

Safety assessment of natural products in Malaysia: current practices, challenges, and new strategies

ABSTRACT

The belief that natural products are inherently safe is a primary reason for consumers to choose traditional medicines and herbal supplements for health maintenance and disease prevention. Unfortunately, some natural products on the market have been found to contain toxic compounds, such as heavy metals and microbes, as well as banned ingredients such as aristolochic acids. It shows that the existing regulatory system is inadequate and highlights the importance of thorough safety evaluations. In Malaysia, the National Pharmaceutical Regulatory Agency is responsible for the regulatory control of medicinal products and cosmetics, including natural products. For registration purpose, the safety of natural products is primarily determined through the review of documents, including monographs, research articles and scientific reports. One of the main factors hampering safety evaluations of natural products is the lack of toxicological data from animal studies. However, international regulatory agencies such as the European Food Safety Authority and the United States Food and Drug Administration are beginning to accept data obtained using alternative strategies such as non-animal predictive toxicological tools. Our paper discusses the use of state-of-the-art techniques, including chemometrics, in silico modelling and omics technologies and their applications to the safety assessments of natural products.

Keyword: Chemometrics; Herbal medicines; In silico; Omics; Predictive toxicology; Safety assessments