

# Errors in Patients' Information Leaflets of Marketed Medicines in Pakistan

Adeel Arsalan<sup>1\*</sup>, Sameer Qureshi<sup>2</sup>, Mehtab Alam<sup>2</sup>, Sadia Ahmed<sup>1</sup>, Osama Shakeel<sup>3</sup>, Anwar Ali<sup>3</sup>, Wardah Jabeen<sup>3</sup>

<sup>1</sup>Baqai Institute of Pharmaceutical Sciences, Baqai Medical University, Toll Plaza, Super Highway, Gadap Road, Karachi-74600, Pakistan.

<sup>2</sup>Department of Biochemistry, Dow University of Health Sciences, Gulzar-e-Hijri, Suparco Road, KDA Scheme, Karachi-75270, Pakistan.

<sup>3</sup>Karachi Medical and Dental College, University of Karachi, Karachi-74700, Pakistan.

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## ABSTRACT

The curing of patient is the top most priority of health associated professionals. Complete and proper information of medicine is always the willing of the patients and their close ones. The primary source of information for patients' regarding the medicine is patients' information leaflet (PIL). The main aim of the present study is to evaluate the errors and incomplete information in leaf inserts sold with marketed medicines in Pakistan. For the present study, 11 different classes of oral medicines of different multinational and national pharmaceutical industries were purchased from different community and hospitals pharmacies in Karachi. The present study has been revealed incomplete information related to medicines in PILs. 9 out of 11 PILs have 48.84% (n= 63) major while minor errors were 51.16% (n= 66). The major errors were included incomplete information of indications, adverse drug effects, drug mechanism, dosage errors, drug-drug and drug-food interactions, precautions and warning, pharmacokinetic profile and pregnancy and lactation. Whereas, omission of structural formula, molecular formula, molecular weight, chemical names, laboratory tests, clinical trials data, font size, paper quality, and use of national language (Urdu) have been observed as minor errors. It has been concluded that majority of PILs sold with marketed medicines were not up to the mark and met the regulatory requirements. In countries like Pakistan, with high illiteracy rate and low financial status, patients' were unaware about the importance of PILs. Mainly pharmaceutical industries have not called attention on information of marketed drugs medicines in Pakistan which has been proven a shocking situation regarding the negligence of healthcare matter in Pakistan.

## INTRODUCTION

People are anticipated and claimed to receive good quality information regarding to their medicines. Health-associated professionals and/or providers should have to inform the right knowledge about the medicines (Coulter et al., 1999). Even in this information rich society, one of the most primary source of information to number of individuals about their medications is the patient's information leaflets (PIL). PILs are furnished with all medicines. PIL provides the essential information to patients enable them to use the medicine safely and achieve their pharmacologic benefits (Kenny et al., 1998) other sources of information related to medicine, the PIL has been highly regulated. The basic regulatory requirements of

PILs have to be met the criteria of respective drug regulatory bodies (Shrank and Avorn, 2007). The PILs have been reviewed and approved by the respective drug regulatory bodies before being supplied with the medicine. Usually the quality of the information between same generic drugs has been changed. Later improvements have highlighted the developing necessity for patients to have the ability to access high quality information about their medicines. The information must be given within it is set out in national legislation (Waller and Evans, 2003). The lawful frame covering PILs should have in force for various years, however, the information provided has been still neglected to meet the patients' need. PIL is a source of drug information that provides essential medication information to consumers (Gal and Prigat, 2005). WHO has been recognized the imperativeness of PIL and recommended the drug manufacturers to follow the guidelines of concerning content. Similarly, many countries have been concerned with this significant stuff and abided drug manufacturers to provide PIL with medicines.

