International Journal of Research in Medical Sciences
Chhaya MU. Int J Res Med Sci. 2017 Feb;5(2):529-532
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20170145

Original Research Article

Analysis of package inserts of orally administered drugs available in the Indian market

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Received: 28 November 2016
Revised: 20 December 2016
Accepted: 23 December 2016

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ABSTRACT

Background: The package insert of a medication forms an important source of information to the patient while taking a drug. The package insert is expected to contain complete information regarding the drug aiding the patient to obtain additional knowledge regarding the drug.
Methods: 100 package inserts of orally administered drugs were obtained from local chemists and were analysed according to the Sections 6.2 and 6.3 of Schedule D (II), Drugs and Cosmetics Act (1940) and Rules (1945).
Results: The posology and contraindications were mentioned in 98% and 96% of the inserts, respectively, whereas the list of excipients, incompatibilities and shelf life was mentioned in 12%, 19%, 16% of the inserts, respectively.
Conclusions: There is a wide variation in the information available on the package inserts of drugs available in the Indian market. The package inserts should be carefully scrutinized for completeness before the respective drug is marketed.

Keywords: Drug, Excipients, Package insert, Posology, Schedule D, Shelf Life

INTRODUCTION

The doctor patient ratio in India is 1:1700 which is much less than the recommended 1:1000.[1,2] In such a scenario, it becomes very difficult for the doctor to impart detailed information regarding a particular drug to the patient. At the same time it is difficult for the patient to remember every detail described by the doctor. A package insert thus forms a good source of information for the patient in addition to the instructions given by the doctor.

A package insert is a document, approved by the administrative licensing authority, which is provided with the package of a drug.[3] Many a times, it is not feasible for the doctor to refer to research articles to look for recent advances in relation to a particular drug, in such a circumstance, the package insert forms a critical source of information to the physician aiding the physician in prescribing the drug safely. It is therefore imperative that the package inserts be revised and updated regularly as a large part of the society depends on them to gather information. Regulatory requirements for drug package inserts vary across nations. United States-Food and Drug Administration (US-FDA) and the Directorate-General for Health and Food Safety, European Commission, state their regulations governing the content and format of labelling for drug products from time to time.[4,5]

In India, the regulations for the manufacture, import, distribution and sale of pharmaceutical products are specified in the 'Drugs and Cosmetics Act (1940) and Rules (1945)'. 'Section 6.2 and 6.3' of 'Schedule D (II)' of the Rules deals with the labelling and packaging information of drugs as well as enlists the captions

according to which information should be delivered in the package inserts.[6] The purpose of this study is to look for wholeness of information, both therapeutic and pharmaceutical, stated in the package inserts.

METHODS

100 package inserts of orally administered drugs marketed between May 2015 and May 2016 were obtained from local and regional chemists. Package inserts of topical and injectable preparations were excluded. The package inserts were examined in accordance with the points mentioned in the Sections '6.2' and '6.3' of Schedule D (II), Drugs and Cosmetics Act (1940) and Rules (1945).

Each insert was scored 1 point each for every caption included, maximum score being 16 and minimum score being 0. Each caption was awarded 1 point for every insert that sited it, a maximum score being 100 and a minimum being 0.

RESULTS

The package inserts of 100 orally administered drugs were analysed. The package inserts included were of drugs marketed between May 2015 and May 2016 and manufactured by different pharmaceutical companies, Indian and Foreign.

Table 1: Captions under Sections '6.2' and '6.3' of schedule D (II), drugs and cosmetics act (1940) and rules (1945).

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

According to Section 6.2 the package inserts should be in English and it was found that all the inserts examined were in English and not in regional languages. Section 6.2 also included the therapeutic indication which should be addressed to in the package insert while Section 6.3 gives guidelines about the pharmaceutical information that should be present in the package insert. The Table no. 1 represents the points mentioned in the Sections '6.2' and '6.3' of Schedule D (II), Drugs and Cosmetics Act (1940) and Rules (1945).

Table 2: Completeness of information in the package inserts with respect to Section '6.2' of Schedule D (II), Drugs and Cosmetics Act (1940) and Rules (1945).

