Judgement of Pharmaceutical Package Insert Available in Pakistan from Local and Multinational Companies

Najia Rahim[1]*, Kiran Rafiq[2]

1.Assistant Professor, Department of Pharmaceutics, Dow College of Pharmacy,
Dow University of Health Sciences, Karachi, Pakistan.
2.Assistant Professor, Department of Pharmaceutical Chemistry, Dow College of Pharmacy,
Dow University of health Sciences,Karachi, Pakistan.

ABSTRACT

Pharmaceutical package insert (PPI) is a good source of information about the medicines we take. The aim of the present study was to evaluate information written on PPI of products marketed locally in Pakistan. The study comprised of analysis of PPIs (n=80) against 20 criteria extracted from literature. PPI were categorized in prescription and OTC (over-the-counter) drugs and as local and multinational products. Results were summarized as number and frequencies. Chi-square test using 0.05 level of significance was performed to observe the association of medication type and manufacturer type with the PPI meeting the criteria. Most of the PPIs assessed met the criteria set. In some PPIs, there was lacking of information like, direction of drug use, duration of use and drug interactions. It is concluded that information written on PPIs of drugs marketed in Pakistan was incomplete and non-comprehensive. The PPIs should be improved for the safe and effective use of medications.

INTRODUCTION

Pharmaceutical package insert (PPI) is a source of written information about the medicines, not only for health care professionals but also for the patients or care givers. The awareness among the patients about medications that they are using ultimately results in the improvement of the safety and efficacy of the treatment. This is very important that the information written on PPI must be comprehensive, up to date, clear and readable for patients and care givers. Correct and clear information on PPI can reduce the incidence of medication errors when the drugs are in the hands of patients and caregivers.[1] Researchers also revealed that medication error and poor patient compliance may be the consequences of problem faced by patients in reading and understanding of PPI.[2, 3] It was also observed that patients misinterpret information of PPI. [4-7] PPI must be regularly evaluated in terms of quality and quantity in order to ensure patient safety and treatment success.[8] Different studies in the world have been conducted to critically analyze PPI, [9, 10] but still there is a need of improvement in PPI. Therefore, it is very important to implement evidence based PPI.[11] Many studies revealed that there is a great difference between PPI of the products marketed in different part of the World.[12-14] As there is no strict regulations for monitoring these PPI in many countries, manufacturer market these products with very little information on PPI. This not only results in reduction in effectiveness of medication but at the same time harm the patients. In countries like Pakistan, rules and regulations are made for PPI but many manufacturers and companies are not following these regulations. In this scenario it is very important to evaluate the PPI of products marketed in Pakistan. The present study provided the current status of quality of PPI which guide Ministry of Health, Pakistan to improve the quality of PPI to meet international standards. This study results gave the indicator of extent to which PPI are working to improve patient health. The literature reveals that such type of data has not been repotted yet from Pakistan; hence the present study provides a platform for the improvement of PPI according to the need of Pakistani patients to implement evidence based clinical practice.

METHODOLOGY

Study Design

The study was prospective type and conducted during the months of August and September 2012. PPIs of local and multinational companies were collected from different areas of Karachi, Pakistan. PPI of the medicines marketed in Pakistan purchased from retail and wholesale pharmacies were included in the study. PPI of medicines marketed outside Pakistan, of consumed medicines, sale promotional samples of medicines, duplicates of same drug and same brand were excluded.

Table 1: The availability of informations in a sample of Pharmaceutical Package Insert (PPI)

Informations	Number	Percentage
Active ingredient	80	100
Adverse drug reactions	77	96.2
Warnings and precautions	77	96.2
Clinical indication	80	100
Contraindication	78	97.5
Drug-Drug interaction	56	70
Drug-Food interactions	7	8.8
Dosage instructions (as number of tablets or capsules, as volume, drops or amount of the drug instead of in milligrams)	76	95
Direction for use (such as take the medicine before, after or independent of a meal)	41	51.2
Duration of use	7	8.8
Over dosage toxicity	51	63.8
Effects on ability to drive or use machines	35	43.8
Pregnancy implications	67	83.8
Lactation implications	55	68.8
Expiry after opening or reconstitution	8	10
Storage condition	77	96.2
Storage conditions after opening or reconstitution of the drug	6	7.5
Provides advice on when to consult a physician/pharmacist	3	3.8
Storage conditions, precautions, warning in Urdu	65	81.2
Complete PPI in Urdu along with English	24	30

