A STUDY ON THE COMPLETENESS OF INFORMATION IN DRUG PACKAGE INSERTS

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Objectives: To analyse the completeness of the information provided in the package insert as per the guidelines and also to compare it between local and multinational companies.

Methodology: A total of 312 package inserts were collected from one of the largest pharmacy in Malaysia situated in Petaling Jaya. The PIs were analysed based on the Asian labelling requirements which has specific requirements for Malaysia. As per this we looked into 18 requirements. Descriptive statistics were used to analyse the data.

Results: Among 292 PIs analysed we found that 64 PIs were from local companies and 228 from multinational companies. All the PIs were for adult use except one which was for paediatric use. Package inserts analysed were maximum for antihypertensive drugs (24%) followed by drugs used for endocrine disorders (12%). Most of the formulations were tablets (93%). Of the 292 PIs 5 were not legible and they did not follow the guidelines of font size. All the PIs had product name, dosage form, name of the active ingredient and the strength of the drug. The route of administration was not mentioned in 1% of the PIs. None of the PIs had the manufacturing and expiry dates. Warning and precautions were not present for 2% of the PIs which included more for multinational companies compared to local companies. The words ‘Keep medicine out of reach of children’ was absent in 70% of the PIs, out which most were from multinational companies.

Conclusion: Most of the companies followed the guidelines for package inserts. Mutinational companies followed the guidelines better than the Local companies.

Key words: Drug companies, Package inserts, Information