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Paper for the Panel on Health Services

Report of the Subcommittee on Registration of Proprietary Chinese Medicines

Purpose

This paper reports on the deliberations of the Subcommittee on Registration of Proprietary Chinese Medicines ("the Subcommittee").

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. CMO stipulates, among others, that all products falling within the definition of proprietary Chinese medicines ("pCms") must be registered before they can be imported, manufactured or sold in Hong Kong. The regulatory regime has been implemented by the Chinese Medicine Council of Hong Kong ("CMC") established under CMO in September 1999. To be registered, all pCms must meet the registration requirements prescribed by the Chinese Medicine Board ("CMB") under CMC regarding their safety, quality and efficacy. In view of the history of sales of pCms in Hong Kong, CMO also provides a transitional registration system for pCms manufactured, sold or supplied for sale on 1 March 1999 in Hong Kong. CMB under CMC has accepted applications for registration of pCms since 19 December 2003, and relevant provisions related to the mandatory registration of pCms have commenced since 3 December 2010 after transitional applications had been dealt with. Those related to the requirements of label and package inserts have commenced since 1 December 2011.

3. Since the enactment of CMO, the Panel on Health Services ("the Panel") has been following up on the relevant issues. Issues relating to the mandatory

registration of pCms and the label and package insert requirements are of particular concern to the Panel. The Panel held two special meetings on 17 January and 15 February 2011 to receive views from 55 deputations on the implementation progress of the mandatory registration of pCms. Members generally expressed concern on whether adequate support had been provided to the pCm trade in complying with the registration requirements for pCms and considered it high time to conduct a review on the policy regulating pCms.

The Subcommittee

4. At the Panel meeting on 14 March 2011, members agreed that a subcommittee should be appointed under the Panel to study issues relating to the mandatory registration of pCms. The Subcommittee's terms of reference and membership list are in **Appendices I and II** respectively.

5. Under the chairmanship of Dr LEUNG Ka-lau, the Subcommittee held a total of four meetings. The Subcommittee decided not to invite views from deputations, as the Panel had received their views in January and February 2011.

Deliberations of the Subcommittee

6. The Subcommittee has focused its deliberations on the following areas –

(a) implementation of the mandatory registration of pCms;

(b) classification categories of pCms;

(c) support for the pCm trade; and

(d) implementation of the label and package insert requirements.

<u>Implementation of the mandatory registration of pCms</u>

7. The Subcommittee notes from the Administration that as at early November 2011, CMB received about 16 990 applications for registration of pCms, of which about 14 100 applied for transitional registration. Over 10 000 pCms had been issued with "Notice of confirmation of transitional registration", "Certificate of Registration" or "Notice of confirmation of (non-transitional) registration". About 6 100 applications had been rejected. Up to mid-January 2012, a total of 188 pCms were granted a formal registration status.

Low success rate

8. Members have expressed concern about the low success rate of applications for registration of pCms. They in particular share the pCm trade's concern about whether it is appropriate for CMB to assess the applications for registration of pCms from the perspective of Western medicine, whether there are Chinese medicine practitioners ("CMPs") on CMB and whether CMB has gone through careful deliberation before rejecting any application.

9. According to the Administration, about 6 100 applications have been rejected due to failure to furnish sufficient information. About half are related to the failure of providing the three basic safety test reports of the pCms under application in terms of heavy metals and toxic elements, pesticide residues and microbial limit ("the three basic safety tests"); about 1 600 have been withdrawn by the applicants; and around 1 000 more are related to the failure of submission of the required registration documents and/or fulfilling the definition of pCm under CMO. The Administration has also explained that CMB mainly includes representatives of the Chinese medicine trade, CMPs, consumer representatives and public officers from the Government Laboratory and Innovation and Technology Commission. The registration applications of pCms have been assessed by professionals from various disciplines such as Chinese medicine practice, Chinese medicines and pharmacognosy, chemistry and so forth. All applications are submitted to CMB for careful deliberation. CMB has informed failed applicants of the reasons for rejection. Failed applicants could re-apply if they can make up for what they have failed or apply for review of their applications.

10. The Subcommittee notes from the Administration that as at November 2011, CMB received some 1 209 applications for review. Most of the review applications which are being followed up are related to the failure of providing the three basic safety test reports or the required quality specification, method and testing reports, etc. About half of these applications have been reinstated after providing the required reports.