Evaluation of PPI

During the present study, PPI were judged upon 20 criteria extracted from literature [8-10] as mentioned in table-1. PPI were categorized prescription and OTC (over-the-counter) drugs and as local and multinational products. Data was entered in Statistical Software SPSS-17. PPI meeting the criteria was summarized as number and frequencies. Chi-square test using 0.05 level of s significance was performed to observe the association of medication type and manufacturer type with the PPI meeting the criteria.

PPI of the medicines marketed in Pakistan purchased from retail and wholesale pharmacies were included in the study. PPI of medicines marketed outside Pakistan, of consumed medicines, sale promotional samples of medicines, duplicates of same drug and same brand were excluded.

RESULTS AND DISCUSSION

In this study, 80 PPI of pharmaceutical products available in local market of Pakistan was assessed against 20 criteria compiled from literature.53 (66.2%) PPIs were of prescription drugs, whereas, 27 (33.8%) of OTC drugs. 39 (48.8%) and 41 (51.2%) PPIs were of local and multinational manufacturer, respectively (Figure 1 & 2).Most of the PPIs had information regarding active ingredient, indications and contraindication, i.e. 100%, 100% and 97.5%, respectively (Table-1). It was very alarming that some PPIs analyzed did include drug-drug and drug-food interactions, i.e. 70% and 8.8%, respectively. Drug-food interaction greatly affect the bioavailability of drugs.[13] The study in USA reported the missing drug interactions in PPIs.[9] Information regarding use of drug (before or after meal or bedtime) and duration of use of drug were mentioned only in 51.2% and 8.8%. These results were comparable with the results of another study conducted in Saudi Arabia i.e. time of drug administration in 27% and duration of use in 50%.[14]

PPIs should have clear information regarding use in pregnancy and lactation and also the effect of drug use on ability to drive or operate machines. It is of great concern that 83.8% and 68.8% of PPIs assessed during the study included pregnancy and
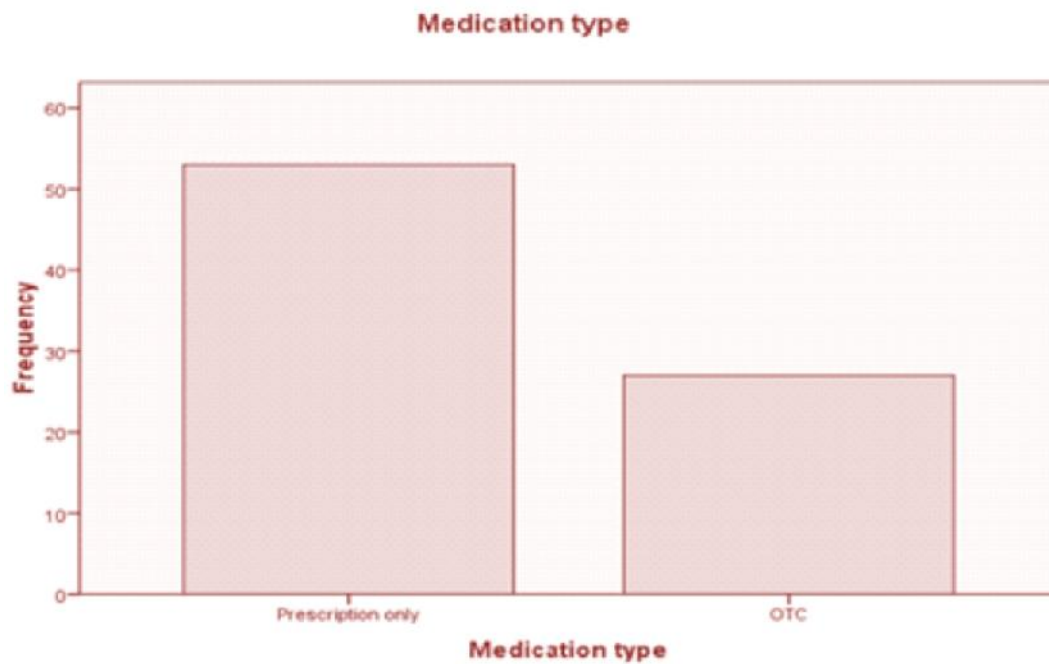
Medication type

