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Current research on standards of medicinal plant products: Decoction pieces, granules and proprietary products as phytomedicines

The quality, safety and efficacy (QSE) of herbal medicinal products depend on correct authentication and good agricultural & collection and manufacturing practices (GACP, GMP). Chinese materia medica (CMM) are medicinal plant parts that are prescribed by traditional Chinese medicine (TCM) practitioners to patients for prevention and treatment of illnesses, and also utilized by herbal industry for manufacturing proprietary Chinese medicines (PCM). These medicinal products should comply with minimum pharmacopeia standards for use in TCM practice and PCM manufacturing. Problems and difficulties are recognised by manufacturers in coping with regulatory requirements to implement the QSE of herbal products containing unidentified chemical entities in the finished products; as the actual bioactive components are seldom fully known. Therefore the GACP & GMP is the key role to provide traceability of the starting materials used for producing the final product for registration. Pharmacopoeia standard of starting materials for research and manufacturing is the minimum requirement to comply with the regulatory guidelines for registration purpose. Some international authorities such as the EMA (EU), FDA (USA), MHRA (UK), NHPR (Canada), SFDA (China), and TGA (Australia), have guidelines for registration of herbal products. Yet they are so vastly different that it not easy to cope with. A recent commentary on global variation of pharmacopoeia monographs of Chinese materia medica indicated that harmonisation of a minimum requirement is urgently needed upon the quality of CMM. This presentation updates recent methodology that may be accepted by regulatory agents for harmonization.

Biography

Kelvin Chan (DSc PhD FCP FSB FRPS FRSM) is the Joint Chair of Traditional Chinese Medicine (TCM) at the University of Sydney and University of Western Sydney appointed to establish strategic research & development of the TCM in NSW and to understand the cultural role of the discipline in community healthcare. Trained in Industrial Pharmacy, then specialised in Clinical Pharmacology in the UK, he has taught pharmacology in orthodox medicine, pharmacy and biomedical science in TCM at universities in Hong Kong, UK and UAE. His research interests are working closely with counter parts in key labs in Hong Kong, Heilongjiang, and Macau in China and with colleagues in the EU/UK, include R & D of Chinese medicines: Methodology on quality control of Chinese materia medica (CMM); 'Omics' approaches in bioactivity screening; Integrative research in TCM with biomedical medicine applying patients' reported outcomes and quality of life measure in clinical studies; Promoting education & training curriculum towards integrative medicine.

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