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Evaluation of Medication Package Inserts

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Editorial

Patients require accurate and reliable information to help them use their medications safely and effectively. Inadequate patient knowledge may contribute to medication nonadherence which could negatively affect treatment outcomes. The purpose of this study was to evaluate the presentation and completeness of medication package inserts (MPIs) which are available in the market. A cross-sectional document review was performed in February and March of 2019. All MPIs which were authorized by EFDA to sell in the market and available during the data collection period were considered. The mean overall completeness score of 200 MPIs was 18.39 ± 4.30. Of the 200 MPIs, only 20% were from domestic pharmaceutical companies. Antimicrobials represented 24% of the total MPIs. Topical preparations, cardiovascular drugs, gastrointestinal drugs, and nonsteroidal anti-inflammatory drugs, accounted for 12.5%, 12.5%, 11%, and 9% of the MPIs, respectively.

The majority of the MPIs presented information about the drug's use during pregnancy and lactation, 77.0% and 74.0%, respectively. However, only half of the MPIs, 49.5%, gave information about special warnings and precautions. Only a few of the MPIs provided information about instructions to convert tablets or capsules into liquid forms and the possibility of tablet splitting, 4.8% and 8.7%, respectively. Furthermore, only 1.0% had local language translation. Regulatory authorities should implement stringent regulations to ensure the provision of vital information which extends beyond checking the mere presence of an MPI. They should also act to the possible standardization of MPIs.

Drug treatment is the most common intervention by healthcare providers. Patients require accurate and reliable information to help them use their medications safely and effectively. However, inadequate information provided by healthcare providers is common because of heavy workloads, many patients unable to retain verbal information they have been told for a long time, and misunderstanding of verbal information. Insufficiency of pharmacological knowledge and communication skill by health professionals might also contribute. Furthermore, both physicians and pharmacists broadly vary in the frequency and types of information they give about drug products. As a result, there is consensus among the medical community about the need for high-quality written information for patients about their medications. Written information about drug products such as the medication package inserts (MPIs) is one of the sources that patients use to obtain information about their medication.

Many countries force MPIs to be included in the medication package. The European Union requires all medicines to be marketed within its member states and to be packed with an MPI as a legal requirement. Providing an MPI with medicine is a precondition for marketing by the Food and Drug Authority (EFDA) (formerly known as Food, Medicine, and Health Care Administration and Control Authority FMHACA)). EFDA also states that "the MPI should not be described or presented in a manner that is false, misleading, or deceptive or is likely to create an erroneous impression regarding its use in any respect, either pictorially or in words".

Even though MPIs are vital to providing reliable information, patients usually do not find the information they are looking for. An online literature search reveals that there is no prior study about the MPIs. Therefore, the purpose of this study was to evaluate the presentation and completeness of MPIs which were available in the market.

Based on this study, we concluded that the MPIs available in Ethiopia provide inadequate information about the safety of drug products and local language translation. Drug companies should act responsibly and provide information in their MPI's including an additional insert with the local language(s). Regulatory authorities should implement stringent regulations to ensure the provision of vital information which extends beyond checking the mere presence of an MPI. They should also act to the possible standardization of MPIs.

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