25 November 2014
For information

Legislative Council Panel on Health Services
Subcommittee on Issues Relating to the Development of Chinese Medicine

Registration and Testing of Proprietary Chinese Medicines

PURPOSE

This paper briefs Members on the background information and the latest progress of the registration and testing of proprietary Chinese medicines ("pCms").

BACKGROUND

2. The Chinese Medicine Ordinance (Cap. 549) ("CMO") was enacted in July 1999 to provide for the regulation of the practice, use, trading and manufacture of Chinese medicines in Hong Kong. The CMO stipulates, among others, that all products falling within the definition of pCms must be registered before they can be imported, manufactured and sold in Hong Kong. The regulatory regime has been implemented since September 1999 by the Chinese Medicine Council of Hong Kong ("CMC") established under the CMO. To get registered in Hong Kong, a pCm must fulfil the registration requirements regarding safety, quality and efficacy as prescribed by the Chinese Medicines Board ("CMB") under the CMC.

3. Having taken into account the history and practical circumstances of the sale of pCms in Hong Kong, the CMO provides an arrangement of transitional registration. Where a pCm was manufactured, sold, or supplied for sale in Hong Kong on 1 March 1999, the relevant manufacturer, importer or local agent/representative of a manufacturer outside Hong Kong may, in accordance with

the CMO, apply for transitional registration of the pCm within the designated period (i.e. from 19 December 2003 to 30 June 2004):

(i) "Notice of confirmation of transitional registration of pCm" (i.e. "HKP") will be issued if the pCm has been assessed by the CMB as meeting the registration requirements. To facilitate the processing of transitional registration of pCm to formal registration, holder of the HKP concerned has to submit the necessary documents in respect of safety, quality and efficacy to the CMB. "Certificate of registration of pCm" (i.e. "HKC") will be issued if the pCm has been assessed by the CMB as meeting the registration requirements;

(ii) Those applications which are not eligible for transitional registration but have submitted three basic test reports[1] will be issued with "Notice of confirmation of (non-transitional) registration application of pCm" (i.e. "HKNT").

4. Relevant legislation related to the mandatory registration of pCms has come into effect since 3 December 2010. The legislation related to the requirements of label and package inserts has become effective since 1 December 2011.

PROGRESS OF pCm REGISTRATION

5. As at the end of November 2014, the CMB has received about 17 970 applications for registration of pCm, of which about 14 110 also applied for transitional registration. Of these, about 8 600, 420 and 600 have been issued with HKP, HKC and HKNT respectively after approval by the CMB.

Requirements for the testing of pCms

6. According to section 122 of the CMO, in approving a registration application for a pCm, the CMB must take into account its safety, quality and efficacy. As such, whenever a pCm applies for registration, the applicant must submit documents in support of the safety, quality and efficacy as required by the

[1] The basic test reports must include three acceptable test reports, i.e. (1) heavy metals and toxic element test report; (2) pesticide residue test report; and (3) microbial limit test report.

CMB. In this regard, the trade has expressed that they have encountered the following difficulties in the testing of safety and quality:

(i) The testing costs are expensive;

(ii) It is difficult to identify laboratories which are accredited by the CMB for the testing. Laboratories in the Mainland refuse to conduct testing due to voluminous workload; and

(iii) The threshold for the standard of testing reports is too high. For example, there are technical difficulties in establishing product specifications, and a long period of time is required to work out suitable testing methods.

Measures to facilitate the trade to migrate their transitional registrations to formal registrations

7. Having assessed the overall situation of the trade, the CMB resolved in June 2013 to extend the deadline for submitting the product specification and general stability test reports by HKP holders from 30 June 2013 to 30 June 2015. In addition, having assessed the progress of submission of registration documents by the holders and feedback from the trade, the CMB has adjusted the processing arrangements in May 2014 with a view to expediting the processing of transitional registration of pCm to formal registration. The adjusted arrangements mainly focus on the following three aspects:

(i) Product efficacy documents: Adjust the qualification of the author of the formula and principle of formulating the formula;

(ii) Product quality documents: Adjust the technical requirements of product quality and stability test reports; and

(iii) Change of particulars of the manufacturer: Adjust the requirement for re-submission of documents.

