SCOPE OF IMPROVEMENT OF PATIENT INFORMATION LEAFLETS IN RANDOMLY SELECTED THERAPEUTIC CLASSES OF DRUGS

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ABSTRACT

Background: Patient information leaflets (PILs) or drug package inserts are leaflets containing specific information about medical conditions, doses, side effects that packed with medicines.

Objective: The objective of this study was to point out a wide-scope of improvement in manufacturer's way of presentation so that maximum benefits can be achieved by both the manufacturers and the consumers.

Materials & Methods: The survey was conducted in the southern region of Moga, Punjab, India over a period from July 2017 to January 2018. Leaflets were sought from pharmacies located in the region for drug products. The clinical information included in the package inserts was analyzed according to Sections 6.2 and 6.3 of Schedule D of Drugs and Cosmetics Rules, 1945. The completeness of information was verified by comparing it with product monograph. We also tried to find out the "Scope of Improvement" of the product and scored regarding 10 different attributes under a Binary Scale Method.

Result: The 50 patient information leaflets studied included 25 oral, 15 injectable, and 10 topical preparations marketed by 50 different pharmaceutical companies in India. None of the reviewed inserts contained all 17 sections as required by the Drugs and Cosmetics Act. The best value of compliance was 82%. Only 16% of the inserts contained instructions for use of the medicinal product. However, shelf life after dilution and shelf life after first opening the container was given much less importance as compared to the shelf life as packed for sale. Incompatibilities were provided only in 30% of the inserts. In case of "Scope of Improvement". The obtained information content was scored out of 10 and was found to be in the average score range of maximum 6.2 (scored by Antihypertensives) to minimum 3.4 (scored by Vitamin Supplements).

Conclusion: Labels of medicines without sufficient information can be dangerous and inefficient in use by the consumers. Therefore there is a need to frame strict regulations and focus on its proper implementation to make the labels standard and of maximum-benefit both for producers and consumers

Keywords: Drug package inserts, Direct-to-consumer pharmaceutical advertising, Patient information leaflets, Drug information leaflets.

1. INTRODUCTION:

Nowadays patients are more enthusiastic to know about their treatment and the medicines they are taking. For this patients look in the direction of health professionals that are the most popular source for drug advice[1]. Conventionally the responsibility for informing the patient has rested with the prescribing physician, despite the fact that there is evidence that he does not always have adequate pharmacological knowledge, is not always good at communication, and is often short of time[2]. The patient also has the right to know what he is taking and how it can have an effect on them. If they are not provided information about their medications it can lead to poor non-compliance and medication adherence that can render drugs ineffective. This can likely have consequences on the patients health. Most studies have shown that providing written material helps patients to remind information[3]. The problem can be overcome by providing Patient information leaflets in the drug product packages.

Patient information leaflets (PILs) or drug package inserts are leaflets containing specific information about medical conditions, doses, side effects and they are packed with medicines. They are the simple, cheap and bedrock methods used to give the user information about the product. The Branded Medicines in India comes with a variety of Quality and Prices. Although regulatory bodies governing the prices of medicines are whole sole responsible for the quality and approval of different variety of products. It is mandatory for the market authorisation holders (MAHs) to provide package inserts in form of patient information leaflet alongside the product. Patient information leaflets are the reliable source of information that provides accurate and dependable information for the new molecules in the market[4]. Incomplete and incorrect product information may advance irrational prescribing and may have serious consequences, including disability and death. The information in it must be continuously updated as and when any appropriate preclinical and clinical data crop up[5].

In India, regulations for package insert are provided under 'Section 6.2' and 'Section 6.3' of 'Drugs and Cosmetics Act (1940) and Rules (1945).The final amendment to the act had been enforced in 1986. The Drugs and Cosmetics Rules do not specify the user of package insert but it appears to be directed to the healthcare professionals[6]. Also, the text in 'Schedule Y' of the rules does refer to package inserts as prescribing information[7]. The patient information leaflets should follow certain criteria according to Drugs and Cosmetics Act, 1940 they are shown in table 1.

But do they really provide necessary information to the consumers. That's what we tried to find out in our study.

2. MATERIALS AND METHODS:

There is a wide range of upcoming discrepancies among the pharmaceutical products and patient-information delivered to the consumers. The objective of this survey was to point out a wide-scope of improvement in manufacturer's way of presentation so that maximum benefits can be achieved by both the manufacturers and the consumers.

