

立法會
Legislative Council

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LC Paper No. CB(2)2421/10-11
(These minutes have been seen
by the Administration)

Panel on Health Services

**Minutes of special meeting
held on Tuesday, 15 February 2011, at 2:30 pm
in the Chamber of the Legislative Council Building**

- Members present** : Dr Hon LEUNG Ka-lau (Chairman)
Hon Albert HO Chun-yan
Ir Dr Hon Raymond HO Chung-tai, SBS, S.B.St.J., JP
Hon Fred LI Wah-ming, SBS, JP
Hon CHEUNG Man-kwong
Hon Andrew CHENG Kar-foo
Hon LI Fung-ying, SBS, JP
Hon Audrey EU Yuet-mee, SC, JP
Hon CHAN Hak-kan
Hon CHAN Kin-por, JP
Hon CHEUNG Kwok-che
Dr Hon PAN Pey-chyou
Hon Alan LEONG Kah-kit, SC
Hon Albert CHAN Wai-yip
- Members attending** : Hon LEUNG Yiu-chung
Dr Hon Priscilla LEUNG Mei-fun
- Members absent** : Dr Hon Joseph LEE Kok-long, SBS, JP (Deputy Chairman)
Hon Cyd HO Sau-lan
Hon IP Kwok-him, GBS, JP
- Public Officers attending** : Dr Ronald LAM Man-kin
Assistant Director (Traditional Chinese Medicine)
Department of Health

Miss Janny WUN Yuen-ming
Secretary (Chinese Medicine Council)

Mr Frank CHAN Ling-fung
Senior Pharmacist (Traditional Chinese Medicine)
Department of Health

Attendance by invitation : Hong Kong and Kowloon Chinese Medicine Merchants Association Ltd.

Mr TSANG Chiu-hing

Association of Hong Kong & Kowloon Practitioners of Chinese Medicine Limited

Mr HO Kwok-wai

San Jiu Pharmaceutical (Hong Kong) Limited

Mr ZHANG Jin-song

Chinese Ancient Healings Medicines Conservation Association

Mr YU Hung-chiu
Chairman

Pok Oi Hospital

Mr WONG Fan-foung
Chairman

Po Che Tong Poon Mo Um

Mr POON Po-sum
Managing Director

South Natural Herbs Health Shop

Mr LAU Pak-chun

國際中醫藥研究學院

Mr WONG Kai-cheong

Yuen Kut Lam Company Limited

Mr YUEN Yee-lum

中國香港中醫急救協會

Mr TING Shui-yan

Mr KWAN Chi-yee

Registered Chinese Medicine Practitioner

Fook Sang Tai Limited

Mr WONG Kam-pui

Managing Director

Hong Kong Composite Materials and Technology
Association

Mr Albert FOK

Chairman

Hong Kong Chinese Meridian Ligamentous Chinese
Medical Research Institute

Mr LAM Yau

The Hong Kong Association of Traditional Chinese
Medicine Ltd.

Ms YU Ming-chu

Hong Kong Chinese Prepared Medicine Traders
Association Limited

Mr TAM Kwok-leung

Modernized Chinese Medicine International
Association Limited

Dr Albert WONG

Founding President

Glory-In Chinese Medical Co. Ltd.

Mr WONG Che-ming

Hong Kong Pharmaceutical Manufacturers
Association

Ms Polly TANG
Vice President

Hong Kong SME Development Association

Mr LAM Kwok-hung
President

Hong Kong Wah Ha Medicine Association

Mr WONG Chi-pong

**Clerk in
attendance** : Ms Elyssa WONG
Chief Council Secretary (2)5

**Staff in
attendance** : Mr Watson CHAN
Head of Research Division

Miss Lettice AU YEUNG
Research Officer 5

Ms Maisie LAM
Senior Council Secretary (2)6

Ms Priscilla LAU
Council Secretary (2)5

Ms Sandy HAU
Legislative Assistant (2)5

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I. Commencement of provisions related to proprietary Chinese medicines in the Chinese Medicine Ordinance (Cap. 549)

(LC Paper Nos. CB(2)776/10-11(01) and (02), (17) to (26), CB(2)824/10-11(01) and (02), CB(2)1002/10-11(01) and (02), CB(2)1027/10-11(01), CB(2)1054/10-11(01) and (02) and IN07/10-11)

Attendance of the Administration

Mr CHAN Hak-kan sought explanation for the non-attendance of the Secretary for Food and Health ("SFH") at the meeting to explain the policy on the registration regime of proprietary Chinese medicines ("pCm") and receive views from attending deputations despite the Panel's request. In his view, the Director of Health should also attend the meeting.

