Subcommittee on Registration of Proprietary Chinese Medicines

Summary of issues of concerns/suggestions raised at the meetings of the Panel on Health Services on 17 January and 15 February 2011 on commencement of provisions related to proprietary Chinese medicines ("pCm") in the Chinese Medicine Ordinance (Cap. 549)

Issues of concerns/suggestions
1. Commencement of provisions related to the mandatory registration of pCm and the requirements of label and package inserts
• The mandatory registration of pCm would threaten the survival of local pCm manufacturers who are mainly small and medium-sized firms. The Administration should defer the implementation of the relevant provisions and provide a transition period, say one year, for the trade to register their pCm, and to print and replace the labels and package inserts. pCm which had passed the three basic tests of heavy metals and toxic element, pesticide residues and microbial limit should be allowed to continue to be sold in Hong Kong during the transition period. • The trade was not given enough time to prepare for the implementation of the requirements and a number of pCm which had been currently used by members of the public and Chinese medicine practitioners ("CMPs") had to be recalled from the market. The Administration should defer the implementation of the relevant provisions and provide a transition period for the trade. • Provisions relating to the requirements of label and package inserts should only be commenced when the vetting of label and package inserts of pCm had been completed by the relevant authority, so that the trade would have sufficient time to replace labels and inserts for their products. • There was a worry that under the new regulatory regime, some pCm would no longer be available as the Chinese medicine traders might not be willing to incur the high registration cost for these products. • Government consultation and communication with the trade were inadequate. The trade had not fully understood the legislative requirements, and there was a lack of government support for assisting the trade in complying with the requirements. • There was concern about the impact of the mandatory registration of pCm on the trade. In particular, pCm not yet registered but were being used by

Issues of concerns/suggestions
CMPs for treating their patients had to be recalled from the market. This caused inconvenience to patients and CMPs. There was a rise in the price of pCm after the implementation of the mandatory registration of pCm. • The Administration should provide clear guidelines on the requirements of label and package inserts and complete the vetting of label and package inserts of pCm before the commencement of the related provisions in December 2011, so that the trade would have sufficient time to meet the new requirements.
2. Registration procedure of pCm
• The Chinese Medicines Board ("CMB") and the Department Health ("DH") which provided administrative support to CMB should expedite the vetting and approval procedure for the registration of pCm and handle the registration applications in a more flexible and less stringent manner. pCm should be deemed to have registered in accordance with the Ordinance if their three basic test reports on heavy metals and toxic element, pesticide residues and microbial limit had been submitted to the relevant authority. • There was discontent with the lack of transparency and the slow processing of the registration applications of pCm. Applicants were not provided with sufficient time to supply additional information or test reports since CMB and DH had taken a long time to process their applications. CMB and DH were urged to provide performance pledges for the processing of applications of registration. • The Administration should adopt a flexible approach to the regulation of concentrated pCm, which were in the form of powder or granule and sold under prescription only. • The Administration should protect the patent of pCm manufacturers by refusing registration of replicated pCm.
3. Registration requirements of pCm
• Most operators in the trade were small manufacturers or self-employed CMPs. They had great difficulties, in terms of technical and financial viability, in proving the product safety, efficacy and quality when applying for registration of pCm. The requirements for registration were too stringent. There were substantial differences between Chinese medicines and Western medicines, but the existing regulatory system for Chinese medicines failed to take into account these differences as well as the past practice of the trade.

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• Although the Ordinance had provided a transitional registration for pCm manufactured or sold in Hong Kong on 1 March 1999, it was difficult for some Chinese medicine traders to provide documentary proofs to show that the pCm under application was, on 1 March 1999, manufactured, sold or supplied for sale in Hong Kong. It was because it was quite common for the trade not to disclose the full and complete information of the master formula in the sales pack of pCm in order to avoid being replicated. As a result, they had to apply for non-transitional registration. • In assessing the registration applications, due regard should be given to those pCm which had already been registered in China and/or Taiwan.
4. Inadequate laboratory support in testing of pCm
• There was a grave concern about the inadequate laboratory support in Hong Kong. Some traders have to use the laboratory services in China. Owing to the different laboratory testing standards between Hong Kong and China, some test reports certified by the laboratories in China might not be able to satisfy the requirements of CMB, thus causing delay and incurring greater costs in the application process. • Financial assistance, such as the setting up of a loan scheme, should be provided to assist the trade in meeting the high testing costs. Consideration should be given to providing laboratory support to the trade through Government laboratories.
5. Mandatory registration of pCm
• According to Cap. 549, a pCm which is compounded by or under the supervision of a listed or registered CMPs at the premises where he practises can be exempted from registration if, and only if, such pCm is being used to a patient under his direct care. The Administration should consider extending such exemption to all patients under the direct care of listed or registered CMPs, as the same compounded pCm could be administered or supplied to a number of patients with similar medical needs. • pCm for sale to the general public and pCm sold under prescription should be subject to a separate regulatory framework. Consideration should be given to extending the exemption to pCm compounded by licensed pCm manufacturers in accordance with prescription given by CMPs.

6.	**Requirements of labels and package inserts**
•	As the imported pCm for the purpose of re-export could be exempted from the requirements of label and package inserts under the Regulation, the Administration was urged to consider granting the same exemption to locally-produced pCm for the purpose of export to ensure fairness in trade. Moreover, the local requirements for labels and package inserts might not be the same as those of the exporting countries, requiring the trade to comply with both sets of requirements would only have adverse impact on the trade.
7.	**Possession of pCm**
•	With the commencement of the mandatory registration of pCm, the sale, import or possession of unregistered pCm was an offence. To prevent the general public from breaking the law unknowingly by purchasing unregistered pCm, it was suggested that the definition of "possession of pCm" in section 119 of the Ordinance should be amended as "possession for the purpose of sale".
8.	**Regulation and development of Chinese medicines**
•	Given the characteristics and long history of Chinese medicines, it was inappropriate to regulate Chinese medicines by adopting the Western medicines perspectives. There was a call for a review of the existing regulation system of pCm, as well as greater involvement of Chinese medicine experts in the formulation of the regulatory policy and framework.
•	There were suggestions for the further development of Chinese medicines, including the setting up of a new regulatory body to review and formulate policies regulating Chinese medicines, establishing a Chinese medicine hospital, training more CMPs, the setting up a fund to support the local small and medium-sized pCm manufacturers and revitalizing old industrial buildings to support the local pCm manufacturing industry.
•	The Government had proposed an initiative to introduce the standard of Good Manufacturing Practice in regulating Chinese medicines. Given the huge investment required, there was concern on the financial viability of the local small and medium-sized pCm manufacturers.
•	There was a lack of overall planning to support the development of Chinese medicines in Hong Kong. The Government should review the existing policy and formulate a long term strategy for the sustainable development of Chinese medicines and the training of CMPs and professionals in Chinese medicines.

9. Others
• Some products, although containing Chinese herb, could still be regarded as food under certain circumstances. The Administration should provide clearer definitions of and distinctions between food and pCm. • The number of representatives from the trade in the Chinese Medicine Council should be increased in order to reflect their views and interests of the trade in the formulation of policy and regulations on Chinese medicine. Members of the Council should be elected by the trade.

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