### \* Corresponding Author

Adeel Arsalan, Baqai Institute of Pharmaceutical Sciences, Baqai Medical University, Toll Plaza, Super Highway, Gadap Road, Karachi-74600, Pakistan. Email: [adeelarsalan@hotmail.com](mailto:adeelarsalan@hotmail.com)

Beside government and health associated professionals, consumers themselves has also been aware that PILs are helpful, and need them for safe medication. Consumers find that it is useful for them to be properly complied with drug regimen from PIL (Yach *et al.*, 2004). Though a PIL should be provided with the medicinal product, it has not been enough to make sure that consumers medicate with the drug effectively and safely. When taking a medicine, patient should read, understand, and follow drug instruction consistent with medicine information present in a PIL. Therefore, understanding the drug information written in a PIL has played a significant role in treatment. Comprehending the flyer substance could bring about completely agreeing to the pill bearing. By understanding the PIL contents, patients' may obtain the more beneficial effects and reduce the chances of side effects (Mills and Sullivan, 1999). It has been noted due to insufficient information related to medicines has been found as a major factor. It has been found a number of reasons that patients do not take their medicines as the prescriber intends (Kitching, 1990). People have right to know about the informed decisions regarding their medicinal products. A large number of patients did not know potential side effects of their medicine. It has been also noticed physicians and even pharmacist did not give appropriate advice warnings and precautions of their medicinal products. This may leads to lack of understanding and information to patients. PIL have also been developed to educate patients in self-care of chronic illness like hypertension, arthritis, psychological problems, diabetics, gastrointestinal diseases, and back pain, and instructions to take the medicaments properly. The supportive information in PILs has been increased patients interest in treatments and decision making for the management related to health problems. It has to be the prime object of pharmaceutical industry with good intentions to develop informative PIL, but good intentions are not enough to guarantee quality and usefulness (McIntosh and Shaw, 2003). PILs play an important part in supplementing and reinforcing information provided to physicians, pharmacist, pathologist, and others healthcare professionals which should be given to patient. The medicine manufacturers must be conformed, the comprehensibility and relevance of medicine in their particular PILs (Shepperd *et al.*, 1999). Though, it has been observed that the providing of information to patients may reduced compliance, increased anxiety, and/or have more propensity to know about the side effects. The primary source of information in PILs should have knowledge how to take the drug; specific dose; amount of drug per tablet or other dosage form; average dose and dose range of adult and child. PILs are not good alternate for good verbal discussions, although, lack of consultation timing it has been noticed that patients do not receive the information they want and need (Kitching, 1990). In 2005, a German survey has been found, patients thought PIL were too long, and not furnished with their negative information. Pharma industries has been preferred more solid action-directed information. Morrow and co-workers (2005) have been observed the reduction in length of information of medicine in PILs, similarly, Fuchs and Hippus (2007) have been also observed in German PILs. Both studies have shown major

enhancement in the usability of PILs, while their amendments were free from regulator policies and significantly altered the content and the global structure of the PILs.

## METHODOLOGY

This retrospective analysis of patients' information leaflets (PILs) supplied with different group of medicines purchased from different community and hospital pharmacies at Karachi, Pakistan. The areas of consensus and dissimilarity were identified in the information design of PILs. PIL has been prepared in two parts as disease and drug. 11 oral medicines of multinational and national pharmaceutical industries have been purchased from randomly selected community and hospital pharmacies of different areas of Karachi. The PIL has been present in the packaged medicines. During the present study, comparison of major and minor errors of PILs has been observed. The major and minor errors have been observed. The major errors have been included the absence of detailed indications, absence of detailed adverse drug effects, drug mechanism, dosage errors (including pediatrics or geriatrics doses), over dosage limits and there treatments, errors in precautions and warnings, how to take medication and some important pharmacokinetics data. The minor errors were included omission of structural formula, molecular formula, molecular weight, chemical names, lab tests, clinical trials data, font size, paper quality, and use of national language (Urdu) have been observed.

## RESULT

The present study revealed out of 11 oral medicines, 9 packaged medicines PILs have major and minor errors. The absence and insufficient knowledge regarding medicine in PILs have been summarized in table 1 and table 2. During present study, major errors including the errors in indications, adverse drug effects, drug mechanism, dosage errors, drug-drug and drug-food interactions, precautions and warning, pharmacokinetic profile and pregnancy and lactation informations were either insufficient and absent. The minor errors like omission of structural and molecular formula, chemical names, lab tests, clinical trials data, font size, paper quality, physical characteristics, inactive ingredients and use of local language (Urdu). The comparison of the leaflets of these drugs with standard leaflets, present in PDR (physician desk reference) revealed different errors (major & minor) showing the pharmaceutical industries mistakes within pharmaceutical leaflets. PILs must be written in clear and understandable language pattern. It has been made sure by medicine manufacturers for the preparation of PILs, that these should be taken into account of the needs and views of patients. PILs should fulfill the requirements of font size, color, national language, and layout in an important factor in overall readability and information related to active pharmaceutical ingredient(s) (Walsh and Shaw, 2000; Hellier *et al.*, 2006). The major and minor errors in the PILs have been thoroughly discussed as under each medicine leaflet. The number of major and minor errors in a leaflet is in table 3 and Fig. 1.