2. The Chairman said that as reported at the Panel's regular meeting on 14 February 2011, subsequent to the special meeting on 17 January, he had written to SFH requesting his presence at this meeting to explain the policy on the regulation of pCm and answer questions from members and attending deputations. However, SFH had declined to attend the meeting and indicated that the Department of Health ("DH") was well-positioned to address concerns of the trade in this regard.

3. Assistant Director (Traditional Chinese Medicine), DH ("AD(TCM), DH") advised that he had relayed to the Food and Health Bureau views expressed by members and deputations at the special meeting of the Panel held on 17 January 2011. SFH noted that some members of the trade might still have concerns over the details of implementation as well as some technical aspects of the registration regime. It was considered that DH, being the department responsible for the enforcement of the Chinese Medicine Ordinance ("the Ordinance"), was well-positioned to address these concerns.

4. Dr Priscilla LEUNG considered that as the official responsible for the policy on the regulation of Chinese medicines, it was most important for SFH or the Under Secretary for Food and Health to attend these two special meetings of the Panel to allay the concerns of deputations about the practical difficulties encountered by the trade in meeting the registration requirements for pCm. Such a responsibility could not be discharged by representatives of DH on their behalf.

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5. Dr Raymond HO declared interest that his family members were working in the healthcare sector. Dr HO pointed out that under the accountability system, principal officials had the responsibility to attend Panel meetings of the Legislative Council to explain the Government's policy decisions and exchange views with members in both the policy formulation and implementation processes. He surmised that the reason for the non-attendance of SFH and the Director of Health at these two Panel meetings was that the Administration had all long attached less importance to Chinese medicines.

6. Mr Andrew CHENG proposed to request the Chairman of the House Committee to relay to the Chief Secretary the Panel's grave dissatisfaction and regret with the non-attendance of SFH or the Under Secretary for Food and Health at these two special meetings.

7. Dr PAN Pey-chyou said that the Hong Kong Federation of Trade Unions was disappointed that SFH had turned a deaf ear and disregarded the views of the attending deputations. He considered it necessary to relay the great dissatisfaction of members to SFH.

8. Ms Audrey EU also expressed regret with the non-attendance of officials from the Food and Health Bureau at these two special meetings of the Panel.

9. The Chairman said that he would raise the matter with the House Committee. The Chairman further said that the Panel had agreed at its regular meeting on 14 February 2011 to appoint a subcommittee to study issues relating to the registration of pCm. In the meantime, the Panel would follow up on the subject pending the activation of the subcommittee. It was hoped that SFH or his Under Secretary would attend meetings convened by the Panel or the subcommittee to discuss matters concerning the registration of pCm.

Views of deputations

10. At the invitation of the Chairman, the following 21 deputations presented their views on the commencement of the legislative provisions related to pCm –

- (a) Hong Kong and Kowloon Chinese Medicine Merchants Association Ltd.;

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- (b) Association of Hong Kong & Kowloon Practitioners of Chinese Medicine Limited;
- (c) San Jiu Pharmaceutical (Hong Kong) Limited;
- (d) Chinese Ancient Healings Medicines Conservation Association;
- (e) Pok Oi Hospital;
- (f) Po Che Tong Poon Mo Um;
- (g) South Natural Herbs Health Shop;
- (h) 國際中醫藥研究學院;
- (i) Yuen Kut Lam Company Limited;
- (j) 中國香港中醫急救協會;
- (k) Mr KWAN Chi-yee;
- (l) Fook Sang Tai Limited;
- (m) Hong Kong Composite Materials and Technology Association;
- (n) Hong Kong Chinese Meridian Ligamentous Chinese Medical Research Institute;
- (o) The Hong Kong Association of Traditional Chinese Medicine Ltd.;
- (p) Hong Kong Chinese Prepared Medicine Traders Association Limited;
- (q) Modernized Chinese Medicine International Association Limited;
- (r) Glory-In Chinese Medical Co. Ltd.;
- (s) Hong Kong Pharmaceutical Manufacturers Association;

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- (t) Hong Kong SME Development Association;
- (u) Hong Kong Wah Ha Medicine Association

A summary of the views of the deputations is in the **Appendix**.

