

**Business Facilitation Advisory Committee
Retail Task Force**

*Update on the Trade's Concerns
on the Regulation and Development
of Proprietary Chinese Medicine*

Purpose

This paper provides an update on the trade's concerns on the regulation and development of proprietary Chinese medicine (pCm).

Background

2. In view of the concerns expressed by the trade in the application for pCm registration, the Retail Task Force (RTF) of the Business Facilitation Advisory Committee (BFAC) decided to review the issue at its meeting on 16 October 2006. Representatives of the Department of Health (DH) attended meetings of the RTF on 11 December 2006 and 12 February 2007 to brief members on the matter. DH's latest responses to the trade's concerns and improvement proposals were set out in *RTF paper 35* considered in the RTF meeting held on 14 May 2007.

3. Upon the advice of the RTF, the Secretariat invited the trade representatives to comment on *RTF paper 35*. In response, two trade associations/groups (*the Concern Group on Registration of pCm under the Chinese Manufacturers' Association of Hong Kong [香港中華廠商聯合會中成藥註冊關注組]* comprising nine related trade associations and the *Hong Kong Society of Chinese Medicines [香港中藥學會]*) had provided their further comments in writing. They basically reiterated some of their previous concerns as outlined in *RTF Paper 35*, including –

- Technical difficulties and high costs involved in meeting requirements for product specifications and general stability;
- Restriction under the Chinese Medicine Ordinance (CMO), Cap. 549, which provides no exemption from registration for possession of not-for-sale pCm and export pCm;

- Complicated and rigid pCm registration requirements, including difficulties in obtaining approval to change the ownership right of applications for pCm registration;
- Difficulties encountered in compliance with the Protection of Endangered Species of Animals and Plants Ordinance, Cap. 586;
- Over-stringent regulation on medical advertisements under the Undesirable Medical Advertisements Ordinance (UMAO), Cap. 231; and
- Inadequate support for the pCm industry.

4. To facilitate mutual communication, the Secretariat held a meeting on 12 September 2007 for the trade representatives and the representatives of DH to exchange views. The meeting was well received by the trade representatives who appreciated the DH's and the Secretariat's willingness to listen to their views and to explore possible ways to address their concerns while safeguarding public interests. Summaries of the discussion are set out in paragraphs 5 to 24.

Progress of pCm registration

5. The registration system for pCms commenced on 19 December 2003. Since then, the Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong (CMC) has received over 16,100 applications (including about 14,000 for transitional registration and about 2,100 for non-transitional registration).

6. In accordance with sections 120 to 122 of the Chinese Medicine Ordinance (CMO), Cap. 549, an application for pCm registration is required to submit documents to prove the safety, quality and efficacy of the pCm. pCms are registered under three classification categories, namely (1) established medicines, (2) non-established medicines, and (3) new medicines. The requirements for registration of a pCm are subject to the classification of the pCm under application, and the registration group selected by the applicant. The CMO also provides for transitional registration of pCm under section 128 of the CMO. Applicants for transitional registration are required to submit application from 19 December 2003 to 30 June 2004, and provide documentary proof to show that the applying pCm was manufactured or on sale in Hong Kong on 1 March 1999. For pCms eligible for transitional registration, the necessary medicinal information may be submitted to the CMB in phases. The basic test reports including the test reports on heavy metals and toxic element, pesticide

residues and microbial limits, could be submitted before 30 June 2005. The product specification, the methods and certificate of analysis, the stability test reports can be submitted between 2009 and 2014.

7. As at the beginning of September 2007, the CMB and its committee, Chinese Medicines Committee, have processed over 8,000 applications for transitional registration. It is estimated that the “Confirmation Notice for transitional registration of pCm” (Notice) of these applications will be issued by early 2008. For the remaining 6,000 odd applications, they include cases involving change of ownership, cases with outstanding basic test reports, cases with outstanding documentary evidence of manufacture or on sale on 1 March 1999, etc.

8. The CMB issued a letter to all pCm registration applicants in August 2007, informing them that the first batch of “Notice” will be issued in late 2007/early 2008. For those applications which have yet to meet all the registration requirements, DH will remind the applicants to submit the outstanding proof and/or basic test reports without delay. DH will continue to process these applications and issue the Notice by batches when the registration requirements are complied with. Meanwhile, the pCms are allowed to be manufactured/ sold/ imported/ exported, and a letter will be issued by DH to the traders to facilitate their export to other countries.

