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**Panel on Health Services**

**Subcommittee on Registration of Proprietary Chinese Medicines**

**Updated background brief prepared by the Legislative Council Secretariat for the meeting on 22 June 2011**

**Registration of proprietary Chinese medicines**

## Purpose

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

## Background

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

3. The Ordinance stipulates, among others, that all pCm must be registered by the Chinese Medicines Board ("CMB") under 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, efficacy and quality.

4. The Chinese Medicines Regulation (Cap. 549F), enacted in December 2002, sets out, among others, the registration system for pCm. 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.

5. To minimize disruption to the Chinese medicine trade, the Ordinance provides a transitional registration system for pCm manufactured or sold in Hong Kong on 1 March 1999. Manufacturers, importers or local agents/representatives of manufacturers outside Hong Kong may apply for transitional registration of such pCm within the specified period of 19 December 2003 to 30 June 2004. Subject to CMB's vetting and approval, a "Notice of confirmation of transitional registration of pCm" will be issued for applications meeting the eligibility criteria for transitional registration. Such pCm shall then be deemed to have registered in accordance with the Ordinance. The transitional registration will remain valid until the pCm concerned 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.

6. CMB will also issue the "Notice of confirmation of (non-transitional) registration application of pCm" to pCm which has submitted an application for registration as well as its basic test reports on or before 31 March 2010. Such pCm would be allowed to continue to be sold in Hong Kong until it is formally registered, or until the application for its registration is refused.

7. By the Commencement Notices made under the Ordinance and the Chinese Medicines Regulation gazetted on 8 October 2010, SFH appointed 3 December 2010 as the commencement date of the mandatory registration of pCm and the sale, import or possession of unregistered pCm in Hong Kong will become an offence, liable on conviction to a maximum fine of $100,000 and two years' imprisonment.

**Past discussions**

Commencement of the registration of pCm in December 2003

8. A subcommittee was formed by the House Committee on 31 October 2003 to study the Chinese Medicines Regulation (Commencement) (No. 2) Notice 2003 and two other Commencement Notices made under the Ordinance and the Chinese Medicine (Fees) Regulation gazetted on 24 October 2003 ("the Subcommittee"). 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.

9. The Administration advised that objective assessment criteria and procedures for registration of pCm 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 application for registration met the requirements on safety, quality and efficacy. In assessing an application, CMB 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 make available 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 CMC and its Boards/committees.

10. 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 of 17 December 2003. CMB has accepted applications for registration of pCm since 19 December 2003.

Commencement of the mandatory registration of pCm in December 2010

11. On 12 July 2010, the Administration consulted the Panel on its plan to commence the provisions in the Ordinance and the Regulation related to the mandatory registration of pCm and the requirements of label and package inserts in December 2010 and December 2011 respectively. Members were advised that pCm which had been issued with the "Notice of confirmation of transitional registration of pCm" or "Notice of confirmation of (non-transitional) registration application of pCm" would be allowed to continue to be sold in Hong Kong after the mandatory registration of pCm came into force in December 2010, until the pCm was formally registered, or until the application for its registration was refused, or until such date to be promulgated by SFH in the Gazette (applicable to "Notices of confirmation of transitional registration of pCm" only), whichever date was the earliest.

12. Noting the concerns raised by some Chinese medicines traders that the consultation period on the commencement of the relevant legislative provisions related to mandatory registration of pCm lasted less than one month from 26 May to 23 June 2010 and there was insufficient time for them to comply with the new requirements, some members urged the Administration to extend the consultation period.

13. The Administration did not see the need for extending the consultation period. It pointed out that both CMB and the Department of Health ("DH") had made considerable efforts and carried out a number of consultation

activities to prepare the trade for the full implementation of the mandatory registration of pCm. The statutory requirements of pCm registration were also published in the "Chinese Medicine Traders Newsletter" which had been distributed to all licensed Chinese medicine traders and trader associations. In addition, a letter was issued by DH on 6 May 2010 to all applicants for pCm registration to inform them of the Administration's plan for the commencement of the provisions in the Ordinance and the Regulation related to the mandatory registration of pCm, and the requirements of label and package inserts. Seven briefing sessions had also been held for the major trade associations from late May to early July 2010 to collect feedback of the trade/stakeholders on the commencement of the legislative provisions. Having regard to the views of the trade, the consultation with the trade and stakeholders on the commencement of the legislative provisions through the electronic platform was extended by two weeks to end on 6 July 2010.

14. Members noted the difficulties of some Chinese medicines traders to provide documentary proofs showing that the pCm under application was, on 1 March 1999, manufactured, sold or supplied for sale in Hong Kong as it was quite common for them not to disclose the full and complete information of the master formula in the sales pack of pCm to avoid being replicated. As such, they had to opt to apply for non-transitional registration. Concern was raised as to whether these traders had sufficient time to furnish the required information to prove the efficacy of their pCm in order to have them registered before December 2010. The Administration advised that there should be no question of having insufficient time to prepare for the documents, as applicants could submit by phases the necessary test reports for non-transitional registration.

15. Members were also advised by the Administration on the assessment of CMB in respect of the efficacy of a pCm under application for registration. They noted that for pCm classified under the "Established medicines" category and was formulated according to an ancient prescription, or a modified ancient prescription or pharmacopoeia prescription; or any other prescriptions originated from the National Drug Standards of the People's Republic of China, the applicant had to submit copies of relevant materials from Chinese medicines bibliography, Pharmacopoeia or any other National Drug Standards of the People's Republic of China.

16. On the other hand, for "Health-preserving medicines" under the "Non-established medicines category", the claimed functions had to be supported by research studies, or the functions of which had been described in the health care literature compiled by Chinese medicines professionals. For "Single Chinese medicine granules" under the "Non-established medicines category", copies of relevant materials from Chinese medicines bibliography or Pharmacopoeia should be submitted.