Figure 1: Percentages of Prescription-only and OTC drugs
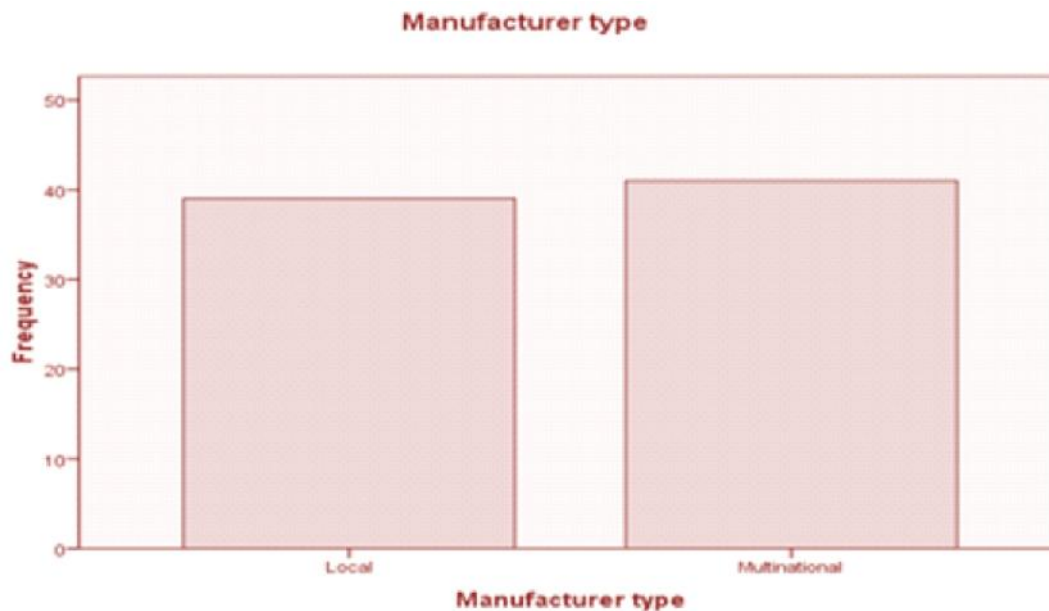
Manufacturer type

Figure 2: Percentages of local and multinational manufacturer

lactation implication and only 43.8% of PPIs had guidance on effect of drug use on ability to drive or operate machines. It was noted that these information was only included in PPIs of drugs which are contraindicated in such conditions. Storage conditions including temperature were written in most of the PPIs assessed (96.2%) but information about this after opening or reconstitution was mentioned on 7.55 PPIs. Information on PPIs of topical, geriatric and antidepressant drugs regarding contraindication, drug interactions and precautions were found missing.[15-17] Results of present study also revealed that important information was missing in PPIs analyzed. This lack of information not only affects the treatment success but also harm the patients. There is

no set criterion for assessing PPIs internationally.[18] Although the criteria used in this study, was previously used in other studies but still have some limitation. There is an urgent need of setting gold standards globally.

For the understanding of patients using the medications, the information on PPIs should be in their mother tongue. Otherwise it is difficult to understand PPIs by general public. Out of 80, 65 (81.2%) of PPI had storage conditions and precautions in Urdu along with English and only 24 (30%) of PPI had complete information in Urdu. Patients will better understand these information if, these are in their mother language. As the Ministry

of Health, Pakistan has no rules and regulations regarding language used in PPIs of products marketed in Pakistan, most of PPIs assessed were in English.

The results of present study was statistically analyzed which revealed that there is no association of the drug type i.e. prescription and OTC drugs and the PPIs meeting the criteria. The association between manufacturer type (local and multinational) and PPIs meeting the criteria was only observed in lactation implication (i.e.χ=7.868, p=0.005). The study conducted in Palestine revealed the significant difference in quality and detailing of information written on PPIs of local and imported pharmaceutical products.[19]It is suggested that PPI should be improved to meet international standards.