9. The trade is concerned about the impact of issuing the first batch of “Notice” and the status of other pCms that may not have received the “Notice”. To avoid confusion and misunderstanding on the status of different classes of pCm, i.e. whether it is legitimate to continue selling products not yet registered/under consideration, **DH will work out a clear and practicable plan before the issuance of these Notices, and duly educate the retailers and other parties concerned of the position.** DH reassured the trade that all applications for transitional registration would be thoroughly evaluated before the issuance of the first batch of “Notice”. **DH will also consider other measures proposed by the trade, like the use of different registration numbers for the different classes of products under application, and propose to the CMB for consideration.**

Technical requirements for the quality test reports

10. Laboratories performing the tests for pCm registration should meet requirements set by the International Standardization Organization (i.e. ISO/IEC 17025) or Good Laboratories Practice (GLP). Recognizing the limited capacity of local laboratories and the fact that many pCms are produced in the Mainland,

the CMB also accepts 16 Municipal testing laboratories recommended by the State Food and Drug Administration. This gives more options for Chinese medicines traders and avoids additional costs for repeated testing for pCm manufactured in the Mainland as well as ensuring the laboratories conducting these tests are creditable.

11. In view of the complexity in pCm testing, the CMB has agreed to allow more time for submission of the quality test reports for all transitional registrations. Technical guidelines have been prepared and published, and regular dialogue is maintained with both local laboratories and those in the Mainland, in respect of the technical requirements for pCm testing. Besides, the applicants and their testing laboratories can write to DH to enquire about the individual testing methods and product's specification.

12. As regards the traders' concerns on the high cost of conducting laboratory tests and request for DH to provide prior confirmation on testing items and methods, **DH agreed to explore possible ways to enhance its existing enquiry service on pCm testing.**

13. To enhance communication, **DH will organize more technical workshops and seminars for the traders and the testing laboratories. The applicants are encouraged to send in their technical enquiries in writing with proposed testing methods, and DH's experts will provide written advice after assessment. If there are any updates related to the testing requirements and standards for pCm, DH will consult the experts, the trade and the laboratories before finalizing the advice.**

Statutory requirement for the registration of pCm

14. Under section 119 of the CMO, no person shall sell or import or possess any pCm unless the pCm is registered. Hence, pCms manufactured locally for the purpose of export and possessed not for sale are still required to be registered. In formulating these stipulations, references were made to the enforcement experience as well as international practices. This requirement is in line with the World Health Organization's recommendation that the manufacturing country should properly control the quality of its medicines. In assessing the overall risk and taking into account the practice of the trade, there are provisions in the law that a pCm may be exempted from registration if it is –

- (a) imported by a wholesaler of pCms for the purpose of re-exporting by the same wholesale dealer; or

- (b) imported by a holder of a valid certificate for clinical trial and medical test and is to be used for the purposes of the clinical trial and medical test to which the certificate relates; or
- (c) compounded by or under the supervision of a registered Chinese medicines practitioner (CMP) or a listed CMP at the premises where he practises and only if such pCm is used for administering or supplying to a patient under his direct care; or
- (d) individually prepared or compounded for one patient by a person nominated under CMO or under such person's supervision, at the premises in respect of which a retailer license is in force and in accordance with the prescription given by a registered CMP or a listed CMP.

15. The trade claimed that the non-provision of exemption to the possession of not-for-sale pCm might hamper the development of the pCm industry, particularly the export of pCm, and suggested that export pCm and possession of not-for-sale pCm should be exempted from registration. DH remarked that the date for commencement of section 119 of CMO has yet to be determined. **Adequate time would be given for the trade to take remedial actions and recall their products, if necessary, before the commencement date. Before the commencement of section 119, pCm can still be sold in the market and apply for import and export licences. DH also agreed to convey the trade's views on the need to amend the CMO and its schedules to the Administration for consideration of a review at an opportune time.**

Change of applicant for application in process

16. The trade is concerned that some traders have faced difficulties in getting approval to change the applicant whilst the application for transitional registration is still being evaluated by CMB. DH opined that if an applicant was changed during the evaluating process, the new applicant might not be the person who was manufacturing / wholesaling the particular pCm on 1 March 1999, thus the change of applicant during the evaluation could be a change of ownership and warranted individual assessment.