**Table 1:** Major Errors In Patients' Information Leaflets.

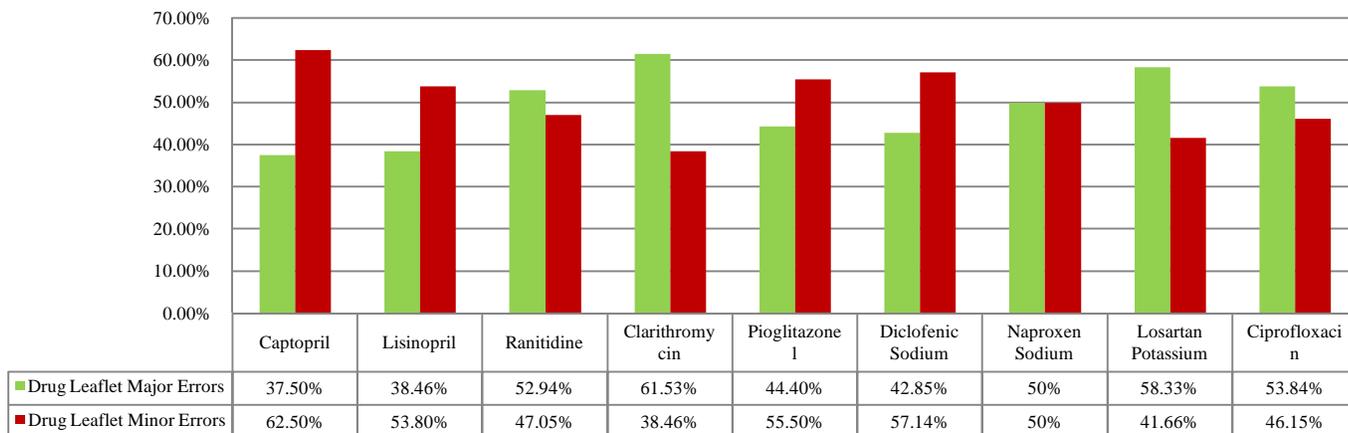
Generic Name	Detailed Indications	Detailed Adverse Effects	Detailed Drug Mechanism	Dosage	Drug- Drug and Drug-Food Interactions	Precautions and Warning	Pregnancy and Lactation	Pharmacokinetic Profile	Others
<b>Captopril</b>	—	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Absent	—	—
<b>Lisinopril</b>	Insufficient	Insufficient	Insufficient	—	Insufficient	—	Absent	—	Company name and address is missing
<b>Ranitidine</b>	—	Insufficient	Absent	Insufficient	Absent	Insufficient	Absent	Absent	—
<b>Clarithromycin</b>	Insufficient	Insufficient	Absent	Insufficient	Absent	Absent	Absent	—	—
<b>Pioglitazone</b>	—	Insufficient	—	Insufficient	Insufficient	Insufficient	Absent	Insufficient	—
<b>Diclofenic Sodium</b>	—	—	Absent	Insufficient	Insufficient	Absent	—	Insufficient	Company name and address is missing
<b>Naproxen Sodium</b>	Insufficient	Insufficient	—	Absent	Insufficient	—	Absent	Absent	—
<b>Losartan</b>	Insufficient	Insufficient	—	—	—	Absent	—	Absent	Company name and address is missing
<b>Ciprofloxacin</b>	Insufficient	—	—	Absent	—	—	Absent	Insufficient	—