CONCLUSION

It was concluded that the information written on PPI of drugs available in Pakistan were not sufficient and non-comprehensive. The important information regarding drug-food interaction, duration of use, storage conditions after opening or reconstitution, were not mentioned in many PPIs. Most of PPI was in English language which may create problems in reading and understanding by general public specifically for those who are not familiar with this language. There was no significant difference in availability of information on PPI of local and multinational companies, except lactation implication. These PPIs .should be improved for safe and effective use of medications in terms of content as well as design to meet the international standards.

REFERENCES

1. Nabors LA, Lehmkuhl HD, Parkins IS, Drury AM. Reading about over-the-counter medications. Issues ComprPediatr Nurs. 2004;27(4):297-305.

2. Davis TC, Wolf MS, Bass PF, et al. Literacy and misunderstanding prescription drug labels. Ann Intern Med. 2006;145(12):887894.

3. Wolf MS, Davis TC, Shrank W, et al. To err is human: patient misinterpretations of prescription drug label instructions. Patient EduCouns. 2007; 67(3): 293300.

4. Berry DC, Knapp P, Raynor DK. Provision of information about drug side-effects to patients. Lancet. 2002; 359 (9309): 853854.

5. Carrigan N, Raynor DK, Knapp P. Adequacy of patient information on adverse effects: An assessment of patient information leaflets in the UK. Drug Saf. 2008; 31(4): 305312.

6. Maat HP, Lentz L. Improving the usability of patient information leaflets. Patient EduCouns. 2010; 80(1): 113119.

7. Shrank W, Avorn J, Rolon C, Shekelle P. Effect of content and format of prescription drug labels on readability, understanding, and medication use: a systematic review. Ann Pharmacother. 2007;41(5):783801

8. Fuchs J, Hippius M, Schaefer M. Analysis of German Package insertsInt J ClinPharmacolTher. 2006; 44(1): 813.

9. Raynor DK, Svarstad B, Knapp P, Aslani P, Rogers MB, Koo M, Krass I, Silcock J. Consumer medication information in the United States, Europe, and Australia: a comparative evaluation. J Am Pharm Assoc (2003).

2007;47(6):717-724

10. Shivkar YM. Clinical information in drug package inserts in India. J Postgrad Med. 2009;55(2):104-107.

11. Coulter A. Evidence based patient information is important, so there needs to be a national strategy to ensure it. BMJ. 1998;317(7153):225226.

12. Al-Ramahi R, Zaid AN, Kettana N, Sweileh W, Al-Jabi D. Attitudes of consumers and healthcare professionals towards the patient package inserts - a study in Palestine. Pharmacy Practice (Internet) 2012 ;10(1):57-63

13. Leon Shargel, Susanna Wu-Pong, Andrew Yu, Yu Andrew B. C., Andrew B.C. Yu. In: Applied Biopharmaceutics& Pharmacokinetics, edition 5th, McGraw-Hill Companies.

14. Sinaa A Al-aqeel Evaluation of medication package inserts in Saudi Arabia Drug, Healthcare and Patient Safety 2012:4: 3338.

15. Zaghi D, Maibach HI. Survey of safety and efficacy information in drug inserts for topical prescription medications. Am J ClinDermatol 2007; 8(1):4346.

16. Steinmetz KL, Coley KC, Pollock BG. Assessment of geriatric information on the drug label for commonly prescribed drugs in older people. J Am Geriatr Soc. 2005;53(5):891894

17. Haw C, Stubbs J. Patient information leaflets for antidepressants: are patients getting the information they need? J Affect Disord. 2011; 128(12):165170.

18. Luk A, Aslani P. Tools used to evaluate written medicine and health information: document and user perspectives. Health EducBehav 2011;38(4):389403

19. Sawalha AF, Sweileh WM, Zyoud SH, Jabi SW. Comparative analysis of patient package inserts of local and imported anti-infective agents in Palestine. Libyan J Med. 2008;3(4):181-185.