17. As regards issues related to the change of ownership for transitional registration, the CMB had sought legal advice and was advised that **it was not in order to give blanket approval to change of ownership.** Taking into account the trade's concern about the transitional eligibility and costs of testing for a new application, **the CMB will exercise discretion in considering the applications on a case by case basis in accordance with the relevant provisions in the CMO.**

Compliance with the Protection of the Endangered Species of Animals and Plants Ordinance, Cap. 586

18. Regarding the new law on the Protection of the Endangered Species of Animals and Plants (the Ordinance), the trade pointed out that though materials listed in Appendixes II and III of the Ordinance could still be used in pCm subject to the possession of the required import permit, it was in fact difficult to obtain such permits from China. It was hoped that the CMB would allow more flexibility for medicine traders to replace endangered species with other ingredients and retain their registration under transitional registration or the established medicines category.

19. To facilitate the trade's understanding of the Schedules of the Ordinance, the Agriculture, Fisheries and Conservation Department had sought input from DH and issued a letter together with a user-friendly reference list to the trade on the endangered species before the commencement of the Ordinance. The CMB had also discussed the trade's proposal critically, and agreed that it was professionally unsound to grant across the board relaxation for the replacement of endangered species with other ingredients. **The CMB will consider applications for replacement of the ingredients listed in Appendixes II and III of the Ordinance on individual merits.** There are also successful applications which the pCms can retain their eligibility for transitional registration even the endangered species are replaced or removed from the formula.

Undesirable Medical Advertisement Ordinance (UMAO), Cap. 231

20. The UMAO prohibits the advertising of medicine, surgical appliance or treatment for prevention or treatment of certain diseases or conditions in human beings as specified in Schedules 1 and 2 of the Ordinance in order to prevent the adverse effects of improper self-medication by members of the public. The label of a pCm constitutes an advertisement whereas the package insert does not. The trade considered that the restrictions on medical advertisements under the UMAO were outdated and too stringent, restricting the consumers' right to know and hampering the sale of pCm. They remarked that even a pCm was registered and proven to be effective for certain indications, the claim was not allowed to be publicized. Since there were limited sales channels for pCm, forbidding medical claims or description of the pCm's efficacy on its external package would hamper its sale.

21. DH explained that advertisement of medicines, surgical appliances, or treatment for prevention or treatment of certain diseases or bodily conditions as specified in the Schedules of the UMAO are prohibited in order to protect the public from being induced by advertisements to seek improper self-medication or treatment instead of consulting medical practitioners. In fact, doctors and other medical professions are also subject to controls of the UMAO, apart from pCm and western medicine traders. The Administration does not have any immediate plan to review the UMAO, which was reviewed in 2004 and the amendments were passed in 2005. The new Schedule 4 of UMAO listed six higher risk health claims to be prohibited in orally consumed products while restrictions on certain diseases or disease conditions have been suitably lessened in Schedule 1. **DH will continue to work with the trade and assist the traders by providing more guidelines and more specific advice in compliance with the UMAO.**

Support for the pCm Industry

22. The trade has a general consensus that the Government should do more to promote and support the pCm industry which has the potential to develop into a high value-added and knowledge industry with the provision of a more conducive business environment by the Government.

23. The trade has suggested that the Government should proactively explore possible ways to assist the industry, including the following means –

- (a) To provide financial assistance to the trade in testing and upgrading old factories;
- (b) To expand the coverage of subsidy funds, simplify their application procedures and relax the approval criteria;
- (c) To promote the use of pCm in the public medical sector and liaise with the Hospital Authority to include pCm in the Hospital Authority Drug Formulary;
- (d) To develop a scheme for mutual recognition of pCm registration with the Mainland authorities; and
- (e) To assist pCm traders to promote the sale of their products in overseas market.

24. The Secretariat has referred the trade's views and proposals to the Commerce and Economic Development Bureau and the Food and Health Bureau for consideration. A reply is awaited.

Way forward

25. Members are invited to note the update on the trade's concerns on the regulation and development of pCm. Representatives of DH will attend the RTF meeting to brief members of the progress.

Business Facilitation Advisory Committee Secretariat
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