Briefing by Research Division of the Legislative Council Secretariat

11. The Head of Research Division briefed members on the registration of pCm in Macao, Taiwan and the Mainland, details of which were set out in the information note prepared by the Research Division (LC Paper No. IN07/10-11).

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12. In response to Ms Audrey EU's enquiry on whether the registration requirements for pCm were more stringent in Taiwan and the Mainland, Head of Research Division advised that the Research Division had only collected some preliminary information on the registration system of the selected places and no comparison had been made in this regard. Ms EU requested the Administration to provide after the meeting a comparison of the pCm registration requirements among Hong Kong, Taiwan and the Mainland.

The Administration's response to the views expressed by deputations

13. Responding to the views expressed by the deputations, AD(TCM), DH made the following points -

- (a) the Food and Health Bureau had been in close collaboration with DH in formulating and implementing the registration regime for Chinese medicines. The Administration also attached great importance to the views of the trade in the implementation process and had held a number of briefing sessions for the trade since the commencement of registration of pCm in December 2003. Subsequent to the special meeting of the Panel on 17 January 2011, another exchange session with the traders was held to listen to their views on the registration of pCm. DH would continue to maintain an active dialogue with the trade and provide them with appropriate assistance;
- (b) promoting the development of Chinese medicines in Hong Kong had been high on the agenda of the Administration. One case in point was the Administration's target to develop

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standards for around 200 Chinese herbal medicines by 2012 to ensure the safety and quality of Chinese medicines as set out in the 2009-2010 Policy Address. To further strengthen the regulatory regime of Chinese medicines, the Chief Executive had announced in the 2010-2011 Policy Address that efforts would be made to actively engage the industry to work out a timetable for mandatory compliance with the Good Manufacturing Practice for the manufacture of pCm to safeguard public health;

- (c) the Administration did not see the need to suspend the implementation of the legislative provisions on mandatory registration of pCm, as the overall implementation of the provisions was smooth. So far no violation of regulation for selling unregistered pCm was found by DH in its active inspections of Chinese medicine traders. To facilitate smooth commencement of the provisions concerning label and package inserts on 1 December 2011, DH had issued/continued to issue to individual applicants a letter with a checklist of registered information of the pCm submitted as well as missing information on label and package inserts requiring follow-up, if any. The Administration would like to take this opportunity to call on the traders in receipt of the letter to contact DH as early as possible for arranging a face-to-face discussion if necessary;
- (d) the registration regime of pCm emphasized self-regulation by the trade. Under the above principle, the implementation of the registration regime was overseen by the Chinese Medicine Council of Hong Kong ("CMC"), a statutory body established under the Ordinance and the membership of which comprised, among others, Chinese medicine practitioners and representatives from the trade of Chinese medicines;
- (e) while the Administration understood the difficulties faced by some traders in testing their products, the requirement that pCm manufacturers should be responsible for ensuring the safety, efficacy and quality of their products was in line with international practice. It should be noted that among the 5 800 rejected applications for registration of pCm, the majority of which had failed to furnish the three acceptable basic test reports (i.e. test reports on heavy metals and toxic

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element, pesticide residues and microbial limit). The remaining applications were rejected mainly due to the reason of not fulfilling the definition of a pCm and thus were not required to apply for pCm registration;

- (f) DH had set up a hotline to answer enquiries from traders as well as members of the public. Staff manning the hotline would be able to provide traders with advice on the pCm registration requirements, such as differentiation between food and medicines. DH would also continue its efforts to familiarize the trade with the registration requirements. Where necessary, further guidelines would be developed to assist the trade to comply with the requirements; and
- (g) the spirit of section 119 of the Ordinance which stipulated that no person should, among others, possess any pCm unless it was registered was to prohibit any unregistered pCm to circulate in the market to safeguard public health. The Administration would enhance public education and publicity efforts to encourage members of the public not to purchase and use any unregistered pCm for the sake of their own health.

