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Adherence to regulatory requirements related to primary labels of medicines and devices available in a selected state hospital in Sri Lanka

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Background: Labelling of medicines can greatly impact the quality and safety of medicine use. Labels must at least adhere to regulatory requirements of a country.
Objective: To assess the availability of vital information in primary labels of medicines/devices in a selected State hospital as specified by the Regulations of the National Medicines Regulatory Authority (NMRA) Act No 5 of 2015.
Method: An in-house pretested checklist was developed based on NMRA guidelines on labeling of medicines/devices. Using the annual estimation list of medicines/devices for State hospitals from the National Medicine Supplies Division as our population (medicines=1078 and devices=19), a convenience sample of 110 (medicines=107, devices=3) products were selected using an online random number generator. Primary labels of these selected medicines were obtained from the study hospital and were reviewed for the availability of essential information against the checklist.
Results: Among 110 primary labels assessed, 102 were orals (others were, injectables n=2, inhalations n=2, transdermal patches n=1, devices n=3). Almost all the labels had generic medicine name 99.0% (109/110), but only 65.4% (72/110) had brand name. Strength, and quantities of each active ingredient, was indicated in 98.1% (105/107) and 99.0% (106/107) respectively. Schedule of the medicine was only found in 24.2% (26/107), and only a few 6.5% (7/107) mentioned therapeutic group. All products had batch number and manufacturer's information, and 97.2 % (107/110) had date of manufacturing, date of expiry, and storing method. Information such as relevant name of pharmacopoeia, special warning to store medicines out of reach of children, and State logo were missing in 15.8% (17/107), 10.0% (11/110), and 20.9% (23/110) labels respectively. Most (74.5%, 82/110) did not provide specific warnings/precautions/cautions as specified by NMRA guidelines.
Conclusion: Although most labels had basic medicines/devices information, the majority did not completely fulfill regulatory requirements specified by NMRA on labeling of medicines/devices.