

## Information in Package Inserts: A study in Eastern India

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### Abstract

**Introduction:** Package insert (PI) is the printed leaflet available with the medicines containing information about the drug based on regulatory guidelines for its safe and effective use. Information in a PI is incorporated since the developmental phase of a pharmaceutical product with careful scrutiny of available information. PI contains evidenced based information about a drug, updated from time to time as soon as relevant preclinical and clinical data were obtained. Various studies had shown poor compliance 50-60% to the medicine prescribed for the treatment of chronic conditions like hypertension, diabetes and dyslipidemia. These diseases proved to be major cause of mortality and morbidity related to cardiovascular diseases in India. The information of the PI has an important impact on patient's compliance and hence effectiveness of the drug used and for health professionals they can serve as reliable and accurate sources of drug information.

**Material & Methods:** Present study was observational and Prospective with study duration of 1 month. 93 package inserts were collected from different pharmacies of the Patna on request. Analysis of content of Package Insert was based on criteria laid down by Indian Drug and Cosmetic Rules, 1945 under section 6.2 of schedule D.

**Result:** A total number of 106 PI were received, among which 93 PIs were analysed for the result remaining 13 PIs were discarded due to duplicity and unauthenticity. Out of them, 87 were from Indian pharmaceutical companies and 6 from multinational companies [Graph-2]. All PIs of antihypertensives and hypolipidemic were of oral preparations. Out of 93 PIs 37 were antihypertensives, 34 were antidiabetics and 22 hypolipidemics. Out of 34 anti-diabetic PIs, 22 (59.6%) were oral and 12 (40.4%) were injectable preparations. Out of 93 PI's, 40 (43%) belonged to Grade 'A' (including all injectable preparations) and remaining 53 (57%) to Grade 'B'. No PIs belongs to Grade 'C'. 87 PI's were from Indian companies and 6 PI's were from multinational companies. It was observed that more PIs from Indian companies belonged to Grade A.

**Conclusion:** we are facing the pandemic of diseases like hypertension, diabetes mellitus and other diseases. In such situation PI can play a vital role in improving the patient compliance and thereby the prognosis of disease. Hence a smart PI which is complete, reliable and up-to-date is the need of the hour.

**Keywords:** Antidiabetic, Antihypertensive, Hypolipidemic, Package insert

## 1. Introduction

Package insert (PI) is the printed leaflet available with the medicines containing information about the drug based on regulatory guidelines for its safe and effective use [1]. The contents of PI information in India are regulated 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; Section 6.2 mandates that the PIs must be in 'English' and Section 6.3 mandates description of pharmaceutical information on list of excipients [2].

Information in a PI is incorporated since the developmental phase of a pharmaceutical product with careful scrutiny of available information [3]. PI contains evidenced based information about a drug, updated from time to time as soon as relevant preclinical and clinical data were obtained [1].

Various studies had shown poor compliance 50-60% [4, 5] to the medicine prescribed for the treatment of chronic conditions like hypertension, diabetes and dyslipidemia. These diseases proved to be major cause of mortality and morbidity related to cardiovascular diseases in India.

### 1.1 Rationale of the study

The information of the PI has an important impact on patients compliance and hence effectiveness of the drug used [4, 5], and for health professionals they can serve as reliable and accurate sources of drug information [1]. Keeping this in mind, present study was designed to assess the presentation and completeness of clinical information provided in the presently available PIs for anti-diabetic, antihypertensive and hypolipidemic drugs in Patna.

**1.2 Objective of the study**

To assess the presentation and completeness of clinical information provided in the currently available package inserts for anti-diabetic, antihypertensive and hypolipidemic drugs in India.

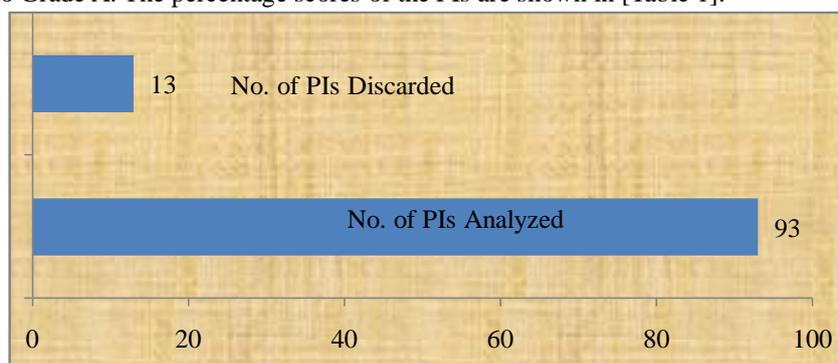
**2. Material & Methods**

Present study was observational and Prospective with study duration of 1 month (1<sup>st</sup> to 30<sup>th</sup> June 2015). 93 package inserts were collected from different pharmacies of the Patna on request