Transitional registration of pCms

11. Members note that of the 16 990 applications for registration of pCms received as at November 2011, 9 123 pCms have been granted a transitional registration status. Members in general consider that the existing transitional registration arrangement for pCms should remain unchanged for a certain period, as its early withdrawal will not be conducive to the development of the pCm trade. There is a view that in the event of rejection of the application for

formal registration of a pCm, its transitional registration status should no longer remain valid. In addition, should a pCm with a formal registration status fail to continue to fulfil the registration requirements, it should not be allowed to apply for transitional registration. Concern has also been raised about whether a transitionally-registered pCm can continue to be sold if its efficacy is not scientifically proven but it has been proved harmless for use. Some members are of the view that pCm traders should not apply for formal registration of pCms if their efficacy has not been proved. They call on the Administration to balance the development of the trade and the protection of public health and continue to exercise vigilance in monitoring the sale of pCms (especially those popularly sold).

12. The Administration has informed members that the transitional registration arrangement has been clearly stipulated in CMO. The Administration does not have any plan at the moment to change the transitional arrangement for pCms or ban the sale of transitionally-registered pCms.

Exemptions from registration

13. Another main concern of members is the enforcement of section 119 of CMO under which no person should sell, import or possess any pCm unless the pCm has been registered. Members have sought clarification on whether a CMP would commit an offence if he supplies or administers a non-registered pCm to his patients. According to the Administration, CMPs' professional judgments about the administration of medicines to their patients should be respected. Under section 158(6) of CMO, an exemption from registration is given to a pCm compounded by or under the supervision of a registered or listed CMP at the premises where the CMP practises if and only if the pCm is used for the purpose of administering or supplying to a patient under his direct care. Therefore, if the CMP imports Chinese herbal medicines to formulate a pCm for prescription to his patients, the pCm concerned is exempted from registration. However, it would be an offence if the CMP imports an unregistered pCm for sale in Hong Kong. The Administration has advised members that it has fully communicated with CMPs on the above.

Possession of unregistered pCms

14. Members have also expressed worry that members of the public may inadvertently contravene section 119 of CMO. They consider that in enforcing the provision, the Administration should have regard to the nature and severity of the contravention. To prevent the public from inadvertently contravening the law by purchasing unregistered pCms, the definition of "possession of pCms" should be confined to possession of pCms for the purpose of sale. The

Administration has reiterated that CMO has already been implemented for quite some time and is well accepted by the public. Enforcement of the provision against the possession of unregistered pCms has been very smooth.

Classification categories of pCms

15. The Subcommittee notes from the Administration that only a small number of pCms has been granted a formal registration status and they are all "Established medicines", which refers to, among others, an ancient prescription documented in Chinese medicines bibliography in or before the Qing dynasty or a modified ancient prescription which is based on an ancient prescription with reasonable and rational modifications. Members have expressed concern about whether the existing classification categories of pCms are too stringent. They also point out that the pCm trade has complained about the lack of transparency and objectivity in assessing and determining whether a pCm is formulated according to an ancient prescription. There is a worry that while certain pCms have been sold on the market for dozens of years, regarded by their manufacturers as ancient prescriptions and registered under the transitional registration system, their applications for formal registration may be rejected by CMB on the grounds that such pCms are not ancient prescriptions and their safety, efficacy and quality should be supported by scientific proof.

16. Members further point out that many pCms have been sold in Hong Kong for decades but pCm traders have preferred to apply for transitional, instead of formal registration, as such pCms do not fulfill the standards of "Established medicines" defined by CMB and it is unrealistic for them to fulfill the standards of "New medicines" which refers to, among others, a prescription comprising a newly discovered Chinese herb. Under the current mandatory registration requirements for pCms, should a pCm be classified by CMB as an "Established medicine", its application for formal registration will only be required to provide test reports on its safety and certain basic documents in respect of its safety, efficacy and quality, and will be exempted from providing various high-cost test reports on its efficacy and quality, as the pCm concerned has been authoritatively documented. On the other hand, should a pCm be classified as a "New medicine", its applications need to be accompanied with test reports on the safety, efficacy and quality of the pCm concerned and the costs incurred will be as huge as those of providing scientific support to a new western medicine.

17. Some members consider that as the existing classification categories of pCms are not stipulated in CMO but determined by CMB, any alterations to such categories should not require legislative amendments. They have called on the Administration and CMB to review the existing classification categories of pCms and in particular consider pCm traders' suggestion to formulate a new

classification category, such as "Empirical formula", to accommodate pCms which may not fulfill the standards of "Established medicines" or "New medicines" but have been sold in Hong Kong for many years and empirically proved safe or harmless for use.