The survey was conducted in the southern region of Moga, Punjab, India. Leaflets were sought from pharmacies located in the region for drug products. The survey was conducted over a period from July 2017 to January 2018. The products were no greater than 2 years old. The package inserts were analyzed for the presentation and wholeness of clinical and pharmaceutical information as mentioned. The clinical information incorporated in the package inserts was analyzed according to Sections 6.2 and 6.3 of Schedule D of Drugs and Cosmetics Rules, 1945. The package inserts were checked for the presence of the headings mentioned in Section 6.2 and 6.3

Details are shown in Table 1

Table 1. Criteria of Patient information leaflets according to Drugs and Cosmetics Act, 1940:

Section 6.2: Therapeutic Information	• Posology and method of administration • Contra-indications. • Special warnings and special precautions for use, if any. • Interaction with other medicaments and other forms of interaction. • Pregnancy and lactation, if contra-indicated. • Effects on ability to drive and use machines, if contra-indicated. • Undesirable effects/side effects. • Antidote for overdosing.
Section 6.3: Pharmaceutical Information	• List of excipients • Incompatibilities • Shelf life in the medical product as packaged for sale. • Shelf life after dilution or reconstitution according to direction. • Shelf life after first opening the container. • Special precautions for storage. • Nature and specification of the container.

The wholeness of information was verified by comparing it with product monograph. If a heading was not present in a package insert, the entire insert was checked for the presence or absence of information appropriate to the concerned heading. If the information was present under the relevant heading or elsewhere in the package insert it was scored as one, otherwise a score of zero was assigned. After each of the selected package inserts had been scored, the total scores for each heading were calculated by totaling the scores from individual package inserts. The total scores were expressed as absolute numbers and percentages. In this survey, We also tried to find out the "Scope of Improvement" of the product and patient related information which was depicted by randomly chosen five different drugs of each 10 different therapeutic class of pharmaceutical products were analyzed and scored regarding 10 different attributes such as : 1) Patient Information Leaflet, 2) Prescription Information, 3) Composition, 4) Dosage, 5) Indication, 6) Directions for use, 7) Storage Condition, 8) Adverse Drug Reactions, 9) Quality of product packaging, 10) Contraindications/Cautions; under a Binary Scale Method.

3. RESULTS:

The package inserts of 50 drugs were evaluated in this study. The 50 patient information leaflets studied included 25 oral, 15 injectable, and 10 topical preparations marketed by 50 different pharmaceutical companies in India. The data regarding the presence of important sections described in the leaflets is provided in Table 2. None of the reviewed inserts contained all 17 sections as required by the Drugs and Cosmetics Act. The best value of compliance was 82%.

In general, the appearance of clinical information was complete, though it was not easy to locate and retrieve information easily due to lack of a common design and headings. Indications for use, posology, side effects, special warnings, drug interactions and contraindications were mentioned in at least 94% to 88% of the package inserts studied (Table 2). However, only 6% of the inserts enclosed information on antidote in case of overdose. Only one of the leaflets (2%) warned about the potential impact on driving or activities that would require the patient to be vigilant. This is possibly of low relevance considering the fact that none of the drugs had central nervous system activity. Only 16% of the inserts enclosed directions for use of the medicinal product. The information related to side effects and adverse drug reactions was also good (100%). However, shelf life after dilution and shelf life after first opening the container was given much less significance as compared to the shelf life as packed for sale. The list of excipients, nature and specifications of container were represented in at least 90% of the inserts. Storage instructions were satisfactorily represented in 94% of the leaflets. Incompatibilities were provided only in 30% of the inserts.

The overall design of the inserts needs to be more uniform across the inserts. The prints were legible and the paper was intact for all of them. The size of the inserts was appropriate with respect to the information presented therein.

Details are shown in table 2.

Table 2. Results of survey of Patient information leaflets:

Section 6.2	Sum of positive scores	Percentage of positive scores (Out of 50)
Indication	50	100
Posology and method of administration	47	94
Contraindication	44	88
Special warning and precaution for use	45	90
Interaction with the medication and other interaction	42	84
Pregnancy and lactation, if contraindicated	43	86
Effects of ability to drive and use medicines, if contraindicated	1	2
Undesirable effects/side effects	50	100
Antidote for overdosing	3	6
List of excipients	45	90
Incompatibility	15	30
Shelf life in the medical product or package for sale	18	36
Shelf life after dilution/reconstitution	0	0
Shelf life after first opening the container	30	60
Special precaution for storage	47	94
Nature and specification of the container Instruction for use	8	16

In case of "Scope of Improvement". The obtained information content was scored out of 10 and was found to be in the average score range of maximum 6.2 (scored by Antihypertensives) to minimum 3.4 (scored by Vitamin Supplements). The average score obtained by respective therapeutic classes in ascending order is as follows : VITAMIN SUPPLEMENTS (3.4) < ANTIDIABETICS (4.0) < PROTON PUMP INHIBITORS (4.2) = ANTIPLATELETS (4.2) < ANTIANGINAL AGENTS (4.4) = ANTIHYPERLIPIDEMIC AGENTS (4.4) < ANTIASTHAMATIC AGENTS (5.4) < ANALGESICS (5.6) < ANTIBIOTICS (5.8) < ANTIHYPERTENSIVES (6.2). The study clearly indicates that there is a targeted scope of improvement in front of above mentioned each therapeutic class in their efficacy of delivering product and patient related

information, which when expressed in percentage, comes to be in descending sequence of 66% > 60% > 58% = 58% > 56% = 56% > 46% > 44% > 42% > 38% respectively.

