

# Survey on the Usage of Active Pharmaceutical Ingredients by Modern Pharmaceutical Manufacturers (II)

HUI-LING CHEN, TSE-MIN WANG, CHIH-WEI CHEN,  
CHYN-LIAN HUANG AND HWEI-FANG CHENG

Division of Risk Management, FDA

## ABSTRACT

In view of rampant situation of counterfeit and inferior drugs recently, the Executive Yuan convened the 25<sup>th</sup> session of “Strength on cracking down on the counterfeit/inferior drugs and illegal radio stations” on September 29<sup>th</sup>, 2010 and passed a resolution of “Block Source and Ban Illegality”. In order to block the source of counterfeit and inferior drugs, inspection on raw materials used by modern pharmaceutical manufacturers will be reinforced to prevent the raw materials from being used illegally.

Since November 2010, in order to cooperate with the follow-up GMP inspection of modern pharmaceutical manufacturers, the inspections of raw materials usage by modern pharmaceutical manufacturers during 2010 to 2011 were conducted at the same time. Forty-seven were found to have deficiencies in a total of 66 inspected manufacturers in 2010, and 28 in a total of 44 in 2011. It indicated that raw materials should be managed with more attention, at the present stage, by developing the feedback system on the application and usage of raw materials, reinforcing the management of agents, implementing the high standard PIC/S GMP in the future, implementing GMP on raw materials and amending Pharmaceutical Affairs Act, to protect the safety of public drug usage.

Key words: GMP, raw materials, modern pharmaceutical manufactures