8. In addition, to address the difficulty encountered by the applicants in producing safety and quality testing reports as evidence for fulfilling the registration requirements, the CMB has provided the following relief measures for the trade:

(i) If an applicant fails to submit the testing reports within the prescribed deadline, he may apply for extending the deadline with the CMB if he can provide reasonable justifications;

(ii) If necessary, the CMB may request the regulatory authorities in the Mainland to expand the list of recommended laboratories so as to increase the number of laboratories qualified for conducting the testing; and

(iii) The Department of Health ("DH") has been regularly holding briefing sessions on "Technical Issues in Registration of pCm" to brief the trade on the registration requirements of pCm and exchange views on technical issues for establishment of quality specifications.

9. To assist the trade to resolve the difficulties encountered in the testing of pCm, the DH has been actively communicating with the trade and applicants through various channels on the requirements for pCm registration and testing of pCm. These include the conduct of a series of seminars, briefings or interview with applicants, and the promulgation of the "Chinese Medicines Traders' Newsletter" by the CMB. The updated information and the updated list of accredited laboratories have been uploaded to the CMC's website (www.cmchk.org.hk).

IMPLEMENTATION OF pCms REGISTRATION

10. Since the implementation of the legislation for the registration of pCms on 3 December 2010, the DH has kept up its efforts to conduct market surveillance of pCm and proactive inspection. An enquiry hotline has since been set up to answer public enquiries on pCm registration. Up to the present, twelve non-compliance cases have been found and prosecution actions have been taken. Overall speaking, implementation of the legislation has been smooth and is generally supported by the public, the trade and the stakeholders.

11. In addition, the legislation for the requirements of label and package insert of pCms has become effective since 1 December 2011. Having considered the actual operation of the trade, the CMB resolved that if a pCm is found in violation of the label and package insert requirements but has not posed health hazards to the public, the DH generally would require the trader concerned to cease

selling that pCm and a warning letter would be issued to the trader. However, DH may consider taking prosecution action if serious offence is found. The pCm would only be approved for sale in the market after meeting the label and package insert requirements.

12. As at the end of November 2014, over 42 980 registered pCms were checked and only 402 pCms were found failing to meet the requirements on label and package insert as prescribed under the law. The traders concerned were asked to remove these pCms from sale, and warning letters were issued to them. Information of non-compliance has been uploaded to the website of the Chinese Medicine Division (www.cmd.gov.hk) for the public's and trade's information.

13. A review on the aforementioned enforcement arrangements was conducted one year after the implementation of the legislation, and another review was conducted in April 2014. Generally speaking, the implementation of the legislation was well received by the public and the trade. A great majority of pCms have complied with the statutory requirements. The CMB has agreed to continue with the existing enforcement arrangements and subsume the active surveillance under the prevalent regular market surveillance mechanism. Since the implementation of the relevant legislation, the DH and the CMB have sustained the efforts on publicity and educational activities, including launching Announcements in the Public Interest related to label and package insert requirements of pCms in the television and radio; sending out "Ambassadors" to visit Chinese medicines traders as well as dispensaries to familiarise the traders with the statutory requirements; and holding roving exhibitions in 18 districts of Hong Kong to introduce the registration system of pCms as well as the requirements for label and package insert of registered pCms.

PROMOTION OF CHINESE MEDICINES TESTING IN HONG KONG

14. As mentioned by the Chief Executive in the 2013 Policy Address, Hong Kong is well positioned to develop into a major testing and certification centre in the region, and thus will focus promotion efforts on six selected industries with potential demand for testing and certification services. Chinese medicines industry is one of the selected industries. Strengthening the Chinese medicines testing services would not only expand the overall business for the testing industry, but also enhance consumers' confidence in Chinese medicines manufactured in Hong Kong, thereby facilitating the expansion to overseas markets. In this connection, the

Chinese Medicine Development Committee[2] is now focusing the discussion and study of specific measures in various key areas, including the promotion of Chinese medicines testing in Hong Kong, in order to promote the development of Chinese medicine.

ADVICE SOUGHT

15. Members are invited to note the contents of this paper.

Food and Health Bureau
Department of Health
November 2014

[2] The Government set up the Chinese Medicine Development Committee ("the Committee") in February 2013, to give recommendations to the Government concerning the direction and long-term strategy of the future development of Chinese medicine in Hong Kong. The Committee is chaired by the Secretary for Food and Health and comprised of representatives from the Chinese medicine practice, Chinese medicine trade, academia, research and development, testing and healthcare sectors, as well as lay persons.