Signal Detection and Assessment of Herbal-Drug Interactions: SFDA Experience

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Abstract

Introduction: There is a general perception of the safety of use for herbal medicines. Moreover, limited studies addressed herbal-drug interactions (HDI). The Saudi Food and Drug Authority (SFDA) established Herbal-Drug Interaction project to detect and assess HDIs to ensure safety. The aim is to detect safety signals and assess them based on available evidence. Methods: First, a number of SFDA-registered herbal products (n=30) were selected and prioritized based on commonly used herbs. Second, reported HDIs were retrieved from the World Health Organization (WHO) global database of individual case safety reports (VigiBase), AdisInsight® and Natural Medicines database. We excluded non-registered drugs by SFDA and labeled interactions in the product information of SFDA, the U.S. Food and Drug Administration (FDA), and European medicines agency (EMA). Finally, a comprehensive evaluation of potential HDIs using several evidence sources; literature, global cases, local cases and other relevant documents. The Drug Interaction Probability Scale (DIPS) scale used to assess the probability of a causal relationship between interacting herb-drug and the event. Results: The search yielded 566 potential signals, and 41 had published evidence and referred for assessment. The assessment results using DIPS were; 22 possible (53.6 %), 7 probable (17%), and 12 doubtful (29.2%) interactions. Recommendation was to include probable HDIs in the product information, including Turmeric-Tacrolimus, Etoposide-Echinacea, Ginkgo Biloba-Ibuprofen, Green Tea-Warfarin, and Licorice-Thiazides interactions. Conclusion: The HDI project assessed in the screening and identification of potential herbal-drug interactions. The action plan of this project can be used in post-marketing activities to identify potential drug interactions.

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