

## Detection and Assessment of Herbal-Drug Interaction Project: the SFDA Experience

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### Objectives

There is a general perception of safety and efficacy of herbal medicine compared to conventional medicine. However, limited studies addressed herbal-drug interaction (HDI) in the literature. The Saudi Food and Drug Authority (SFDA) established the HDI Project to detect safety signals related to HDI and assess these signals based on available scientific evidence.

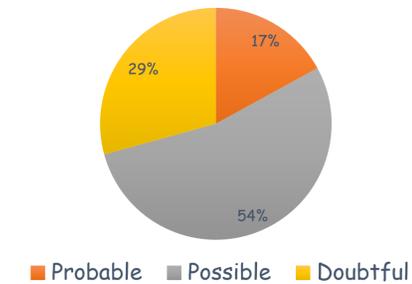
### Methods

First, a list of SFDA registered herbal products (N=30) were selected and prioritized based on commonly used herbs in Saudi Arabia. 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 the interactions of non-registered drugs in Saudi Arabia and labeled interactions in drug and herbal product information, using SFDA, the U.S. Food and Drug Administration and European medicines agency product information. Finally, comprehensive safety evaluation of potential interaction signals were conducted using several evidence sources including literature, results of causality assessment of global cases retrieved from VigiBase and local cases retrieved from the national pharmacovigilance database and other relevant documents. The Drug Interaction Probability Scale (DIPS) was used to assess the probability of a causal relationship between the potential HDI and the events.

### Results

The project yielded 566 potential HDI signals, and 41 interactions had published evidence and referred for extensive evaluation. The assessment results based on DIPS and available evidence were; 24 possibly related (85.5%), 5 probably related (12.1%) and 12 doubtful (29.2%) interactions (Figure 1). The recommendation was to include the probable HDI in the local product information of herbal products and medications include Turmeric-Tacrolimus, Etoposide-Echinacea, Ginkgo Biloba-Ibuprofen, Green Tea-warfarin and Licorice-thiazides interactions.

Figure 1: The causal relationship between the potential HDI and the events



### Conclusion

The HDI project in SFDA assist in screening and identification of potential HDI. The action plan of this project can be used in post-marketing activities to identify potential drug interactions