs. Nonadherence to cardiovascular medications is one of the risk factors for treatment failures and poor outcomes. Considering the importance of this issue, it is suggested that the regulation regarding cardiovascular drugs be stricter, so the overall quality will be higher than average. Providing appropriate information in PIs can be an impressive factor in reducing nonadherence to medications.

Special populations such as pregnant women, pediatrics, and geriatrics require special considerations. Pharmacokinetics and pharmacodynamics of drugs, dosing, and toxicity vary among these populations. The FDA obligates companies to provide a recommendation for dosing in special populations.[17] The result of the present study in pediatric and geriatric consideration is somewhat similar to a study conducted in India, in which pediatric and geriatric use was present in 44% and 13% of the PIs, respectively.[18]

Six out of nine of the antibiotics did not have PIs. Due to the high prevalence of antibiotic self-medication in Iran and not completing the course of therapy;[19] these can lead to microbial resistance, hospital admissions, and additional costs to the healthcare system.[20] It is highly recommended not to forget the importance of antibiotics' PIs.

Patients with G6PD deficiency manifest different levels of enzymatic activity, and because of this, a range of hematological complications can occur in these patients. Given the 6.7% prevalence of G6PD deficiency in Iran[21] and the importance of the disease, it is suggested that the necessary information for these patients be available in PIs. Unfortunately, two out of five medications with a high risk of hemolysis did not mention G6PD deficiency consideration in their PIs.

Patients with celiac disease try to get information on the presence of gluten in their medications through calling the Drug and Poison Information Centers or drug companies or pharmacist; this is very frustrating for these patients. Given the similar incidence of celiac disease in Iran with Europe and the USA,[22] it is recommended that the presence or absence of gluten be mentioned in PIs. This led us to distinguish which of the top-selling medications are gluten-free. Therefore, the list of gluten-free medications was taken from the IFDA website and compared with top-selling medications. Only nine medications were on the list, which means that the list of gluten-free medicines has not yet been completed, and it is necessary to add celiac disease information to PIs.

After careful consideration, it was discovered that the licensed medication by another company from a foreign country has better quality. Similar findings regarding the superiority of information in both the quality and quantity of imported over local medications were found in a recent study in Palestine.[23]

Consultation for patients on taking medications regularly and its administration with/without regard to the meal are other issues that should be mentioned in the PIs. Another problem affecting patients is inappropriate dosage instruction (e.g., 1–3 capsules or take 2–3 times a day) in PIs. To solve this issue, nonquantifiable statements should not be mentioned in PIs without appropriate instructions.

One of the difficult problems that patients are struggling with is information overload. There should be a balance between information overload and relevant and necessary information. The usability of PIs is a valuable factor; a study showed that PIs have a usability problem particularly in finding relevant information.

One of the pharmaceutical companies routinely has printed the leaflet information inside the box; although this approach reduces paper consumption, it can be a factor for confusing patients because it is unlikely that

the printed information will be seen and as such can be missed.

A study in Germany[24] demonstrated that the PIs not only were incomprehensible but also did not pass all the quality criteria for interactions and maximum daily dose. Other aspects such as readability and comprehensibility were not analyzed in this study; further studies should consider evaluating the readability and comprehensibility of PIs because studies have shown that PIs are not patient-friendly enough.

There are ways to reduce this problem such as designing the layout of PIs with bold headings and bullet points using suitable paper with a true transparency and choosing the proper font and size, using short sentences and right words for the public. Another way that comes to mind is to involve the nonacademic people in the PI writing process.

The result of this study was compared with other researches done in different countries. As shown in Table 4, the information on adverse reactions, pregnancy/lactation, and storage condition in this study was similar to other studies. However, compared with other studies, it was found that information on overdosage, drug interactions, and contraindications was mentioned less than others.

As evident in Table 1, the US FDA labeling guidelines in comparison to the IFDA are more complete, understandable, patient-oriented, helping the patients and healthcare professionals to access information easier from PIs. Lack of some items in PIs compared with the US FDA labeling guidelines also reported in other investigations.[27,28]

In this study, the adherence to the IFDA guidelines was evaluated besides other criteria. Until now, there are no standard criteria for evaluating PIs, and this is one of the limitations of this study. Another limitation is that readability and comprehensibility of PIs were not evaluated. Finally, yet importantly, this study only evaluated the first 100 medications in the IFDA list. Despite these limitations, this is the first study to our knowledge on evaluating PIs in Iran.

In this study, 63 PIs were evaluated for their completeness of information required for the patients' best benefit. As shown in the results, none of the PIs were complete, and they did not provide satisfactory information. This study is a reliable source of information on the quality of PIs in Iran. The findings can be a useful guide for the IFDA and companies for improving PIs.

Although PIs have improved in recent years in Iran, there is a need for more accurate and up-to-date information. In this regard, the IFDA should supervise pharmaceutical companies more strictly and should revise its regulations and confirm PIs to the FDA regulations.

Authors' Contribution

Shahriyar Shahbazi Khamas participated in literature search, data analysis, statistical analysis, and manuscript preparation; Hamidreza Taghvaye Masoumi participated in concepts design, manuscript editing and review; Morvarid Zarif-Yeganeh and Atefeh Jafari participated in manuscript preparation and review. All authors read and approved the final manuscript.

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Conflicts of interest

There are no conflicts of interest.

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