Discussion

14. Dr Priscilla LEUNG was concerned that many small and medium-sized pCm manufacturers would be forced to withdraw from the market and close down their business because of difficulties, in terms of financial and technical viability, in proving the product safety, efficacy and quality to satisfy the registration requirements for pCm, thus leaving consumers with less choice. Mr LEUNG Yiu-chung raised a similar concern. Dr Priscilla LEUNG urged the Administration to provide financial assistance, such as the setting up of a loan scheme, to assist the small and medium-sized manufacturers in meeting the high testing costs in order to comply with the registration requirements for the registration of pCm.

15. AD(TCM), DH responded that seven years had elapsed since the Chinese Medicines Board ("CMB") under CMC started to accept applications for registration of pCm in December 2003. Those applicants whose applications for registration were rejected had been given a number of opportunities for providing the three basic reports. However, they had failed to do so despite repeated reminders. AD(TCM), DH stressed that pCm manufacturers had to take responsibility for product

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safety. To the understanding of the Administration, the cost for conducting the three basic tests in the market was in the range of \$3,000 to \$5,000. It should however be pointed out that, apart from testing the end product, it was necessary for the pCm manufacturers to ensure that their products were consistently produced and controlled throughout the manufacturing process. All these investment costs had to be borne by the manufacturers.

16. Ms Audrey EU urged the Administration to amend section 119 of the Ordinance to the effect that the possession of unregistered pCm would not become an offence unless such possession was for the purpose of sale. Ms EU shared Dr Priscilla LEUNG's concern that many well-known pCm which had been in use for many years might be forced to leave the market under the current registration system. She sought information from Yuen Kut Lam Company Limited on whether a number of century-old well-established brand had not been granted approval for pCm registration.

17. Mr YUEN Yee-lum of Yuen Kut Lam Company Limited said that to his understanding, apart from Yuen Kut Lam, a number of pCm manufactured by the well-established brands, such as Ma Pak Leung, Yu Yan Sang, etc., had yet been granted approval for registration. Ms Audrey EU remarked that while it would not be appropriate for the Panel to deal with individual cases, the Complaints Division of the Legislative Council Secretariat could be an avenue for these pCm manufacturers to lodge complaints against the rigid and bureaucratic approach adopted by the Administration in handling their applications for registration of pCm.

18. Dr Priscilla LEUNG invited the views of Modernized Chinese Medicine International Association Limited on the modernization of pCm in order to comply with the registration requirements.

19. Dr Albert WONG of Modernized Chinese Medicine International Association Limited considered that there was still a long way to go before most pCm could attain the efficacy and quality standards for the registration of pCm. The Administration should therefore suspend the requirement that pCm which had been issued with the "Notice of confirmation of (non-transitional) registration application of pCm" or the "Notice of confirmation of transitional registration of pCm" had to furnish within a specified time period the product efficacy and quality documents.

20. The Chairman noted that while the Ordinance established the legal framework to implement a mandatory registration regime for pCm, the detailed registration requirements were hammered out by CMC. Holding

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the view that the existing threshold for registration of pCm, in particular the efficacy of those pCm classified as new medicines, was set at too high a level for the manufacturers to comply with, the Chairman asked whether the trade had been consulted on the requirements.

21. While agreeing that some efficacy requirements might entail very high investment cost and pose a challenge to the pCm manufacturers, AD(TCM), DH explained that it was necessary for pCm classified as new medicines to submit reports on pharmacodynamic studies, pharmacological studies and clinical trials as their compositions, routes of administration, indications or dose forms different from traditional use and scientific evidence essential to ensure their efficacy.

22. Noting that the category and registration group to which a pCm belonged to was determined by CMC whose membership comprised only appointed members, the Chairman considered that such an arrangement was unfair to the trade. AD(TCM), DH responded that the membership of CMC/CMB included, among others, lay persons to represent the interests of the general public and consumers. A statutory mechanism was in place for CMB to arrange meetings with individual applicants for registration of pCm to review their cases.

