

**The Administration's Response to the Concerns
Raised by the Trade of Chinese Medicines**

In July 1999, the Legislative Council enacted the Chinese Medicine Ordinance (“the Ordinance”) to provide for a statutory framework to regulate the practice of Chinese medicine, and the use, trade and manufacture of Chinese medicines. In September 1999, the Chinese Medicine Council of Hong Kong (“the Council”) was established to devise and implement regulatory measures on the practice of Chinese medicine and Chinese medicines, including the systems for licensing of Chinese medicines traders and registration of proprietary Chinese medicine (PCM).

The Chinese Medicines Board under the Council had, in conjunction with relevant trade associations, conducted extensive consultations to ensure that the subsidiary legislation on regulation of Chinese medicines would cater for the actual situation of the Chinese medicines trade and receive the support of Chinese medicines traders. From 2000 to 2002, about 30 consultation sessions were organized to solicit the views of the trade on the proposals of the subsidiary legislation and other regulatory measures. The three items of subsidiary legislation, including the Chinese Medicines Regulation, the Chinese Medicines Traders (Regulatory) Regulation, and the Chinese Medicine (Fees) Regulation were submitted to the Legislative Council and subsequently passed in December 2002.

The licensing system for Chinese medicines traders was implemented in May 2003. Four kinds of Chinese medicines traders, including retailer and wholesaler of Chinese herbal medicines, and wholesaler and manufacturer of PCM, are required to apply for a licence from the Chinese Medicines Board before they can engage in the respective trade. The Ordinance provides for a transitional arrangement for Chinese medicines traders. According to sections 118 and 138 of the Ordinance, those Chinese medicines traders who carried on business in

Chinese medicines on 3 January 2000 shall be deemed to have been granted a licence in the relevant trade, provided they make an application during the application period for transitional registration (from 5 May to 15 July 2003). The licence shall continue in effect until the issue of a formal licence, the refusal of his application, or such date as may be promulgated by the Secretary for Health, Welfare and Food by notice in the Gazette (whichever is the earliest).

The Ordinance also stipulates that all PCM manufactured, or sold, in Hong Kong must be registered, to safeguard public health. We plan to commence the registration system for PCM on 19 December 2003. Applications for PCM registration under transitional arrangement will be accepted up to end June 2004.

Regarding the registration criteria, in determining an application for registration of a PCM, the Chinese Medicines Board shall take into account the safety, quality and efficacy of the PCM. The requirements include measures of heavy metal, pesticide, non-adulteration of western medicines and endangered species, toxicity and stability, etc. These parameters are drawn up taking reference from standards adopted in the Mainland and other overseas regulatory authorities. The Chinese Medicines Board has consulted the traders and local laboratories extensively on the registration requirements. They are in support of the proposed regulation and have generally found the registration requirements acceptable. To ensure adequate infrastructural support, test reports by specified laboratories in the Mainland and Hong Kong are accepted by the Chinese Medicines Board. As traders have up to five years to submit by phases the necessary test reports, there should be adequate time for them to prepare. Technical guidelines are being developed by the Chinese Medicines Board for reference by the laboratories.
