[Downloaded free from http://www.toxicologyinternational.com on Wednesday, April 27, 2016, IP: 14.139.224.243]

Symposium on Safety and Risk-Assessment Approaches for Materials of Herbal Origin: Managing Editor's Remarks

Dear friends,

The National Symposium on "Safety and Risk Assessment Approaches for Materials of Herbal Origin" held on September 3, 2010, Bangalore, India, is a concerted effort by the Unilever Research and Development, in association with Indian Drug Manufacturers Association (IDMA) and *Ayurvedic* Drug Manufacturers Association (ADMA) at the Unilever R & D Centre, Bangalore.

Herbal materials have witnessed renewed consumer interest as means of enhancing the quality of life and addressing modern health and wellbeing needs. The application of herbal materials is therefore extending beyond traditional medicine – to personal care, foods and dietary supplements. The major issues addressed during the symposium and panel discussions were: the identification of gaps in biosafety and risk assessment of herbal materials used as traditional Ayurvedic Medicine, personal care products, foods and dietary supplements, etc; to develop the framework to strategize the robust new R & D approaches to address the issues of safety and risk assessment of herbal materials; the existing guidelines, upcoming regulations, quality standards and enforcement of regulations for herbal materials; The generation of long-term/epidemiological data on traditional system-based remedies following traditional toxicology approaches; the evaluation of final products for quality assurances, inherent toxic constituents, purity of preparation, contamination, compromised quality, and toxicological evaluations; the development of digital databases, predictive *in silico* modelling (QSAR) and application of "omics" technologies in the safety assessment of herbal materials.

The symposium was attended by 120 eminent scientists, policy makers, academia from Government Organizations and Industries. Dr. Vilas Sinkar, Vice President, Research and development and Site Leader (Bangalore) welcomed the delegates and gave a brief overview of Unilever, its Research and Development Centers and Safety of Environmental Assurances Centre. He talked about the increased use of herbal materials (including *Ayurveda* and Traditional Chinese Medicine) and that it necessitates the development of appropriate science-based risk assessment approaches. Following the scientific deliberations, a panel discussion cum interactive session was held under the chairmanship of one of the pioneer Neuropharmacologists of the country Professor Y. K. Gupta, Head, Department of Pharmacology, All India Institute of Medical Sciences, New Delhi. The panel discussions involved open house discussion on several outcomes and formulation of new strategies for future directions of safety and risk assessment of herbal materials.

Access this article online	
Quick Response Code:	Website: www.toxicologyinternational.com
	DOI: 10.4103/0971-6580.85880

This special issue of the *Toxicology International*, an official Journal of Society of Toxicology, India, is having the small write-ups of selected presentations made by experts during the symposium "Safety and Risk Assessment Approaches for Materials of Herbal Origin", held at Bangalore, India, on September 3, 2010. The presentations included in this issue are outlined hereunder:

Dr. Julia Fentem, Head Safety Environment Assurance Centre, Unilever, in her introductory presentation highlighted the growing interest in herbal materials ('naturals') for consumers globally to improve health and well being and the increasing application of herbal materials beyond medicinal products to personal care, foods and dietary supplements.

Emphasizing the need to understand and apply the most up-to-date scientific knowledge and approaches to ensure the safety of these products for consumers globally, Dr. Fentem set up the context of the symposium:

- to share our expertise and insights on assessing safety of herbal materials;
- to identify key gaps in our scientific knowledge and future research needs.

The inaugural address was delivered by Dr. S. K. Sharma, Adviser *Ayurveda*, Department of AYUSH (Government of India), on "Regulatory Status and Recent Development of Herbals." He gave an overview of the existing regulations on herbals, in the context of medical applications. He also talked about upcoming regulations and Government of India's initiatives on education and research in *Ayurveda*.

The keynote address was delivered by Dr. Vasantha Muthuswamy, Senior Deputy Director General (Retired), Indian Council of Medical Research, New Delhi, on "Challenges in Herbal Materials." Giving a brief history of traditional medicines, Dr. Muthuswamy talked about the increasing herbals market globally. She brought out specific limitations and risks associated with herbal materials and the need for quality standards and enforcement of regulations for herbal materials.

The technical sessions started with a presentation from Dr. Ram Manohar, Director, Research, Arya Vaidya Pharmacy on "Principles and Insights from *Ayurveda* on Safety of Herbals." He brought out the key principles of safety and risk assessment ingrained within *Ayurveda* and cited *Ayurvedic* literature that indicated existence of a risk-based framework. He also talked on the safety needs of the herbal remedies and approaches for generating long-term/epidemiological data on traditional system-

[Downloaded free from http://www.toxicologyinternational.com on Wednesday, April 27, 2016, IP: 14.139.224.243]

based remedies in the current context than following traditional toxicology approaches.

Dr. CK Katiyar, Vice President, Health Care Research, Dabur Research and Development, gave a talk on "Modern Challenges for Safety Assessment of *Ayurvedic* Materials." Dr. Katiyar discussed the factors responsible for safety concerns in herbal materials and the challenges in safety evaluation of herbals. He also talked about the modern safety evaluation methods, regulations, and guidelines for the safety evaluation of herbals and using new approaches like nematode models for assessing safety.

Dr. Poonam Kakkar, Head, Herbal Research Laboratory, Indian Institute of Toxicology Research, Lucknow, presented on "Toxicological Assessment of Herbal Materials: Current Status and Progress in India." Dr. Kakkar discussed factors for safety concern such as inherent toxic constituents, purity of preparation, contamination, compromised quality and toxicological evaluations. She presented the science and technology map in India on this aspect. Discussing the future approaches, Dr. Kakkar stressed the importance of predictive toxicology (building relevant databases), *in silico* modelling (QSAR) and "omics" technologies in the safety assessment of herbal materials.

The final talk was delivered by Dr. Bobbie Bradford, Product Toxicologist, Safety of Environmental Assurances Centre, Unilever, who presented Unilever's strategy for the safety assessment of herbals. Through illustrative case studies, she highlighted the use of "history of safe use" approach for herbal materials, which was refined using modern mathematical approaches and advanced analytical chemistry tools, extent of exposure, nature and format in which used, route of administration, and extent of application and contact time. Gaps, if any, on any toxicological end points were addressed using traditional toxicology tools.

The symposium ended with a panel discussion chaired by Professor Y. K. Gupta, Head, Department of Pharmacology, All India Institute of Medical Sciences, New Delhi. The panel discussions involved open house discussion on several out comes of the discussions throughout the day in the symposium.

A research article on a newer approach for risk assessment of botanicals is also included which discusses the multi-criteria decision analysis (MCDA) model that has been developed which assesses the safety of botanical ingredients using a history of use approach. The model evaluates the similarity of the botanical ingredient of interest to its historic counterpart – the comparator, using the evidence supporting the history of use, and any evidence of concern.

Best wishes,

A. B. Pant
Managing Editor,
Toxicology International,
Senior Scientist,
Indian Institute of Toxicology Research,
Lucknow, India.
E-mail: abpant@iitr.res.in; abpant@rediffmail.com

How to cite this article: Pant AB. Symposium on safety and risk-assessment approaches for materials of herbal origin: Managing editor's remarks. Toxicol Int 2011;18:S1-2.