**Table 2:** Minor Errors In Patients' Information Leaflets.

Generic Name	Structural Formula	Molecular Formula	Chemical Names	Lab Test	Clinical Trials Data	Font Size	Paper Quality	National Language	Potency	Physical Characteristics	Inactive Ingredients
<b>Captopril</b>	Absent	Absent	Absent	—	—	—	Inferior	Insufficient	Absent	Absent	Absent
<b>Lisinopril</b>	Absent	Absent	Absent	Absent	Absent	Very small	Inferior	Absent	Absent	Absent	Absent
<b>Ranitidine</b>	Absent	Absent	Absent	Absent	Absent	—	Inferior	Insufficient	Absent	Absent	—
<b>Clarithromycin</b>	Absent	Absent	Absent	Absent	Absent	Small size	Inferior	Insufficient	Absent	Absent	—
<b>Pioglitazone</b>	—	—	—	Insufficient	Insufficient	—	—	—	—	—	Absent
<b>Diclofenic sodium</b>	Absent	Absent	Absent	Absent	—	—	Poor	—	—	Absent	—
<b>Naproxen sodium</b>	Absent	Absent	Absent	Absent	Absent	—	Poor	—	—	—	Absent
<b>Losartan</b>	Absent	Absent	Absent	Absent	—	Small	Inferior	Absent	—	Absent	Absent
<b>Ciprofloxacin</b>	Absent	Absent	Absent	Absent	—	—	—	Absent	—	Absent	Absent

**Table 3:** Percentage Of Major And Minor Errors In Patients' Information Leaflets.

Generic Name	Drug Leaflet Major Errors	Drug Leaflet Minor Errors
<i>Captopril</i>	6 (37.50%)	10(62.50%)
<i>Lisinopril</i>	5 (38.46%)	7 (53.80%)
<i>Ranitidine</i>	9 (52.94%)	8 (47.05%)
<i>Clarithromycin</i>	8 (61.53%)	5 (38.46%)
<i>Pioglitazone</i>	8 (44.40%)	10(55.50%)
<i>Diclofenic Sodium</i>	6 (42.85%)	8 (57.14%)
<i>Naproxen Sodium</i>	7 (50.00%)	7 (50.00%)
<i>Losartan Potassium</i>	7 (58.33%)	5 (41.66%)
<i>Ciprofloxacin</i>	7 (53.84%)	6 (46.15%)



**Fig. 1:** Percentage of Errors in Patients' Information Leaflets.

## DISCUSSION

The present study revealed that currently only few of the patient information leaflets (PILs) meet the standards. It has also been observed that mainly in the PILs side effects and adverse reactions were not fully described and written in such manner that patients cannot manage with these events and must be kept ignorant of medicinal uncertainties. PILs were prepared in such manner that benefits of interventions have been emphasized and their risks and side effects has been coated over and scientific argument were hardly mentioned. Eysenbach *et al.* (2002) has been pointed out, the information contained in PILs was inaccurate or misleading. The material found in leaflets has not been met the standards of regulatory bodies. Usually, private publishing companies have been offered their services for the preparation of contents of PILs, and pharmaceutical industries only determine the formatting of the leaflets. Important information was also sometimes entirely absent.

The biggest shortcoming was in the leaflets' readability. On average, leaflets from all pharmacies met less than half of the criteria for "comprehensibility / legibility." Too-small fonts, large blocks of text with little white space between lines. Clear labeling is crucial for the safe use of all medicines and its primary purpose is for the clear and unambiguous identification of the product and the conditions for safe use. Similarity in packaging is known to contribute to medication error and WHO has published guidance for those involved in the design and layout of labeling to help improve the way in which labeling information is presented (Nilsen *et al.*, 2006).

Standard PIL of same generic medicines have been provided the same types of information. In PILs, it has been observed by Arguello and Fernandez-Llimos (2007) that PILs should be easier to read and comprehend for the average person, e.g., instead of "Contraindications" the section may be headed, "Who should not take this medication?" The PILs should comply with the physician desk reference (PDR), and it has to be more elaborated than PDR. For the awareness of importance of PILs, regulators have been increased some new requirements. It has been included the summary of the most important information related to benefits and risks; a table of contents for easy reference; and toll-free number and internet address to encourage more widespread reporting of information regarding any suspected adverse events.