18. According to the Administration, CMB determines the classification of a pCm based on the information from the applicant. It is an independent statutory body comprising representatives from the profession and the trade and consumer representatives. The Administration has attached great importance to the transparency of the registration system of pCms. To assist the trade in applying for registration of pCms, CMB has issued guidelines including information on the conditions under which a pCm will be classified. The Administration has explained that it is difficult for CMB to grant a formal registration status to pCms when their safety, efficacy and quality have not been proved. CMB needs to assess the impact of a pCm under application on the health of its users in accordance with objective standards. The assessment of whether a pCm is an "Established medicine" will rely on the standards set out in the authoritative sources on traditional Chinese medicine. Under the classification category of "Established medicines", there are certain sub-categories, such as modified ancient prescriptions, which should allow sufficient flexibility for CMB to consider whether to grant a registration status to a pCm which does not fulfill the definition of an ancient prescription but has long been sold in Hong Kong. The Administration has clarified that if a product does not fulfill the definition of pCm as stipulated in CMO, its registration as pCm under CMO will not be required. The product can still be sold in Hong Kong as other products, such as pharmaceutical or health products, if it fulfils the relevant requirements.

Support for the pCm trade

Compliance cost

19. One of the main concerns of the Subcommittee is the high cost incurred for complying with the requirements for proving the safety, efficacy and quality of pCms and the related complicated registration procedures. Members have expressed worry that these requirements may eventually drive out small and medium-sized pCm traders (including manufacturers) from the market and stifle the development of Chinese medicines in Hong Kong. They have called on the Administration to enhance its support measures to facilitate the trade's compliance with the registration requirements, such as the provision of free laboratory test services for pCms which have not been registered. Consideration should also be given to providing financial assistance (such as loans) to the needy traders.

20. In the Administration's view, as CMO has been enacted since 1999, pCm traders have primary responsibility for ensuring the safety, efficacy and quality of their pCm products. This is also in line with international practice. It is inappropriate to use public funding to directly subsidize individual trades or private companies. The Administration also considers that the foremost difficulty for some pCm traders in complying with the mandatory registration requirements is not the cost for conducting the three basic safety tests, which total not more than $10,000, but the submission of documents on the manufacturing process of some pCms, as certain parts of the process, if disclosed, may not be acceptable to the public. The Administration has assured members that although it will not relax the registration requirements, it has been willing and will continue to provide technical support (such as information on laboratory testing) for the trade, especially small and medium-sized manufacturers, to facilitate their compliance with the registration requirements. DH has also provided assistance to traders which have difficulty in submitting documents on the manufacturing process of pCms.

Proof of origin of country

21. The Subcommittee notes that if a pCm is not manufactured in Hong Kong, the applicant applying for registration of the pCm will be required to submit a certified true copy of (a) the production permit or licence of the pCm's manufacturer, and (b) the free sale certificate or certificate of registration of the pCm, issued by the drug regulatory authority of the country of origin. Members have expressed concern that as some pCm traders and CMPs may only be involved in the procurement of pCms, they may not be able to provide such documentary proof. Traders may also need to bear the possible high cost incurred for the provision of proof of the country of origin of each kind of pCm imported by them. The Administration is of the view that pCm traders have the corporate responsibility to provide documents on the country of origin of the pCms imported by them to facilitate CMC to trace their source for the protection of public health. As small and medium-sized pCm traders generally do not import many kinds of pCms, the cost of meeting the relevant requirements should be affordable.

<u>Implementation of the label and package insert requirements</u>

22. The Subcommittee notes that since the commencement of the label and package insert requirements, DH has conducted inspection over 1 930 pCms, which involve 64 retailers, 112 wholesalers and 25 manufacturers, and has identified 64 non-compliant cases, which account for about 3% of the total pCms inspected. Up to mid-January 2012, of the 64 non-compliant cases, nine

had been rectified by the traders concerned, submitted to DH for approval and subsequently allowed to be put on sale again.

Enforcement action

23. Members note that the Administration will require pCm traders to cease selling non-compliant pCms and issue a warning letter to them, provided that no hazard to public health will be caused. Members are concerned whether this is the Administration's policy towards persons who fail to comply for the first time and whether repeat offenders will be prosecuted. They are worried that the risk of repeated offences is high, as the quality of Chinese herbs may be subject to climate or seasonal changes and the functions of the pCms concerned may not meet the health claims stated in their label and package inserts. In the Administration's view, each non-compliant case should be considered on its own facts and merits. If a pCm is found non-compliant for the first time but the offence involved is serious, such as causing hazard to public health, DH will consult the Department of Justice ("DoJ") on whether immediate prosecution should be instituted.

