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Panel on Health Services

**Background brief prepared by the Legislative Council Secretariat
for the meeting on 12 July 2010**

Registration of proprietary Chinese medicines

Purpose

This paper gives an account of the past discussions by Members on the registration of proprietary Chinese medicines ("pCm").

Background

2. The Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") was enacted by the Legislative Council ("LegCo") in July 1999 to provide a statutory framework for the regulation of the practice, use, trading and manufacture of Chinese medicine in Hong Kong. The Chinese Medicine Council of Hong Kong ("CMC") was established by the Administration in September 1999 under the Ordinance to develop and implement these regulatory measures.

3. The Ordinance stipulates, amongst others, that all pCm must be registered by the Chinese Medicines Board ("CMB") under the CMC before they can be imported, manufactured or sold in Hong Kong. To be registered, all pCm must meet the registration requirements prescribed by CMB regarding their safety, quality and efficacy.

4. To minimise disruption to the Chinese medicine trade, the Ordinance provides a transitional registration system for pCm manufactured, sold or supplied for sale on 1 March 1999 in Hong Kong. Manufacturers, importers or local agents/representatives of manufacturers outside Hong Kong may apply for transitional registration for such pCm before 30 June 2004. Subject to CMB's vetting and approval, a "Notice of confirmation of transitional registration of proprietary Chinese medicines" will be issued for applications which meet the eligibility criteria for transitional registration. Such a Notice will remain valid until the pCm is formally registered, or until the application for its registration is refused, or until such date to be promulgated by the Secretary for Food and Health ("SFH") in the Gazette, whichever date is the earliest.

5. The Chinese Medicines Regulation (Cap. 549F), which sets out, amongst others, the mandatory registration system for pCm, came into operation on 30 April 2003. By the Chinese Medicines Regulation (Commencement) (No.2) Notice 2003, the then Secretary for Health, Food and Welfare appointed 19 December 2003 as the day on which the requirements for registration and the certificate of sale of pCm should come into operation. A subcommittee was formed by the House Committee on 31 October 2003 to study the aforesaid Commencement Notice and two other Commencement Notices made under the Ordinance and the Chinese Medicine (Fees) Regulation gazetted on 24 October 2003 ("the Subcommittee").

6. Until now, section 119 of the Ordinance requiring that no person shall sell; or import; or possess any pCm unless the pCm is registered with CMB has not yet commenced operation.

Past discussions

7. During the scrutiny by the Subcommittee, concern was raised about the transparency and objectivity of the assessment criteria and assessment procedure for the registration of pCm.

8. The Administration advised that there were objective assessment criteria and procedures which would be detailed in the guidelines to be issued to the trade. The applicant had to produce proof to the satisfaction of CMB that the pCm under registration complied with the requirements on safety, quality and efficacy. In assessing an application, the Board would consider the professional opinion of an independent expert group on Chinese medicines. If an application was rejected, the applicant would be informed in writing of the reason for rejection. To further enhance the transparency of the assessment criteria, the Administration undertook to publicise the curriculum vitae of members of CMC and its Boards/committees, as well as the application criteria and technical guidelines for the Chinese medicine trade, on the website of CMC. The Administration also undertook to maintain close liaison with the trade to ensure that their views were fully reflected to the CMC and its Boards/committees.

9. Some members indicated support for the commencement of the registration of pCm on 19 December 2003, whilst others considered that, in view of the problems in the licensing of Chinese medicine practitioners, all three Commencement Notices should be repealed. The motion to repeal the three Commencement Notices was negatived at the Council meeting on 17 December 2003. CMB has started to accept applications for registration of pCm since 19 December 2003.

Latest development

10. In his reply to an oral question raised by Hon Fred LI on the regulation of Chinese medicine at the Council meeting on 19 May 2010, Acting SFH advised that as at the end of April 2010, CMB had received a total of about 16 540 applications for

pCm registration, of which 14 100 also made concurrent application for transitional registration. CMB had assessed all these applications for transitional registration and issued a "Notice of confirmation of transitional registration of pCm" for 9 120 applications and a "Notice of confirmation of (non-transitional) registration application of pCm" for 2 100 applications for non-transitional registration in respect of which three acceptable basic test reports had been submitted. In addition, some 4 610 applications for registration of pCm were rejected by CMB for failing to furnish sufficient information. As CMB had completed the assessment of all the applications for non-transitional registration of pCm, the Administration planned to put into full implementation the remaining provisions under the Ordinance related to mandatory registration of pCm by the end of 2010.

Relevant papers

11. Members are invited to access LegCo website (<http://www.legco.gov.hk>) for details of the relevant papers, minutes of meetings and report of the Subcommittee.

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