



INFORMATION AVAILABILITY AND COMPLETENESS OF PRODUCT INFORMATION LEAFLETS OF MODIFIED RELEASE TABLETS REGISTERED IN SRI LANKA

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Abstract

Modified release (MR) dosage forms improve compliance and therapeutic efficacy over conventional dosage forms. Different categories of MR dosage forms are widely used in modern-day healthcare and hence the product information leaflets (PrIL) should be informative enough for healthcare professionals to ensure safe use. We aimed to assess the completeness of essential information in PrILs accompanying MR tablets available in the Sri Lankan market. An audit was conducted using PrILs of MR tablets registered under the National Medicines Regulatory Authority, Sri Lanka and available for sale in pharmacies within a period of six months (September 2018-March 2019). A pre-prepared and content validated checklist comprising of essential information and advices on using MR tablets including availability of information regarding crushing, chewing and splitting, and steps to be taken when prescribed dose is not matching the strength available in the market was used to assess the completeness. Of the 109 product information leaflets, more than 90% leaflets contained standard general information; generic name, brand name, strength, manufacturers' details, indications, and contraindications. However, the availability of specific information related to MR tablets was not satisfactory. Only 53.2% PrILs contained information on crushing MR tablets, 58.7% on chewing, and 55.0% on splitting. Most leaflets lacked information regarding the specific mechanism of drug release (8.3%), steps to be taken when the prescribed dose is not matching the strength available in the market (0%), warnings never to take a double dose (3.7%), and steps to be taken on a missed dose (4.6%). PrILs of MR tablets currently available in the Sri Lankan market lacked consistency in providing information to healthcare professionals and were not comprehensive on essential information. Relevant regulatory authorities must review and standardise PrILs related to MR forms to ensure safe use.

Keywords: product information leaflets, modified release tablets, healthcare professionals, medication safety, Sri Lanka