24. Members have also expressed concern that a pCm trader will suffer a significant loss if its pCm is removed from sale immediately after it is found non-compliant. As DH and the trader concerned may hold different views on whether the label and package insert of the pCm in question is compliant or not, it may be more appropriate for DH to discuss the case with the trader concerned before deciding to order immediate removal of the pCm in question from sale. According to the Administration, the implementation of the label and package insert requirements has been smooth. Before commencement of the relevant requirements, holders of pCm registrations had been issued with letters and informed of the label and package insert information, such as major ingredients, dosage and method of usage, of the pCm concerned for verification. DH has also conducted inspections on pCms based on the detailed information provided by pCm applicants during the registration process. Therefore, traders of non-compliant products should not dispute the decisions of non-compliance. The Administration considers it appropriate to order immediate removal of non-compliant pCms from sale, so that the public will not be misled by the incorrect or incomplete information on the label and package inserts of such pCms. The Administration has assured members that only the non-compliant batch, instead of the whole lot, of the pCm in question will be removed from sale. In addition, pCms manufactured before the commencement of the label and package insert requirements are permitted to continue to be sold on the market if they have been replaced with rectified label and package inserts.

Liability for non-compliance

25. Another major concern of the Subcommittee is the liability of the various parties involved in the sale of a pCm which is found non-compliant with the label and package insert requirements. Some members consider that as retailers may be supplied with counterfeit pCms and put them on sale unknowingly, the retailers concerned should not be held liable for the sale of such pCms if they can produce the documentary proof that such pCms are provided by their suppliers. Members have suggested that the liability of the various parties involved in the sale of non-compliant pCms should be stipulated clearly in the relevant guidelines issued by CMB, and immunity should be provided in relation to the unknowing sale of counterfeit pCms.

26. According to the Administration, if a pCm is found non-compliant, the warning letter is issued to the holder of the pCm registration certificate. However, as the entire supply chain of a pCm is complicated and involves various parties, whether persons other than the registration certificate holder will be held liable for non-compliance will depend on investigation findings and the advice of DoJ. CMB's guidelines on labels and package inserts of pCms have emphasized that retailers and wholesalers should procure pCms from reputable and reliable suppliers. Retailers and wholesalers have been advised to check the basic information on a pCm with their suppliers before putting it on sale. Detailed information on each pCm under registration application is also available at CMC's website.

Recommendations

27. The Subcommittee recommends that the Administration should -

(a) review whether the existing definition of pCm and classification categories of pCms are too stringent, resulting in a small number of pCms being granted a formal registration status;

(b) consider whether to confine the definition of "possession of pCm" under section 119 of CMO to possession of pCms for the purpose of sale, with a view to preventing the public from inadvertently contravening the provision;

(c) consider the pCm trade's suggested formulation of a new classification category, such as "Empirical formula", to accommodate pCms which may not fulfill the standards of "Established medicines" or "New medicines" but have been sold in

Hong Kong for many years and empirically proved safe or harmless for use;

(d) review whether the costs of complying with the provisions related to the mandatory registration of pCms and label and package insert requirements are affordable to small and medium-sized pCm traders;

(e) enhance its support measures to facilitate the pCm trade's compliance with the registration requirements, such as exploring the feasibility of providing free laboratory test services for pCms which have not been registered and financial assistance (such as a loan scheme) to the traders in need;

(f) maintain close communication with the pCm trade on the liability that may be borne by various parties for the sale of non-compliant pCms and clearly stipulate such liability in the relevant guidelines issued by CMB;

(g) given that the Administration and the pCm trader may hold different views on whether the label and package insert of a pCm is compliant or not, consider ways to minimize the impact on the trader concerned before deciding to order immediate removal of the pCm in question from sale; and

(h) report to the Panel on the implementation progress of the mandatory registration of pCms and label and package insert requirements at regular intervals after the conclusion of the Subcommittee's work.

Advice sought

28. Members are invited to note the work of the Subcommittee and support its recommendations.

Council Business Division 2
Legislative Council Secretariat
10 February 2012

Appendix I

Panel on Health Services

Subcommittee on Registration of Proprietary Chinese Medicines

Terms of reference

To review the mandatory registration of proprietary Chinese medicines and the implementation of the relevant provisions in the Chinese Medicines Ordinance (Cap. 549) and the Chinese Medicines Regulations (Cap. 549F).

Appendix II

Panel on Health Services

Subcommittee on Registration of Proprietary Chinese Medicines

Membership list

Chairman	Dr Hon LEUNG Ka-lau
Members	Hon CHEUNG Man-kwong Hon LI Fung-ying, SBS, JP Hon Vincent FANG Kang, SBS, JP (from 1 November 2011) Dr Hon Joseph LEE Kok-long, SBS, JP Hon WONG Ting-kwong, BBS, JP (from 1 November 2011) Hon CHAN Hak-kan Hon CHEUNG Kwok-che Dr Hon PAN Pey-chyou Hon Alan LEONG Kah-kit, SC Total : 10 Members
Clerk	Mr Thomas WONG
Legal Adviser	Miss Evelyn LEE