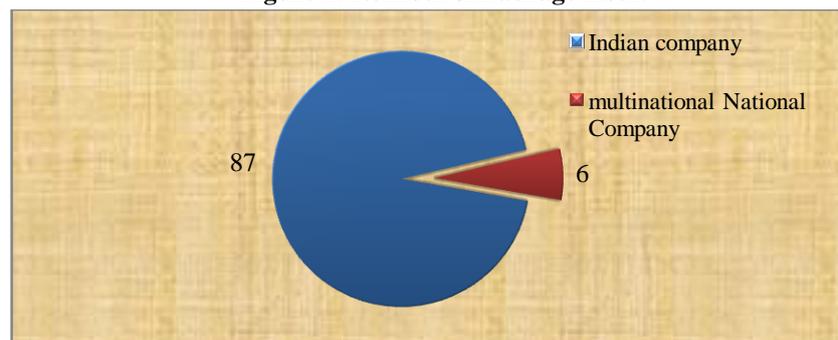
Analysis of content of Package Insert was based on criteria laid down by Indian Drug and Cosmetic Rules, 1945 under section 6.2 of schedule D. Data was extracted twice to minimize the chances of missing any information. A total score of 25 was assigned to each, based on 25 criteria. Presence of information was scored as ‘1’ and absence was scored as ‘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’.

**3. Result**

A total number of 106 PI were received, among which 93 PIs were analysed for the result remaining 13 PIs were discarded due to duplicity and unauthenticity [Figure 1]. Out of them, 87 were from Indian pharmaceutical companies and 6 from multinational companies [Figure 2]. All PIs of antihypertensives and hypolipidemic were of oral preparations. Out of 93 PIs 37 were antihypertensives, 34 were antidiabetics and 22 hypolipidemics [Figure 3]. Out of 34 antidiabetic PIs, 22 (59.6%) were oral and 12 (40.4%) were injectable preparations. Out of 93 PI’s, 40 (43%) belonged to Grade ‘A’ (including all injectable preparations) and remaining 53 (57%) to Grade ‘B’. No PIs belongs to Grade ‘C’ [Figure 4]. 87 PI’s were from Indian companies and 6 PI’s were from multinational companies [Table 1]. It was observed that more PIs from Indian companies belonged to Grade A. The percentage scores of the PIs are shown in [Table 1].



**Figure 1: Number of Package insert**



**Figure 2: Number of Package insert**

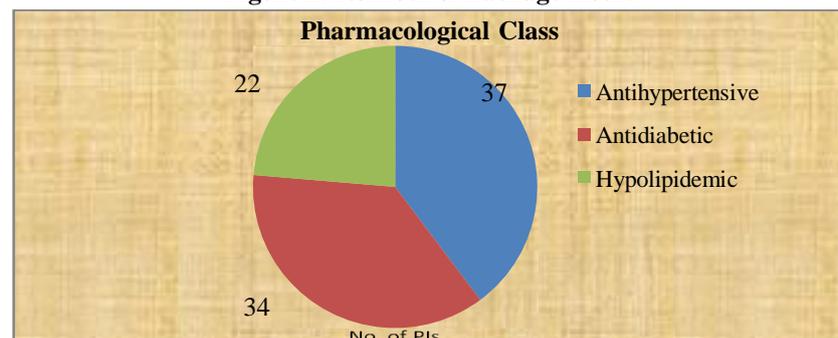


Figure 3: Number of Package insert

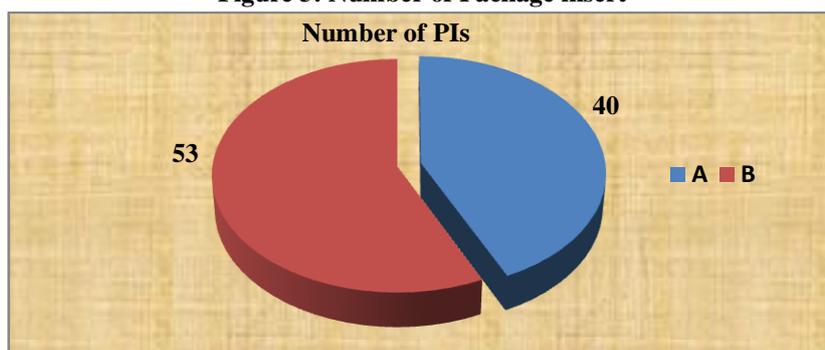


Figure 4: Number of Package insert

Table 1: The percentage scores of the PIs

Criteria number	Criteria	Total score of PIs in percentage
1	Legibility	93.55
2	Approved generic name of active ingredient	100
3	Content of active ingredient per dosage form	100
4	Generic names of other ingredients	18.28
5	Therapeutic indications	100
6	Posology and method of administration	100
7	Contraindications	100
8	Special warnings and precautions	100
9	Drug interactions	96.77
10	Pregnancy and lactation	100
11	Paediatric and geriatric indications	91.40
12	Special conditions and contraindications	100
13	Effect on ability to drive and use machines	38.71
14	Undesirable effects	100
15	Drug dose	100
16	Over dosage	100
17	Pharmacokinetic information	100
18	Storage information	89
19	Instructions for use and handling	95
20	Shelf life	0
21	Date on which information was last updated	53.76
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

