Print ISSN: 2319-2003 | Online ISSN: 2279-0780

IJBCP International Journal of Basic & Clinical Pharmacology

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20163268

Research Article

Analysis of package inserts of anti-diabetic medications in India

Deepak Ramadas*, Ananya Chakraborty

Department of Pharmacology, Vydehi Institute of Medical Sciences and Research Centre, 82 EPIP Area, Whitefield, Bangalore, India

Received: 04 August 2016
Accepted: 03 September 2016

***Correspondence to:**
Dr. Deepak Ramadas,
Email: drdeepakr2013@gmail.com

ABSTRACT

Background: Package inserts are printed leaflets accompanying marketed drug products and contain information regarding safe and effective use of drug according to regulatory guidelines. Package inserts are also known as prescription drug label or prescribing information. Need for the study: information's given in package inserts are suboptimal and can lead to medication error. This study was undertaken to assess the presentation and completeness of clinical information provided in the currently available package inserts for anti-diabetic drugs in India.
Methods: Around 146 package inserts were collected from pharmacies located at different areas of Bangalore. They were analysed based on criteria mentioned in Schedule D of drug and cosmetic act 1945.
Results: Out of 146 package inserts, 56 (38%) belongs to grade A (including all injectable preparation) and remaining 90 (62%) belong to grade B. none of package inserts belong to grade C. Information in package inserts were inadequate in several aspects for example, they had unclear instructions about generic name of other ingredients used, about handling, side effects, shelf life, paediatric and geriatric use and guidelines for use of the drugs.
Conclusions: The study concludes that the information provided in the package insert is not relevant for safe and effective use of medications. It is, therefore, recommended to update the existing package inserts based on criteria mentioned in the Schedule D of drug and cosmetic Act, 1945.

Keywords: Package inserts, Antidiabetic, Drug information

INTRODUCTION

Package insert or prescription drug label is an essential feature of drug packaging.[1] These inserts are present in most of the medicinal and pharmaceutical products as a piece of paper with information pertaining to that particular product. Ethically and legally speaking they should provide all the necessary information of the drugs in correct and easily understandable form for safe and effective use.[2] Often unread they have potential educational and even legal implications. In India, the concept of package insert is governed by the 'Drugs and Cosmetics Act (1940) and Rules (1945). The section 6 of Schedule D (II) of the rules lists the headings according to which information should be provided in the Package inserts. The 'Section 6.2' mandates that the Package inserts must be in 'English' and provides information regarding the specific requirements. The 'Section 6.3' mandates pharmaceutical information on list of excipients.[3]

Patients with chronic conditions like diabetes, adhere only to 50-60% of prescribed medications.[4] Diabetes mellitus has emerged as a major health care burden with a current prevalence of 8.3% in urban India.[5] According to reports, there is increase is estimated to be 58% from 2010. India will have the largest number of diabetic patients by 2030.[6] Every year new drugs have been approved for the treatment of DM and medication compliance is considered one of the self-care behaviours

essential for improved health status and greater quality of life in patients with Diabetes mellitus.

Various studies have concluded that Package inserts because of their easy availability can produce an important impact on patients compliance and thus on the ultimate effectiveness of drug use.[7] They also can serve as reliable and accurate sources of drug information for health professionals.[8]

Keeping this in mind, this study was designed to analyse the presentation and completeness of clinical information provided in the currently available package inserts for anti-diabetic medications in India.

METHODS

Collection of package inserts

Package inserts were collected from various pharmacies located in various parts of Bangalore on request over a period of four weeks in the month of May 2016.

Analysis of content of package inserts

Package inserts were scored based on criteria laid down by Indian Drug and Cosmetic Rules, 1945 under section 6.2 of schedule D. Data were extracted twice to minimize chances of missing any information.

Criteria of package inserts

The Package inserts were analysed based on the following criteria

- Legibility
- Approved generic name of active ingredients
- Content of active ingredient per dosage form
- Generic names of other ingredients
- Therapeutic indications
- Posology and method of administration
- Contraindications
- Special warnings and precautions
- Drug interactions
- Pregnancy and lactation
- Pediatric and geriatric indications
- Special conditions and contraindications
- Effect on ability to drive and use machines
- Undesirable effects
- Drug dose
- Over dosage
- Pharmacokinetic information
- Storage information
- Instructions for use and handling
- Shelf life
- Date on which information was last updated
- Name and address of manufacturer/distributor
- Provision of full information on request should be highlighted
- Retail price of the drug
- References.

