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Availability of key information in package inserts of drugs used in Sri Lanka

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Package inserts (PIs) aim to provide information about drugs to health professionals. Incomplete or missing information in Pis may lead to medication errors and affect patient safety. We aimed to assess the availability of key information in PIs of drugs used in Sri Lanka.

A sample of 100 PIs were randomly selected from drugs dispensed at a government hospital and a private pharmacy. This sample included at least one PI related to a drug in each Anatomical Therapeutic Chemical class (level 1). A list of essential information to be included In a PI was developed by a Senior Pharmacologist and Senior Pharmacist taking into consideration the regulations of the Cosmetics, Devices and Drugs Act (CDDA) No. 27 of 1980 (CDDA). Some essential criteria not mentioned in the CDDA regulations, but deemed important to be included in PIs, were adopted from the 'Guidance for Useful Consumer Medication Information' of the Food and Drug Administration (FDA), USA, 'DISCERN' developed by the British National Library and the University of Oxford in 1997, and guidelines introduced by the Picker Institute of Europe in 2006.

The 100 PIs included, 60%, 29%, 4%, 2% and 5% of inserts related to oral, injection, local application, inhalation and other drug dosage forms respectively. 82% of Pis had at least one deviation from the CDDA regulations. The most frequent deviations were related to pharmacokinetic data, duration of treatment, overdose, and dosage information in special situations. In addition, only 30% of PIs indicated the route of administration, 24% specified what should be done for an adverse reaction, 32% specified maximum dose of the drug, and 50% of PIs provided definite information on pregnancy and lactation. Among the 100 PIs, 56% did not specify to whom the information was aimed at, 93% failed to indicate the sources of information, 87% did not specify where to refer for additional information, and 79% did not indicate the date of publication.

We conclude that information provided in PIs are inadequate. Most PIs did not even contain information specified in CDDA regulations, which is unacceptable and a potential threat to patient safety. There is an urgent need to continuously review PIs prepared by drug manufacturers and for regulatory authorities to ensure that adequate information is available to health professionals.

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