• 計畫中文名稱	中西藥交互作用體外預測模式之建構與評量

• 計畫英文名稱	Construction and Evaluation of in vitro Model for Prediction of Herb-Drug Interactions

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• 英文關鍵字	transport protein；metabolizing enzyme；Quantitative Structure- Pharmacokinetic Relationship (QSPR)		

• 中文摘要	馬兜鈴酸事件對於自古認爲中藥是溫和安全的觀念是一個相當大的打擊， 而且也越來越多的證據說明中草藥對於人體的生理因素有很大的影響性，尤其對於在口服吸收機制與代謝排除過程方面的影響，而由此導致中草藥與化學藥物併服時發生交互作用，互相改變兩者各自的臨床療效，甚至可能發生因吸收過量產生毒性而致人於死。因此中草藥的安全性已不容忽視了，也不能以一句我們已使用上千年的中草藥絕對安全而鴕鳥式欺騙消費大眾，尤其是在國內社會民眾接觸中草藥的機會更多，而又化學藥物的使用也極頻繁，自然發生中草藥與化學藥物交互作用的機率相對提高，所以爲確保國內民眾使用中草藥的安全性，主管單位有義務確認中草藥經由口服管道使用時可能對人體生理機能造成的影響性，並預防性的瞭解一般常用中草藥所調製而成的方劑與化學藥物可能產生的交互作用，以提醒醫師及民眾併服時可能導致的嚴重性。本計劃將由習用中藥中分離純化化合物作爲模板成份，以體外模式評量其對於腸道的輸送醣蛋白質與主要代謝酵素 CYP3A4 之抑制與誘發作用，由此建構其結構與藥動學參數影響性 (QSPR) 之定量性預測關係式，將可以快速有效的用於定量性預測中藥方劑可能與併服西藥發生的交互作用，作爲中藥藥政單位管理中藥與西藥預測是否發生交互作用之參考依據，也可以標示警語以提醒併服西藥的消費大眾或開立處方的中西醫師之注意，以確保中藥臨床用藥的安全性。

• 英文摘要	The development of renal failure and urothelial carcinoma in individuals who used the Chinese herb Aristolochia fangchi is the greatest blow to the tradition concepts that Chinese medicines are safe and mild. Cumulative evidences further demonstrate that

components in Chinese medicines cause profound influence on the physiological factors of human body, especially on those related to oral absorption and metabolism. Due to this kind of interactions, clinical efficacy after co-administration is mutually affected between chemical drugs and herbal drugs, sometimes leading to lethally overdose. Drug safety of Chinese or herbal medicines cannot be ignored. It cannot be taken granted for consumers that Chinese or herbal medicines are safe since it have been used for several thousand years without problems. At present day, the chance to cause interactions between chemical drugs and Chinese medicines are greatly increased with increasing the frequency of using Chinese or herbal medicines and of taking chemical drugs. It is the urgent responsibility of regulatory authority to provide information on the possibility to develop the potential interactions between Chinese medicines and chemical drugs in the first hand to ensue the safety of Chinese or herbal medicines. Warnings on the label would be necessary to remind the consumers for possible serious drug interactions. This proposal will be to construct an in vitro model using a series of template components isolated from Chinese medicines for establishing the relationship between structural fragments and pharmacokinetic parameters to quantitatively predict the potential drug interactions. The induction and inhibition of transport proteins and metabolizing enzyme of CYP3A4 located the intestine will be used as models to rapidly estimate and quantitatively predict the interactions. This will provide as the reference for authority to predict the possible drug interactions between Chinese or herbal medicines and chemical drugs and as the warning label to remind health providers and consumers. Safety of Chinese or herbal medicines, therefore, is ensured.