Scoring and grading of package inserts

A total score of 25 was assigned to each, based on 25 criteria. Presence of information was scored as '1' and absence was scored '0'. Total score was expressed in percentages. If a package insert met more than 20 criteria, it was graded as 'A'; 10 - 20 criteria as 'B', and less than 10 as 'C'.

RESULTS

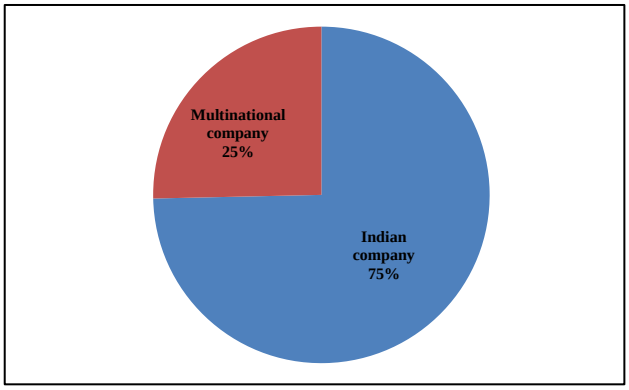

Figure 1: Company wise distribution of anti-diabetic package inserts.

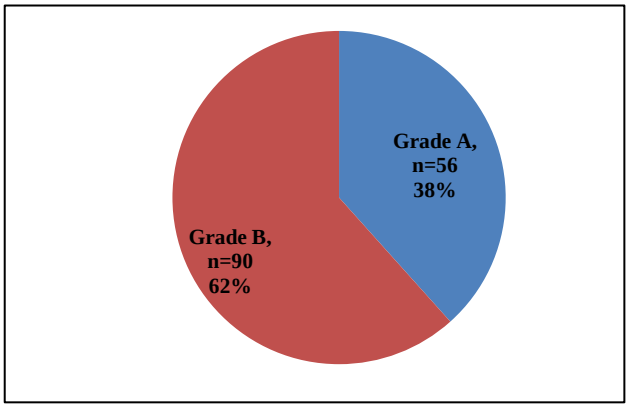

Figure 2: Grading of package inserts of anti-diabetic drugs.

A total of 146 package inserts of anti-diabetic drugs (includes both injectable and oral medications) were collected. Out of 146 package inserts, 109 (75%) package inserts were from Indian company and 37 (25%) package inserts were from multinational company. Out of 146 anti-diabetic package inserts, 122 (83.56%) were oral and 24 (16.43%) were injectable preparations. Out of 146 package inserts, 56 (38%) belongs to grade A (including all injectable preparation) and remaining 90 (62%) belong to grade B. none of package inserts belong to

grade C. The company wise distribution of Package inserts from Indian and multinational companies are shown in (Figure 1). The grading of package inserts of anti-diabetic drugs that were evaluated are shown in Figure 2. It was observed that more package inserts from Indian companies belonged to grade A. The percentage scores of the package inserts are shown in Table 1.

Table 1: Percentage score of package inserts based on criteria lay down by Indian drug and cosmetic rules, 1945.

Number	Criteria	Total score of PIs in percentage
1.	Legibility	95
2.	Approved generic name of active ingredient	100
3.	Content of active ingredient per dosage form	100
4.	Generic names of other ingredients	25
5.	Therapeutic indications	100
6.	Posology and method of administration	100
7.	Contraindications	100
8.	Special warnings and precautions	100
9.	Drug interactions	100
10.	Pregnancy and lactation	94.26
11.	Pediatric and geriatric indications	86.86
12.	Special conditions and contraindications	100
13.	Effect on ability to drive and use machines	36.92
14.	Undesirable effects	37.69
15.	Drug dose	100
16.	Over dosage	100
17.	Pharmacokinetic information	100
18.	Storage information	90
19.	Instructions for use and handling	40.76
20.	Shelf life	0
21.	Date on which information was last updated	41.53
22.	Name and address of manufacturer/distributor	100
23.	Provision of full information on request should be highlighted	100
24.	Retail price of the drug	0
25.	References	0

DISCUSSION

Package insert is a legally required document/label with in the package that is intended to inform the user of the approved and off label use of the drug, its dose and any contraindications or side effects a drug may have.[9] Clear and comprehensible labelling of a drug product is essential for establishing appropriate use among patients and there by maintaining safety and optimizing efficacy and compliance. The labelling must be able to convey the intended use of the product, provide adequate directions for its use, warn against potential harmful effects and provide instructions for appropriate length of treatment and when to seek medical advice.[10] These labels should be prepared keeping in mind the general level of understanding and educational status of common man.