Details are shown in figure 1.

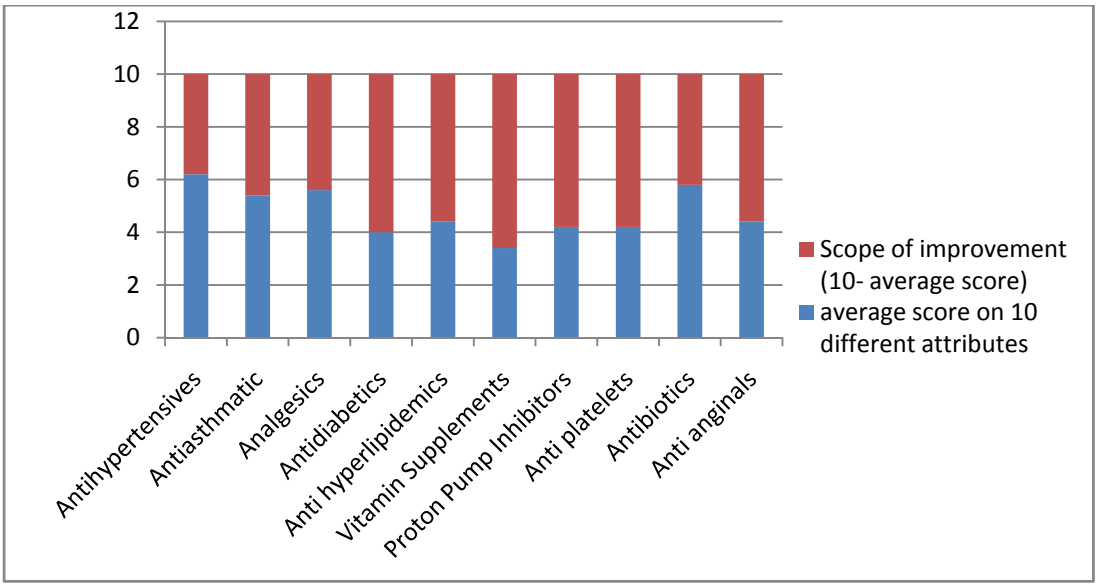

Figure 1. Depiction of average score and scope of improvements (X-axis: therapeutic categories and Y-axis: range of average score on 10 different attributes)

4. DISCUSION:

There is no doubt that Patient information leaflets can help increasing patient compliance and decreasing the medication errors, they also provides patients a satisfaction regarding the product that they are consuming. In our survey it was found that there is a scarcity of proper regulation. There is a need to provide patients with an integrated, consistent information system about their prescription drugs rather than the disused, uncoordinated, and hard-to-read pieces of information they receive now parallel findings are reported in literature as well[8]. The current patient information leaflets contains medical jargons and its format to a great extent is more prescriber friendly than the consumers, in that it provides[9]. India is a country with many different languages that varies region to region and most people are not fluent, or even familiar with the English language who are from low-socioeconomic background. ‘Section 6.2’ mandates that the package insert must be in ‘English' and this can act as a obstacle for the patient who does not have sufficient knowledge to comprehend it[10].This point had been taken note of in recent times and the Department of Chemicals of India had instructed manufacturers to print labels in Hindi. However, this move met with significant obstacles as Hindi is not a prime language in many parts of the country. It is not possible for the manufacturers to print leaflets in many different languages. The leaflets can be made more understandable if pictograms are also incorporated in them this method has been proven to be useful in increasing the understanding of patients while reading leaflets[11]. There is also inconsistency of information that is being provided on a similar package by different manufacturers these findings are similar to findings reported in past[12]. There are also no regulations in India for consumer testing to determine the most effective design as compared to the Europe which has European Guidelines for consumer testing. The consumer testing can yield productive results that can be used to adjust the patient information leaflets according to the consumer needs according to the region[13]. There is a scope of improvement in the patient information leaflets the model has to be tailored in such that it can serve as a better tool for the dissemination of information to the patients and the prescribers[5], [9], [14]–[17].

5. CONCLUSION:

Labels of medicines without sufficient information can be dangerous and inefficient in use by the consumers, which can further lead to discontinuation of the product owing to lack of satisfaction, and in turn, a loss for the manufacturers. A lot is needed to be done in this arena. Things that are required to be done includes:

- Revising and standardising the patient information leaflets format.
- Formulating guidelines similar to lines of European guidelines for consumer testing.
- The supply of the package inserts should be made compulsory to be enclosed in the package along with the drugs.
- A governing body should be formed to regulate, monitor and ensure effective implementation of these rules and guidelines.

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