### Captopril

Chemical name is missing. Molecular weight is not mentioned. Physical characteristics are not given i.e. white to off white crystalline powder, sulfurious odour, its solubility etc are missing. Structure is not drawn. Strength information is incomplete according to the given standards. Inactive ingredients are missing. Mechanism of action is short and precise and not discussed in detail as according to standard. Precautionary use in hemodialysis is not mentioned. Drug interaction with agents causing rennin release, cardiac glycosides, allupurinol and loop diuretics is not mentioned. Details of animal toxicology are

missing. Some adverse reactions of the drug i.e. dysgeusia, angioedema body are not mentioned. Dosage and administration of the drug in diabetic nephropathy is not given. Quality of leaflet paper is inferior. Less information is given in national language. Standard of the drug i.e. USP is not mentioned. Recommended dose of the drug in myocardial infarction is missing.

### Lisinopril

Description of the drug is missing. Chemical name, structure, physical characteristics, empirical formula of the drug is missing. Inactive ingredients are missing. Clinical pharmacology i.e. MOA is not given. Usage of drug in diabetes mellitus is not indicated in any given standards but it is indicated in the leaflet. Interaction with NSAIDS is not mentioned. Carcinogenesis, mutagenesis, impairment of fertility is missing. Paper quality is information in Urdu is not sufficient. Sequence of components is haphazard. Lab test findings are not given. Font size is very small which causes difficulty in reading. Standard of the drug i.e. USP is not mentioned. How supplied is not given.

### Ranitidine

Descriptions, physical properties (i.e. texture, form, solubility, and molecular Weight), structure of the drug is missing in the scientific literature of the drug provided by the company for the product. Mechanism of action of the drug i.e. clinical pharmacology of the drug is not explained in the leaflet, which is the important part of the information that must be provided according to the standard. How the drug act and functions inside the body is the information usually required by the physician. Use, indication, and appropriate dosage according to conditions in geriatrics are not mentioned. Laboratory test and other clinical findings that are affected by the drug are not mentioned in the scientific literature of the product. Carcinogenesis, mutagenesis, and impairment of fertility related information is not given in the leaflet. Teratogenic effects and pregnancy category of the drug which is the most important information regarding use of drug in pregnancy / lactation or in nursing mothers is not mentioned in the leaflet. All Adverse effects are not completely discussed or mentioned in the leaflet. In over dosage, over dose or excessive dose is not given. In over dosage, according to clinical trials of over dose LD<sub>50</sub> information is not mentioned. Dosage and administration of drug in the conditions of GERD (gastroesophageal reflux disease) is not mentioned. Dosage adjustment of drug in renal compromised patients is not given. Preparation of drug before ingestion or method of ingestion of tablet is not mentioned as given in the standard. "How supplies" which is an important requirement according to standard is not mentioned in the leaflet. Insufficient information is provided in the national language i.e. Urdu. So provides incomplete information to the illiterate people which include the majority of the population. Quality of the paper use to make leaflets is not up to standard. In the end of the leaflet, proper and complete address of the company is not provided. According to which standard the drug is prepared and the leaflet is designed is not mentioned i.e. USP.

### Clarithromycin

Reference source for the standard i.e. USP, according to which the drug prepared and the leaflet designed was not mentioned. Molecular weight molecular formula and empirical formula of the drug are missing in the leaflet as compare to standard. Physical characteristic of the drug are not properly given i.e. solubility of the drug in water, methanol, ethanol etc texture and appearance of the drug taste and odor of the drug is missing. Mechanism of action of the drug i.e. clinical pharmacology of the drug is not explained in detail in the leaflet which is the important part of the information that must be provided according to the standard. How the drug act and functions inside the body is the information usually required by the physician. Clinical studies or clinical trials done on the drug and the results obtained are not mentioned in the leaflet whereas according to standard it must be given in the leaflet. Carcinogenesis, mutagenesis, and impairment of fertility related information is not given in the leaflet. Insufficient information is provided in the national language i.e. Urdu. So provides incomplete information to the illiterate people which include the majority of the population. Laboratory test and other clinical findings that are affected by the drug are not mentioned in the scientific literature of the product. Use, indication, and appropriate dosage according to conditions in pediatrics and geriatrics are not mentioned. Safety of the drug use according to its dosage and strength is not mentioned in the leaflet. Insufficient information regarding the drug interaction is discussed as compare to that given in the standard. Warnings and precautions of the drug use and safety is not properly provided in the leaflet with the product. Microbiology of the drug is not properly elaborated as given in the standard i.e. information given is not sufficient for the patients and especially for the physicians and pharmacist. Quality of the paper use to make leaflets is not up to standard.