Content	Mentioned (%)	Not Mentioned (%)
Posology and method of administration	98	2
Contra-indications	96	4
Special warnings and special precautions for use, if any	96	4
Interaction with other medicaments and other forms of interaction	89	11
Pregnancy and lactation, if contra-indicated	89	11
Effects of ability to drive and use machines, if contra-indicated	16	84
Undesirable effects/side effects	97	3
Antidote for overdosing	84	16

An observation was made that, in comparison to the therapeutic indications, the number of inserts providing pharmaceutical information was very less. The inserts were scored corresponding to the subtitles that they remarked upon. Accordingly, it was observed that 79% of package inserts scored above 8 i.e. more than 50%, of which 48 had a score of 9. The minimum score recorded was 3 in 3 packages inserts while the maximum score was recorded as 13, also in 3 package inserts. Figure 1 represents the scores achieved by the package inserts.

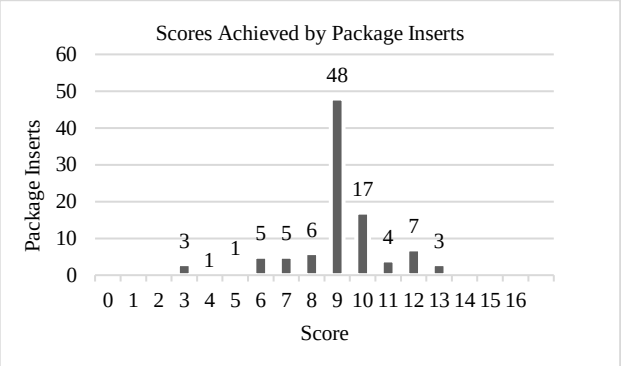

Figure 1: Scores achieved by package inserts.

Amongst the 100 package inserts analysed, a 100% of inserts mentioned the indication for the drugs' use and 98% gave the posology and method of administration of the drug. 96% package inserts provided complete information regarding the contraindications as well as special warnings and precautions for drug use. 89% specified about drug interactions in much detail, while interactions other than these were not mentioned in any insert. 89% gave the subtitle of use in pregnancy and lactation of which 60 inserts categorized the drug safe in pregnancy, 21 inserts mentioned the absence of safety studies in this particular population, while 8 inserts contraindicated the drugs' use in pregnancy and lactation. 16% of the inserts informed caution while driving and using machines. 97% listed the adverse reactions possible with the drug. 84% mentioned drug overdose, of which 13 gave specific antidotes while remaining 71 speak about symptomatic management. As far as the pharmaceutical information is concerned, 92% gave the container details while 95% gave the storage precautions. However, only 12% gave the list of excipients, 19% mentioned incompatibilities and 16% gave the shelf life. Tables 2 and 3 represent the completeness of information with regards to Section '6.2' and '6.3' of Schedule D (II), Drugs and Cosmetics Act (1940) and Rules (1945), respectively.

Table 3: Completeness of information in the package insert with respect to section '6.3' of schedule D (II), drugs and cosmetics act (1940) and rules (1945).

Content	Mentioned (%)	Not Mentioned (%)
List of Excipients	12	88
Incompatibilities	19	81
Shelf life in the medical product as packaged for sale	16	84
Shelf life after dilution or reconstitution according to direction	0	100
Shelf life after first opening the container	0	100
Special precautions for storage	95	5
Nature and specification of the containers	92	8
Instructions for use/handling	0	100

As the inserts belonged to Indian as well as Foreign (non–Indian) pharmaceutical companies, an analysis regarding their completeness was made in this respect as well. Out of a total of 100 package inserts, 64 were from Indian companies and 36 were from non–Indian companies. 16 out of 64 (25%) Indian inserts had a score of above 9 while 15 out of 36 (41.6%) Foreign inserts had a score above 9.

From the above statement, it is clear that package inserts published by non–Indian Foreign pharmaceutical companies were much more complete as compared to Indian pharmaceutical companies. Figure 2 represents the scores achieved by the package inserts on the basis of the nationality of their publishing pharmaceutical companies.

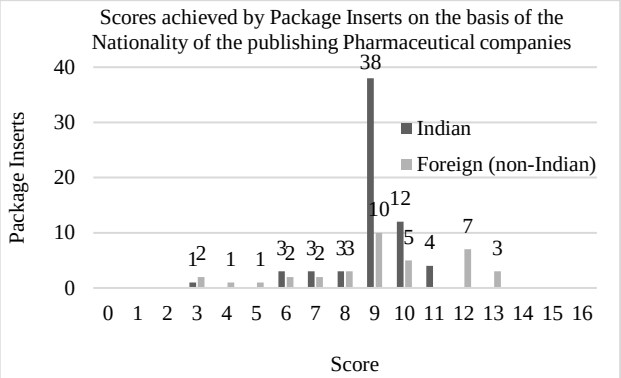

Figure 2: Scores achieved by package inserts on the basis of the nationality of the publishing pharmaceutical companies.

