

# Package Inserts in India: Need for a Revision

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## Abstract:

Package insert is an officially approved document that accompanies a drug, and is intended to provide information for its safe and effective use. However, there is a high incidence of medication errors and the effective use of traditional package inserts is hampered by its complexity and problems of comprehension, for prescribers as well as patients. Thus, there is a need for revising and improving the traditional concept of package inserts in India, to make it more effective in serving its purpose. It can be made more prescriber and patient-friendly by incorporation of some of the concepts, currently followed in the western world.

**Keywords:** Package insert; India; Information; Patient-oriented package insert

## Introduction

### *Concept of Package Insert:*

Package insert is a document, approved by the administrative licensing authority, which is provided with the package of a drug. A package insert, primarily directed at the prescribers, is intended to provide information for the safe and effective use of the respective drug. It is also known as Prescription drug label, Prescribing information, etc.[1]

### *Problem of medication errors:*

Medication errors are of a common occurrence globally, and iatrogenic injuries resulting from the same account for a huge portion of the adverse drug events, observed in a clinical setting.[2] Medication errors may be attributed to the confusion arising due to look alike or sound alike health products, which includes identical doses or dosage forms, similar packaging or labeling, illegible handwriting, verbal communication errors or inadequate knowledge.[2]

Reliable and specific communication of information is necessary for the safe and effective use of medicines. Package insert is one such reliable source of information, which receives prior approval by the respective administrative authority, and which, if used effectively, can be a reliable tool for the minimization of medication errors.

A good package insert contains the approved, essential and accurate information about the drug, is written in a language that is not promotional, false, or misleading, is evidence-based, and updated.[1] However, the effective use of a package insert requires a revision into the traditional concepts, followed in our country.

### *Traditional Concept followed in India:*

In India, the concept of package insert is governed by the 'Drugs and Cosmetics Act (1940) and Rules (1945)'. [3] Section 6 of Schedule D (II) of the Rules lists the headings according to which information should be provided in the package inserts.

'Section 6.2' mandates that the package insert must be in 'English' and must include information on therapeutic indications; posology and method of administration; contraindications; special warnings and precautions; drug interactions; contra-indications in pregnancy and lactation; effects on ability to drive and use machines; undesirable effects; and antidote for overdosing. 'Section 6.3' mandates pharmaceutical information on list of excipients;

incompatibilities; shelf life as packaged, after dilution or reconstitution, or after first opening the container; special precautions for storage; nature and specification of container; and instruction for use / handling.

It is not mentioned clearly, if the package inserts are directed only at the physicians or at the patients as well.[4]

***Suggested modifications:***

The traditional concept of package insert, followed in India, needs a revision for its utilization in a more effective manner. The concept can be modified such that it can serve as a better tool for the dissemination of information to the patients, as well as the prescribers.

***A. As a tool for the Patients:***

- *The need of the hour:* There is a growing realisation that patients need to be made aware of the therapeutic intervention they are undertaking.

The Indian community, traditionally, considers the physician as a 'God', and believes more in their physicians' instructions instead of instructions given in package inserts. However, this trend is changing with the growing literacy and the increasing awareness in the community, regarding its own healthcare and safety issues. Also, it is evident that medication compliance can be improved only by improving the patient awareness.[5]

This is, also, particularly important for the dynamically changing Pharma industry, where new information might be expected to crop up every now and then, which may be missed out, occasionally, by the prescribers.

Also, considering the inadequate doctor : patient ratio in our country, the accessibility of trained prescribers, for the entire Indian population, is difficult. An effective communication may not always be practically possible between the prescribers and the patients. The practice of self-prescription is also quite prevalent in our country, because of similar reasons. Also, the number of drugs available 'Over the counter' has gone up.

All these issues indicate a need for a 'Patient-oriented Package Insert' to accompany the medication packages.

- *Patient-oriented Package insert:* The concept of a Patient-oriented package insert is already in practice in the United States (since 1968; known as the 'Patient Package Insert') and in the European Union (known as 'Patient information leaflets').[1,4-6] This document is written in a non-technical manner, and contains specific information about the drug, how it should be used and how it works. It also contains information regarding any possible safety concerns or precautions necessary when taking the drug.
- *Language barrier:* Apart from the need for a specific, simple, patient-oriented package insert, an important issue, for proper dissemination of information to the patients, is making the information available in the language the patient best understands. For a country like India, where literacy levels are low and various systems of medicines are in place, the language issue becomes all the more important. Information must be disseminated in clear and understandable terms for the users, in the official languages, which the respective users are expected to understand the best. This practice is also under implementation by the multilinguistic European Union, where the 'Patient information leaflets' are disseminated in the respective national languages. [6]

Recently, the European Union undertook a project, 'Patient Information Language Localisation System' (PILLS), to facilitate the development of digital content for the European medical and pharmaceutical products, in multiple forms and languages simultaneously.[7] This concept, although in a nascent stage, is very a promising step towards this direction.

*Availability of patient-oriented package insert, in an understandable language, will be a step forward, for ethical and effective dissemination of healthcare services, in our growing society.*

***B. As a tool for the Healthcare professionals:***

- *Need of the hour:* The package insert is a tool primarily intended to guide the prescribers. However, with the growth of the science of Pharmacology and Pharmaceutics, the package insert has become more of a legal formality, rather than an effective tool for providing timely and accurate prescribing guidance.[1] The

extensive nature of information displayed, and the complexities in the format of package inserts, act as barriers to the intended usage by the prescribers. The lack of timely availability of the desired information is also a matter of consideration for the Indian prescribers.

- Format of package insert: The format of package inserts needs to be simplified, for serving their purpose in a better way, and for a reduction in the incidence of medication errors. This can be best exemplified by the U.S. Food and Drug Administration, who revised its format of Package insert in 2006, for providing clear and concise prescribing information.[1] The revised format included:
  - a) Highlights section: Provides the most important prescribing information about benefits and risks, in a half-page synopsis, for an immediate access.
  - b) Contents section: Easy to use reference to the detailed efficacy and safety information.
  - c) Other changes included Reorganization of frequently referred sections; Easier to read presentation; Consolidated safety information in the Package insert.

This modified format of Package insert is much more prescriber friendly than the traditional one, in that it provides concise sections of essential information, is well structured, is easy to read and comprehend.

*Timely availability:* The timely availability of the required prescribing information is also a point of consideration. In the United States, the package inserts are compiled into a 'Physicians' Desk Reference', which is available for reference in the form of a book, or in an electronic format, accessible from <http://www.pdr.net/>. [8] A similar compilation of the European Union is known as 'Electronic Medicines Compendium', available from <http://www.medicines.org.uk/emc>. [6] Similarly, the South African administration has made their approved package inserts available to the public, in an electronic format, available from <http://home.intekom.com/pharm>. [9] The availability of a comprehensive database for the DCGI - approved package inserts in India, would be of much help for the proper and timely dissemination of healthcare information to the prescribers, as well as the patients.

Thus, the current concept of Package insert, which is followed in India, is inadequate in serving its purpose of providing satisfactory prescribing guidance in an effective manner, to the prescribers or the patients. However, there is a huge scope for improvement in the same, as newer and better concepts have been successfully introduced in some of the developed nations. With the rising healthcare awareness in our society, and to minimize the incidence of medication error-related adverse events, an improvement in the current concept of Package inserts for dissemination of information, is a requirement that must be considered seriously.

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