### Pioglitazone

Adverse reactions in the selected pharmaceutical leaflet (pioglitazone) are not sufficiently explained. No doses mentioned in the leaflet on which the adverse reaction takes place as in the standard leaflet in PDR. No adverse reactions properly explained the leaflet in terms of monotherapy & combination therapy For Example if given ID combination with insulin then can cause edema. Laboratory test data i.e. (FPG & HbA1C) is not given in the selected leaflets which are necessary for the monitoring of disease. Cardiovascular events are not properly mentioned in precautions of selected leaflet as explained in the standard leaflets in PDR. In hematological precautions they did not mentioned the percentage of hemoglobin decline. No over dosage data provided in the selected leaflet which is necessary for patient as Well as for medical personnel i.e. Physician, Pharmacist, etc. Some drug interactions are given but not explained properly as in standard which is an essential requirement. Pregnancy category is not mentioned in the selected leaflet (Category C). Adverse effects are not mentioned during pregnancy. Precautions during pregnancy

are not sufficiently mentioned. Clinical data & clinical trials are not mentioned properly. No pediatric usage data given in it. No elderly use data provided with the selected pharmaceutical leaflet. General description is sufficient but less than present in standard. Timing of elevated serum conc. For drug is not mentioned. No average volume of distribution mentioned in pharmacokinetic profile. Gender differences of pharmacokinetics (C<sub>max</sub>. & AUC) are not mentioned (C<sub>max</sub>. & AUC) increase in 20-60% in females.

### Diclofenac Sodium

No description is available for the physical properties i.e. Color solubility of drug. No description of chemical name as mentioned in the standard leaflet in PDR. No chemical structure is available in the selected leaflet. No pharmacodynamics data is properly described in leaflet i.e. no actual pharmacodynamics. No lab tests are provided in the selected leaflets. Pharmacokinetic parameters are not explained as explained in the standard. (no table for pharmacokinetic). In the contraindication section in selected leaflet some contraindications are not mentioned i.e. a continuous preoperative pain of CABG. In warnings the CVS effects i.e. cardiovascular thrombotic events, HTN, HF are not mentioned only GI effects are included. Renal effects of the drug are also not mentioned in the Warning i.e. renal papillary necrosis. Precautions are given in the leaflet but not explained in detail with separate headings i.e. General ( hepatic effects hematological effects). In selected leaflet the drug interactions mentioned for the drugs are Lithium, Diuretics, NSAID's, Anticoagulants, Antibiotics, Methotrixate, Quinolones but in the standard leaflet additional drugs interactions also given i.e. aspirin, ACE inhibitors, warfarin. No geriatrics doses are mentioned in the selected leaflet. Paper quality is poor. No proper manufacturer date (name, address) provided.

### Naproxen Sodium

No chemical name is provided in description. No molecular Weight is provided. No structural formula is present in leaflet. No pharmacokinetics data is provided in the selected leaflets any information about absorption, distribution, metabolism, & excretion is absent in it. No laboratory tests data is given. CVS side effects are not mentioned in it. For example cardiovascular thrombotic events, HTN. No clinical studies & data is mentioned. Poor paper quality. Indications are not sufficiently mentioned in the selected leaflets i.e. the indications also include Gout & Rheumatoid arthritis which are absent in the standard leaflets. Pregnancy category is not mentioned Category C. Drug interactions include only few of the drugs in leaflet i.e. diuretics (furosemide), beta blockers, methotrixate, zidovudine, ACE inhibitor While in standard leaflet the additional drug interactions also present i.e. antacids & sucral fate, aspirin, cholestyramine, lithium, Warfarin, SSRI's. Drug laboratory test are not mentioned in selected leaflets. No profile or information for pediatric dosage. Over dosage data is given but no treatment of over dosage is given in the selected leaflet.

