

Herbal Medicine Labels And Patient Safety: A Qualitative Study To Evaluate Clinically Relevant Safety Issues In Pharmacy

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Background: Herbal medicines are widely used for health purposes and represent a substantial percentage of sales in pharmacies. Nevertheless, little attention has been paid to the evaluation of safety issues contained in label information. The aim of this study was to evaluate the clinically relevant safety information on herbal medicine labels purchased in a sample of Italian pharmacies.

Methods: The sales of 300 pharmacies were analyzed. We considered the most purchased herbal medicines and verified the presence of 6 relevant safety issues on the labels: common and botanical name of each plant, plant part used, types of extract, dosage, and warnings.

Results: From a total of 6.518.431 purchases, 68.1% was represented by conventional drugs and 31.9% by herbal medicines. This study evaluated the most purchased herbal medicines (n=291) classified in categories according to their use: gastrointestinal (25.6%), respiratory (9.1%), tonic (8.2%), slimming (7.9%), central nervous system (5.5%), anti-oxidant (5.5%), vasoprotective (4.6%), immunostimulant (4.3%), dermatologic (4.3%), microcirculation tone (3%), anti-inflammatory (2.7%), dyslipidemia (2.4%), menopause (2.4%), hair and skin (1.8%), and others. Information for all criteria was present for only 5 herbal medicines, while nine (3.1%) provided no safety information. Safety information has been ascertained for *Citrus aurantium*, *Ipericum perforatum*, *Ginkgo biloba*, red yeast, and soy isoflavones. We also verified the presence of warnings about potential drug/herb interactions, and no information was found for *Ipericum perforatum* and *Panax ginseng*. One (out of 4) product with *Allium sativum* and 7 (out of 22) with Propolis reported the warning. Some labels did not include warnings about use during pregnancy (59.4%) and lactation (86.2%).

Conclusion: The majority of herbal medicines fails to adequately address clinically relevant safety issues on their labels. The importance of these results could be significant because herbal medicines are also sold in venues other than pharmacies, and in this study galenical herbal medicines were not included. Healthcare professionals and consumers may benefit from the examination of herbal medicine labeling requirements by the Italian Ministry of Health.