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Letter to the Editor

Current scenario of drug package inserts in India and the need for their revision

Sir,

Accurate and reliable drug information is essential for safe and effective use of marketed products. The primary source of drug information is a package insert (PI). It is a printed leaflet that contains information based on regulatory guidelines for the safe and effective use of a drug. It is also known as prescription drug label or prescribing information. A good PI contains approved, essential, and accurate information about the drug. It is written in a language that is not promotional, false, or misleading. It is evidence-based and updated time to time as relevant pre-clinical and clinical data become available.[1]

In India, the concept of PI 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 PIs. The "Section 6.2" mandates that the PIs must be in "English" and provides information regarding therapeutic indications; posology and methods of administration; contraindications; special warnings and precautions; drug interactions; contraindications in pregnancy and lactation; effects on ability to drive and use machines; undesirable effects; and antidote for overdosing. The "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.[2]

Regulatory requirements for drug PI or leaflets vary across nations. United States-Food and Drug Administration and European Medicines Agency amend their regulations governing the content and format of labeling for drug products from time to time.[3] In India, the regularity authority is Ministry of Health and Family Welfare, Government of India. The pharmaceutical companies submit the full prescribing information as a part of the new drug application for marketing. This information should be according to the Section 6.2 and 6.3 of Schedule D, 1940 Act. Once the application is approved by the regularity authorities, the information is accompanied with the drug in the package.[4]

Due to the ever growing population of our country, we face a seriously inadequate doctor: patient ratio. Thus, 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 and so a well-crafted PI could serve as an effective guide to help the patient be aware about the medication he has been subjected to. Also, with the tremendous growth of the science of pharmacology and pharmaceutics in recent times, a well-designed PI could serve as an effective tool to guide the prescribers, making the vast relevant information easily accessible and to decrease the medication/administrating errors and thus adverse events. Hence, PIs are effective sources of information not only to the patients and/or paramedic staff, but also aid in updating the knowledge of the prescribing physicians. Currently in India, the structure and content of the information on the inserts is geared toward prescribers only. Given the fact that unauthorized over the counter drug dispensing is a prevalent practice in India, and that patient education is in infancy.[5] There is a need for PI to be more patient-friendly and specifically designed to avoid medication errors. This can be achieved by conducting regular surveys to model the PI for the population. There are many examples of such surveys done in developed countries with an aim to improve the PI and make them user-friendly for patients.[6,7]

India is a country with many languages and most people are not fluent, or even familiar with the English language. User testing of labels and PI are mandatory in many countries, but not in India. Yet, Schedule D pertaining to labeling, instructs manufacturers to print labels in English. 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 as well.[8] However, this move met with significant hindrance as Hindi is not a predominant language in many parts of the country. For a manufacturer producing medicines for the entire Indian market, it is not possible to print labels in all relevant languages. A better means to improve comprehension could be to represent instructions pictorially. The manifest improvement of label comprehension when dosage instructions are presented pictorially has been reported in the past.[9]

Overall, there is a need to improve the format, content and language of the PI in India. Tighter monitoring of the inserts by regulatory bodies can help to enforce ideal labeling

practices. Furthermore, the industry needs to revise its labeling methods, while there is a need to deliver necessary information accurately to the patient, it is also important from a logistical perspective to balance information against over-sized leaflets that are clumsy to handle and daunting to the patient.[3]

The availability of a comprehensive database for the Drugs Controller General of India - approved PI in India, would be of much help for the proper and timely dissemination of healthcare information to the prescribers, as well as the patients.[1] From the above findings, it is suggested that the PIs must be optimized and tested by selected groups of experts prior to the approval of the drug. This will ensure the avoidance of the lack of information and will guide toward informed and better treatment outcomes. The supply of the PIs should be made mandatory in the package along with the drugs. The government should make strict rules to ensure that the pharmaceutical companies comply with the regulatory guidelines.

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