### Losartan Potassium

Physical properties of the drug i.e. color and solubility are not mentioned in the selected leaflet which has its own importance. Structure of the drug is missing from the selected leaflet. Pharmacokinetics data provided in the leaflet is not sufficient. Details of pharmacokinetics of drugs is missing i.e. absorption, metabolism, distribution and elimination details along with AUC, C<sub>max</sub>, half life, and creatinine clearance. Adverse drug effects data in selected leaflet of losartan potassium is less than in standard leaflet of losartan potassium, not mentioned in detail but sufficient. Indications are mentioned in the leaflet but detail of indications is not sufficiently provided. One of the main component of leaflets that is precautions, are missing from it but provided in the standard leaflet with full details. No laboratory test data is given in selected leaflet. Patient information with queries and their answers is missing from the selected leaflet but provided in standard leaflet. Paper quality used is inferior and not up to standard. Small fonts are used which make difficulty in reading and understanding the pharmaceutical leaflet. In the end of the leaflet, proper and complete address of the company is not provided. How supplies" which is an important requirement according to standard is not mentioned in the leaflet.

### Ciprofloxacin

Physical properties of the drug i.e. color and solubility are not mentioned in the selected leaflet which has its own importance. The chemical name for ciprofloxacin HCl that is mono hydrochloride salt of 11-cyclopropyl-6 fluoro-1,4 dihydro-4-oxo-791 piperidenyl)-3-quinolonic aceto oxalic acid, is not given in the leaflet. The molecular weight for ciprofloxacin that is 331.4 is not given in the selected pharmaceutical leaflet. Structural formula as well as molecular formula is missing from leaflet. Pharmacokinetic data provided in leaflet in leaflet is not sufficient. Only absorption of the drug is discussed in the selected leaflet, no data for distribution, metabolism, and excretion is there, as given in standard leaflet if from PDR. No lab test data is given in the pharmaceutical leaflet i.e. susceptibility test. Pediatrics use and dosage information is not mentioned in the selected leaflet. Indications are there but their details are not mentioned i.e. UTI and their causing bacteria. Data is not provided in the local language of country i.e. Urdu. Adverse reactions are present and explained to an extent but not clearly and sufficiently explained. No data about geriatric use is provided. Pregnancy and lactation information provided is not sufficient.

### CONCLUSION

It has been concluded from the present study that majority of PILs with marketed medicines were not up to the mark and meet the requirements. It has been also observed that in developing countries like Pakistan, due to high illiteracy rate patients' were unaware about the importance of drug leaflet information. The PILs has not provided the thorough knowledge regarding the medicines. Mainly pharmaceutical industries do not emphasize on all indications, adverse effects, and dosage regarding

hepato and renal toxicity and insufficiency, drug interactions with food and/or drug of marketed drugs medicines. Even, multinational pharmaceutical industries have not met the criteria, which have been proven a shocking scenario regarding the negligence of healthcare matter in Pakistan.

### RECOMMENDATIONS

The following are the recommendations have been suggested on basis of present study.

1. Information to patients should be always on priority.
2. The design of PILs should according to the need of patients.
3. PILs should contain appropriate use of medicines according to legalistic pattern.
4. PILs should be made more usable by adding the best possible contents and presentations.
5. PILs should be improved the order and information related to side effects.
6. Targeting key messages should be highlighted.
7. PILs should be prepared in short statements to ease in understanding.
8. To provide the information needed for children, adult, and geriatrics patients.
9. Warning and precautions especially for pregnancy and lactation should be in PILs.
10. Dose calculations should be included especially for hepatic and kidney disfunctioning patients.
11. Steps should be taken to promote wide public awareness of PILs and their availability in alternative formats.
12. The main aim is the continual upgrading, and the supporting guidelines should be evaluated periodically.
13. Last not the least, further research should be commended for quality information in PILs that meet patients' needs.

### CONFLICT OF INTEREST

We have declared that there is no conflict of interest with any organization regarding the material discussed in the article.

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