DISCUSSION

Safe and effective use of drugs is of paramount importance for maintaining the health of the society. To achieve this, the prescribers have to be up-to-date with appropriate and accurate information regarding the medication. A package insert, thus, forms a reliable source of information, since is approved by an authority before being published. It is crucial that these inserts are regularly updated with adequate essential data.

An overall improvement in the wholeness of the package inserts, with regards to the therapeutic information, has been observed in this study. The percentage of inserts giving detailed information regarding the contraindications is 96% in comparison to 91% in the study conducted by B. Sowmya et al. However, the pharmaceutical information seems to be neglected much more.[3] Effect of the drug on the ability to drive and operate machines has also received more value i.e. 16% as compared to 2% in the study by Kalam et al, a point which was found to be much neglected.[7] Although the quality of package inserts has improved, it can be concluded that an equal emphasis needs to be given to the therapeutic as well as pharmaceutical information for which a stringent surveillance of the package inserts is necessary.[8]

One has to also take into consideration that the package insert not only aids the physician but also provides assistance and a tool for learning to the patient.[9,10] As mentioned above, all the inserts obtained from the chemists were in English. This could pose a problem to the reader in terms of understanding the information provided. An additional insert in the regional language

would prove to be helpful in this context. Many a times, package inserts for the same drug from different companies may have differing information. A post publishing surveillance to avoid such confusion would be beneficial.[11] It is a known fact that over the counter (OTC) practice in India has become rampant in the past few years. In such conditions, the patient fails to get a hold of the package insert which would otherwise have been helpful. A strict watch on such a practice is the need of the hour for the benefit of the patient as well as the society.

Limitations

The limitation of this study is that package inserts of only orally administered and locally available drugs were included. Inclusion of packing inserts of topical and injectable drugs would give more detailed results.

CONCLUSION

There is a wide variation in the information available on the package inserts of drugs available in the Indian market. The package inserts should be carefully scrutinized for completeness before the respective drug is marketed.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Kumar A. India has just one doctor for every 1,700 people. The New Indian Express, 2013. Available at http://www.newindianexpress.com/ magazine/ India-has-just-one-doctor-for-every-1700-people/ 2013/ 09/ 22/article1792010.ece Accessed 05 May 2016.
2. Deo M. Doctor population ratio for India - The reality. Indian J Med Res 2013;137(4):632-5.
3. Sowmya B, Vijayalakshmi, Narayana R. Critical appraisal of patient package inserts in allopathic medicines. J. Chem. Pharm. Res., 2015;7(3).
4. Food and Drug Administration, HHS. Requirements on content and format of labeling for human prescription drug and biological products. Fed Reg 2006;71:3921-97.
5. European Commission. Guideline on the Packaging Information of Medicinal Products for Human Use Authorized by the Union, July 2015. Available at ec.europa.eu/ health/ files/ eudralex/ vol-2/2015-07_14_3_packaging.pdf. Accessed 11 May 2016.
6. Govt. of India, Ministry of Health and Family Welfare. Drug and Cosmetics Rules, 1945. Available at http://cdsco.nic.in/ html/ Drugs andCosmeticAct.pdf. Accessed 11 May 2016.
7. Kalam A, Anwar S, Fatima A. Drug package inserts in India: Current scenario. Wor J Pha Pharma Scie. 2014;33(44):385-92.
8. Shivkar Y. Clinical information in drug package inserts in India. J Postgrad Med. 2009;55(2):104-7.
9. Morris L. Patient Package Inserts: A new tool for patient education. Public Health Reports. 1977;92(5):421-4.
10. Hermann F, Herxheimer A, Lionel N. Package inserts for prescribed medicines: what minimum information do patients need? Br Med J. 1978;2(6145):1132-5.
11. Storflor J, Pettersen L, Slørdal L, Spigset O. Drug package inserts--varying information for the same medicines. Tidsskr Nor Laegeforen. 2013;133(9):955-9.

Cite this article as: Chhaya MU. Analysis of package inserts of orally administered drugs available in the Indian market. Int J Res Med Sci 2017;5:529-32.