

Comparative evaluation of imported and local brands of drug information leaflets of antibiotics and non-steroidal anti-inflammatory drugs available in community pharmacies in Jaffna Municipal area

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Introduction and Objectives: Drug information leaflets (DILs) are crucial for providing drug-related information to health care professionals and patients for safe medication use. This comparative study was conducted to evaluate DILs of antibiotics and non-steroidal anti-inflammatory drugs (NSAIDs) produced by both local and imported manufacturing companies for the availability and compatibility of essential clinical information.

Methods: This was a descriptive, cross-sectional study. A total of 120 leaflets consisting of both imported and local brands of antibiotics and NSAIDs were evaluated for the availability and compatibility of 20 essential clinical information criteria according to the guidelines of the National Medicine Regulatory Authority (NMRA), Sri Lanka. Clinical information was matched against British National formulary and clinical pharmacology textbooks for compatibility. The maximum score given for a leaflet was 20, and the minimum was 0. The level of compatibility of leaflets was categorized as 0-25%, 26-50%, 51-75% and 76-100%. Descriptive statistics were used to analyze the data using SPSS 25 software.

Results: The total DILs included 70 antibiotics and 50 NSAIDs brands. None of the leaflets included all clinical information according to NMRA guidelines. Especially information regarding the splitting of tablets was absent in all tablet dosage forms of antibiotics and NSAIDs leaflets. All local DILs did not indicate references, excipients, and date of last revision. The maximum and minimum scores obtained for leaflets were 17 and 4, respectively. The mean score obtained for imported and local antibiotics leaflets was 12.6 and 11.5, respectively, and for NSAIDs, leaflets were 11 and 10.8. The majority (69.16%, n=83) of the DILs have obtained scores in the range of 51 -75%.

Conclusion: Some of the essential information were lacked in the DILs. Local products provide less information compared to imported counterparts. Therefore, manufacturers and regulatory authorities should pay attention to design and revise DILs with complete and up-to-date information.

Keywords: Drug information leaflets, Antibiotics, Non-steroidal anti-inflammatory drugs, Evaluation, Local and imported brands