23. Mr LEUNG Yiu-chung shared the views of attending deputations that the existing regulatory system for Chinese medicines had failed to take into account the differences between Chinese medicines and Western medicines in terms of their principles and applications. Mr LEUNG was of the view that the non-attendance of any representatives from CMC at these two special meetings of the Panel was at variance with the Administration's response that it attached great importance to the views of the trade. The grievances expressed by the deputations also revealed that the Administration had taken no heed of their concerns throughout the years. The grace period given by the Administration for the trade to meet the statutory requirements was also insufficient. Taking into account that it might take time for the subcommittee appointed under the Panel to activate its work, Mr LEUNG asked the Administration whether consideration could be given to setting up a working group to work with the deputations on measures to address the problems currently faced by the trade in the process of applying for registration of pCm.

24. While acknowledging that some pCm manufacturers encountered difficulties in complying with the registration requirements, AD(TCM), DH said that the Administration should by no means lower the requirements to facilitate compliance by all existing pCm manufacturers.

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There was however no cause for concern that the registration regime of pCm was biased towards the standards employed under Western medicines, as the existing regime emphasized self-regulation by the trade and the responsibility of vetting the applications for registration of pCm rested with CMB. An appeal mechanism whereby rejected applicants could seek a review of their applications was also in place.

25. AD(TCM), DH further said that the existing exchange platform with the trade had already afforded sufficient avenues for the Administration to understand the difficulties faced by the trade in the process of applying for registration of pCm. Where necessary, DH would arrange face-to-face discussion with individual traders. Mr LEUNG Yiu-chung requested the Administration to provide after the meeting the report of those meetings. AD(TCM), DH said that DH would submit regular reports to the Business Facilitation Advisory Committee on the progress of the pCm registration. The Administration could provide the reports for information of the Panel.

26. The Chairman informed members of his decision to extend the meeting for 15 minutes beyond its appointed time to allow more time for discussion.

27. Dr Raymond HO doubted the effectiveness of the exchange sessions organized by the Administration to receive views of the trade on the registration of pCm, as the Administration had turned a deaf ear to the views expressed by the trade. Dr HO considered that more should be done by the Administration to assist the trade to resolve the various implementation issues, with a view to promoting the development and modernization of Chinese medicines in Hong Kong.

28. AD(TCM), DH reiterated that the Administration would continue to maintain dialogue with, and provide appropriate assistance to, the trade as far as possible.

29. Mr Alan LEONG said that the Civic Party fully understood the concerns of the trade on the registration regime of pCm. It was hoped that the subcommittee appointed under the Panel could activate its work as earliest as possible to provide a platform for members to follow up with the Administration.

30. Concluding the discussions, the Chairman thanked the attending deputations for giving views on the subject.

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31. There being no other business, the meeting ended at 4:30 pm.

Council Business Division 2
Legislative Council Secretariat
19 July 2011

Panel on Health Services

Special meeting on Tuesday, 15 February 2011
on commencement of provisions related to proprietary Chinese medicines in the Chinese Medicine Ordinance (Cap. 549)

Summary of views and concerns expressed by deputations/individuals

Organization / individual	Major views and concerns
Commencement of provisions related to the mandatory registration of pCm and the requirements of label and package inserts	
<ul style="list-style-type: none"> • Hong Kong and Kowloon Chinese Medicine Merchants Association Ltd. • The Hong Kong Association of Traditional Chinese Medicine Ltd. • Pok Oi Hospital • Mr KWAN Chi-yee 	<ol style="list-style-type: none"> 1. The deputations express support for the commencement of provisions related to the mandatory registration of proprietary Chinese medicines ("pCm") in the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") and the Chinese Medicines Regulation (Cap. 549F) ("the Regulation") in December 2010. They consider that the new regulatory regime could prevent the sale of counterfeit and substandard drugs, enhance public confidence in the usage of pCm as well as foster the development of Chinese medicines in the long run. 2. The deputations request the Administration to provide clear guidelines on the requirements of label and package inserts and complete the vetting of label and package inserts of pCm before the commencement of the related provisions in December 2011, so that the trade would have sufficient time to meet the new requirements.
<ul style="list-style-type: none"> • Hong Kong Chinese Prepared Medicine Traders Association Ltd. • Hong Kong SME Development Association 	<ol style="list-style-type: none"> 1. The deputations express support for the implementation of mandatory registration of pCm in December 2010. They consider that the new regulatory regime could help safeguard public health and enhance the safety of pCm. 2. As regards the requirements of label and package inserts, the deputations consider that the relevant provisions should be deferred for one year after the Administration has completed the vetting of label and package inserts of pCm, so that the trade would have sufficient time to meet the new requirements.
<ul style="list-style-type: none"> • Hong Kong Chinese Meridian Ligamentous Chinese Medical Research Institute 	<ol style="list-style-type: none"> 1. The deputations express concern on the impact of the mandatory registration of pCm on the trade. In particular, pCm not yet registered but are being used by Chinese