A study done in private practitioners concluded that the majority of them (72%) found package inserts useful or extremely useful.[7] From patients point of view, package inserts have an important impact on patient compliance and thus on the effectiveness of drug use.[6] This is fortunate as a Saudi-based survey of over 2000 community pharmacy customers found that 88% of respondents claimed that they read the package inserts or ask somebody to read it for them.[11] In Indian scenario, due to inadequate doctor patient ratio, the accessibility to trained prescribers is difficult and physicians are not able to spend enough time with their patients. This gives rise to self-medication, medication errors, and adverse drug reactions. All these issues indicate the need for patient oriented Package inserts.[12]

In this study it was observed that the package inserts were inadequate in many aspects. The presentation of information, font size, and colour was appropriate in 95%, generic names of other ingredients in 25%, information about the effect on ability to drive and use of machines in 35% package inserts. Also, information about use in pregnancy and lactation was present in 94.26%, paediatric and geriatric indications in 86.80% and undesirable effects in 37.69% package inserts. Again, storage information was adequate in 90%, instructions for use and handling in 40.76% and date on which information was last updated in 41.53% of package inserts. However, information about shelf life, retail price of the drug and references were not present in any package inserts. Information on shelf life is important as the drug that has passed its shelf life might still be safe for consumption but its quality cannot be guaranteed. This can lead to poor control of diseases like diabetes. Patients should be informed about retail price of the drug in package inserts. References should be mentioned in the package inserts.

From the above findings it is suggested that package inserts must be tested and updated by special group of experts prior to the drug approval. This will prevent lack of information and will guide towards better treatment of diabetic patients. The government should make strict rules to ensure that the pharmaceutical company to stick with

regulatory guidelines and package inserts should be made mandatory with all the drug packages.

CONCLUSION

Package inserts plays a major role in patient compliance and on effectiveness of drug use. Package inserts should be updated according to regulatory guidelines for the benefit of better health care in our society.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

REFERENCES

1. Joubert P, Lasagna L. Patient package inserts: nature, notions a needs. Clinical pharmacology and therapeutics. 1975;18:507-13.
2. Hollister LE. New ideas about drug labels. Clinical pharmacology and therapeutics. 1973;14:309-13.
3. The Drugs and Cosmetics Act and Rules. Ministry of Health and Family Welfare, Government of India. 2003:312. Available at http://cdsco.nic.in/html/copy%20of%201.%20d & cact121.pdf. Accessed on 15 March 2013.
4. Medication adherence: making the case for increased awareness. Available at http://scriptyourfuture.org/wp-content/themes/cons/m/Script_Your_Future_Briefing_Paper.pdf. Accessed on 16 April 2013.
5. Ramachandran A, Snehalatha C, Latha E, Vijay V, Viswanathan M. Rising prevalence of NIDDM in an urban population in India. Diabetologia. 1997;40(2):232-7.
6. Ramachandran A, Das AK, Joshi AR, Yajnik CS, Shah S, Kumar KMP. Current status of diabetes in India and need for novel therapeutic agents. JAPI. 2010;58:7-9.
7. Joubert PH, Skene D. Attitudes of private medical practitioners towards package inserts and other drug information sources. S Afr Med J. 1984;66:306-7.
8. Fuchs J, Hippius M, Schaefer M. Analysis of German package inserts. Int J Clin Pharmacol Ther. 2006;44(1):8-13.
9. Curran WJ. The drug package insert: useful information or the practice of medicine. American Journal of Public Health. 1972;62:435.
10. Friedman CP, Romeo D, Hinton SS. Healthcare decisions and product labeling: results of a consumer comprehension study of prototype labeling for proposed over the counter cholestyramine. American Journal of Medicine. 1997;102:50-6.
11. Bawazir SA, Abou-auda HS, Gubara OA, Al-Khamis KI, Al-Yamaniet MJ. Public attitude toward drug technical package inserts in Saudi Arabia. J Pharm Technol. 2003;19:209-18.
12. Morris LA. Patient package inserts: a new tool for patient education. Public Health Reports. 1977;92(5):421-4.

Cite this article as: Ramadas D, Chakraborty A. Analysis of package inserts of anti-diabetic medications in India. Int J Basic Clin Pharmacol 2016;5:2240-3.