#### 4. Discussion

PI provides informative material to the patients and physician and greatly enhances the patient compliance and physician knowledge about that drug [6]. During this study we face a lot of problem in the collection of PI as many of the drugs were not supplied with the PI. Present study shows some lacunae in the PI's available along with the drugs. The information, font size and colour was inappropriate in 6 (6.45 %), generic names of other ingredients in 17 (18.28 %), information about the effect on ability to drive and use of machines was not found in 36 (38.71%) PI's. Information about the use of drug in paediatric & geriatric indications was present in 85(91.40%) of the PI's. Also the information regarding the use of drug in pregnancy and lactation was present in (90) 96.77%. The information provided in the PI's regarding shelf life was absent in all the PI, storage (89%) and instruction for use and handling (95%) have to be improved. Date on which the information was last updated were present in 50 (53.76%) of PI's. This study shows the room of improvement in these lacunae's.

The first package insert came for Isoproteronol and later on for the oral contraceptives [7]. As the education level and the awareness is increasing in the Indian society and the citizens are using the PI for the information regarding the drug they consume the long term effect on the patient compliance can be improved by drafting more patient friendly PI[8,9].

This becomes more important in case of chronic diseases like hypertension, diabetes and hyperlipidemia as inadequate and inappropriate information in the PI may affect patient compliance [10-13].

The more appropriate PI will result in more favourable treatment outcome. Result of the present study emphasizes the need of a more rational PI and should be prepared by the experts prior to the drug approval in the market [14,15]. The supply of the PIs should be made mandatory in the package along with the drugs. The government and the local agencies should seek after to ensure that the pharmaceutical companies comply with the regulatory guidelines [14,15].

As the education level and the awareness is increasing in the Indian society and the citizens are using the PI for the information regarding the drug they consume the long term effect on the patient compliance can be improved by drafting more patient friendly PI[17,18]. This becomes more important in case of chronic diseases like hypertension, diabetes and hyperlipidemia as inadequate and inappropriate information in the PI may affect patient compliance.

## 5. Conclusion

As the world is entering into a pandemic of diseases like hypertension, diabetes mellitus and other diseases the PI can play a vital role in improving the patient compliance and thereby the prognosis of disease. Hence a smart PI which is complete, reliable and up-to-date is the need of the hour. The present study has some lacunae as the duration of study was short and the PI for some common disease were scrutinized hence the result cannot be generalized to PI for drugs available for other conditions and this has to be assess in further studies.

## Reference

- [1] Ved JK. Package Inserts in India: Need for a Revision. *International Journal of Pharma Sciences and Research*. 2010; 1(11): 454-56.
- [2] The Drugs and Cosmetics Act and Rules. Ministry of Health and Family Welfare, Government of India. 2003. p. 312. Available from: <http://cdsco.nic.in> Accessed on 03 Feb, 2015.
- [3] Deepak Ramdas, Ananya Chakraborty, Swaroop HS, Syed Faizan, Praveen Kumar V, Srinivas BN. A Study of Package Inserts in Southern India. *Journal of Clinical and Diagnostic Research*. 2013 Nov, 7(11): 2475-2477.
- [4] 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.
- [5] Kokiwar PR, Gupta SS, Durge PM. Prevalence of Hypertension in a Rural Community of Central India. *JAPI*.2012; 60: 26-29.
- [6] Deepak Ramdas, Ananya Chakraborty, Swaroop HS, Syed Faizan, Praveen Kumar V, Srinivas BN. Study of Package Inserts in Southern India. *Journal of Clinical and Diagnostic Research*. 2013 Nov, 7(11): 2475-2477
- [7] LA Morris. Patient package inserts. A new tool for patient education. *Public Health Rep*. 1977 Sep-Oct; 92(5): 421–424.
- [8] Shivkar Y M. Clinical information in drug package inserts in India. *J Postgrad Med* 2009; 55:104-7.
- [9] Mehta S, Gogtay N J. From the pen to the patient: Minimising medication errors. *J Postgrad Med* 2005; 51:3-4.
- [10] Ramachandran A, Snehalatha C, Latha E, Vijay V, Viswanathan M. Rising prevalence of NIDDM in an urban population in India. *Diabetologia*.1997; 40(2): 232-37.
- [11] 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.
- [12] Kokiwar PR, Gupta SS, Durge PM. Prevalence of Hypertension in a Rural Community of Central India. *JAPI*.2012; 60: 26-29.
- [13] Pandya H, Lakhani JD, Dadhania J, Trivedi A. The prevalence and pattern of dyslipidemia among Type 2 diabetic patients at rural based hospital in Gujarat, India. *Indian Journal of Clinical Practice*.2012; 22(12): 36-44.
- [14] Bawazir SA, Abou-aida HS, Gubara OA, et al. Public attitude toward drug technical package inserts in Saudi Arabia. *J Pharm Technol*. 2003; 19:209–18.
- [15] 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 Jan-Mar; 10(1):57-63.
- [16] Lal A, Sethi A. Drug package inserts in India. *Ann Pharmacother*.1996; 30:1041.
- [17] Shivkar YM. Clinical information in drug package inserts in India. *Journal of Postgraduate Medicine*.2009; 55 (2): 104-07.