17. The Administration further advised that based on the information submitted by the applicants, the specialists of the Chinese Medicine Division of DH would assess and recommend to CMB on whether the selected prescription had clearly defined indications or functions, reasonable formulation, correct composition and appropriate dosages for the purpose for which the medicine was proposed to be administered. As regards pCm classified under the "New medicines category", the submission of reports on pharmacodynamic studies, pharmacological studies and clinical trials were necessary as their compositions, routes of administration, indications or dose forms were different from traditional use and scientific evidence was essential to ensure their efficacy.

18. Noting that about 4 610 out of the some 14 100 applications for transitional registration of pCm (i.e. 33%) were rejected, question was raised on the reasons for refusing the applications.

19. The Administration advised that applicants for transitional registration of pCm were required to submit within one year from the deadline of application, i.e. by June 2005, the three acceptable basic test reports. About 3 000 applications for transitional registration were rejected by CMB for failing to furnish the test reports even though the applicants had been reminded several times of the need to submit the relevant information for CMB's assessment. The remaining applications were rejected mainly due to the reason of not fulfilling the definition of a pCm. The Administration further advised that about 920 of the some 4 610 rejected cases had applied for review and about 360 applications for review were being further processed as the required information had been furnished.

Proposal to set up a subcommittee to study the subject of mandatory registration of pCm

20. At the special meetings of the Panel held on 17 January and 15 February 2011, members received views from 55 deputations on the progress of the commencement of provisions related to mandatory registration of pCm under the Ordinance. Many deputations expressed great difficulties, in terms of technical and financial viability, in proving the product safety, efficacy and quality when applying for registration of pCm. They pointed out that there were substantial differences between Chinese medicines and Western medicines in terms of their principles and applications, but the existing regulatory system for Chinese medicine had failed to take into account these differences as well as the past practice of the trade. The deputations were also disappointed at the lack of support from the Government to assist the trade in meeting the testing requirements for the purpose of registration of pCm.

21. Many members shared the views of deputations, and urged the Administration to take into account the fact that quite a lot of pCm were already

on sale and in frequent use for a long period of time. Members also expressed grave concern about the lack of transparency and objectivity of the assessment criteria and procedure for the registration of pCm. There was a suggestion that financial assistance, such as the setting up of a loan scheme, should be provided to assist the trade in meeting the high testing costs in order to comply with the legislative requirements for the registration of pCm.

22. The Administration stressed that the implementation of the legislative provisions on mandatory registration of pCm was essential to safeguarding public health and consumer rights, as well as enhancing public confidence in the usage of pCm. Having regard to the time needed by the trade for adaptation and preparation in order to comply with the legislative requirements, a phased approach had already been adopted in implementing the regulatory regime. The existing regulatory regime implemented by CMB, the membership of which comprised, among others, representatives from the trade of Chinese medicines, emphasized self-regulation by the trade. The primary responsibility therefore fell on the pCm manufacturers to ensure that the products they produced were safe, efficacious and of good quality. When a pCm's safety, efficacy and quality had been proven to the satisfaction of CMB, the product would be issued with a "Certificate of Registration of pCm".

23. The Administration further advised that to help the trade understand the registration requirements, technical guidelines for pCm registration had been developed and related registration information on safety, quality, efficacy, quality specification, etc. had been promulgated through various channels, including the CMC website and the "Chinese Medicines Traders Newsletter". Moreover, seminars would continue to be organized for the trade to help them understand these requirements. Face-to-face meetings with individual traders would also be arranged by the Chinese Medicine Division of DH where necessary. In the Administration's view, the implementation of the provisions on mandatory registration of pCm under the Ordinance was generally smooth. Since the provisions came into effect on 3 December 2010, no complaint about suspected sale of unregistered pCm had been received and no violation of regulation was found by DH during its inspections of Chinese medicine traders.

24. While agreeing that mandatory registration of pCm was conducive to safeguarding public health and consumer rights, members were dissatisfied with the inadequate support from the Government to the trade in meeting the registration requirements for pCm. They considered it high time to conduct a review on the policy regulating Chinese medicines. To enable more focused discussion, members agreed that a subcommittee should be set up under the Panel to study the registration of pCm. The approval of the House Committee was obtained at its meeting on 8 April 2011 for the activation of the Subcommittee on Registration of Proprietary Chinese Medicines in June 2011.

**Latest development**

25. According to the lists of pCm posted on the CMB's website, 9 146, 1 269 and 51 applications have been issued with the "Notice of confirmation of transitional registration of pCm", "Notice of confirmation of (non-transitional) registration application of pCm" and "Certificate of Registration of a pCm" respectively as at 17 June 2011.

**Relevant papers**

26. A list of the relevant papers on the Legislative Council website is in the **Appendix**.

Council Business Division 2
Legislative Council Secretariat
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**Appendix**

## Relevant papers on registration of proprietary Chinese medicines

| Committee | Date of meeting | Paper |
|---|---|---|
| Subcommittee on Commencement Notices under the Chinese Medicine Ordinance, Chinese Medicine (Fees) Regulation and Chinese Medicines Regulation | -- | Report |
| Legislative Council | 17 December 2003 | Official Record of Proceedings Pages 2380-2404 (Motion moved to repeal the Commencement Notices under the Chinese Medicine Ordinance, Chinese Medicine (Fees) Regulation and Chinese Medicines Regulation) |
| Panel on Health Services | 12 July 2010 (Item III) | Agenda Minutes |
| Panel on Health Services | 17 January 2011 (Item I) | Agenda |
| Panel on Health Services | 15 February 2011 (Item I) | Agenda |

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