Organization / individual	Major views and concerns
<ul style="list-style-type: none"> • Hong Kong Composite Materials and Technology Association • Modernized Chinese Medicine International Association Ltd. 	<p>medicine practitioners ("CMPs") for treating their patients have to be recalled from the market. This causes inconvenience to patients and CMPs. The deputations also point out that there is a rise in the price of pCm after the implementation of the mandatory registration of pCm.</p>
<ul style="list-style-type: none"> • Hong Kong Wah Ha Medicine Association • Po Che Tong Poon Mo Un • Yuen Kut Lam Compant Ltd. • 中國香港中醫急救協會 • 國際中醫藥研究學院 	<ol style="list-style-type: none"> 1. The deputations object to the commencement of provisions related to the mandatory registration of pCm and the requirements of label and package inserts. The trade is not given enough time to prepare for the implementation and a number of pCm which have been currently used by members of the public and CMPs have to be recalled from the market. They urge the Administration to defer the implementation of the relevant provisions and provide a transition period for the trade.
Registration procedure of pCm	
<ul style="list-style-type: none"> • Glory-In Chinese Medical Co. Ltd. • The Hong Kong Association of Traditional Chinese Medicine Ltd. • Yuen Kut Lam Compant Ltd. 	<ol style="list-style-type: none"> 1. The deputations urge the Chinese Medicine Board to expedite the vetting and approval procedure for the registration of pCm and handle the registration applications in a more flexible and less stringent manner, particularly for those pCm which have submitted the three acceptable basic test reports on heavy metals and toxic element, pesticide residues and microbial limit, as well as those pCm which have been registered in the Mainland and Taiwan. 2. In the deputations' view, the Administration should adopt a flexible approach in regulating concentrated pCm, which are in the form of powder or granule and are sold under prescription only. 3. The Administration should protect the patent of pCm manufacturers by refusing registration of replicated pCm.
Registration requirements of pCm	
<ul style="list-style-type: none"> • Hong Kong Chinese Meridian Ligamentous Chinese Medical Research Institute • Hong Kong SME Development Association • Modernized Chinese Medicine International Association Ltd. 	<ol style="list-style-type: none"> 1. Most operators in the trade are small manufacturers or self-employed CMPs. They have faced great difficulties, in terms of technical and financial viability, in proving the product safety, efficacy and quality when applying for registration of pCm. They also have great difficulties in complying with the requirements of quality and efficacy even when the pCm concerned have obtained transitional registration. The

Organization / individual	Major views and concerns
<ul style="list-style-type: none"> • Po Che Tong Poon Mo Un • Yuen Kut Lam Compant Ltd. 	<p>deputations consider that the current requirements for registration are too stringent. The regulatory system for Chinese medicines has not taken into account the substantial differences between Chinese medicines and Western medicines nor the past practice of the trade. In view of the difficulties involved in meeting the registration requirements, some operators decide not to apply for the registration of their pCm. In the long run, this would threaten the survival of local small to medium-sized pCm manufacturers.</p> <p>2. While noting that the Ordinance has provided a transitional registration for pCm manufactured or sold in Hong Kong on 1 March 1999, it is difficult for some Chinese medicine traders to provide documentary proofs to show that the pCm under application was, on 1 March 1999, manufactured, sold or supplied for sale in Hong Kong. They point out that it is quite common for the trade not to disclose the full and complete information of the master formula in the sales pack of pCm in order to avoid being replicated. As a result, they have to apply for non-transitional registration.</p>
Inadequate laboratory support in testing of pCm	
<ul style="list-style-type: none"> • The Hong Kong Association of Traditional Chinese Medicine Ltd. • Hong Kong Composite Materials and Technology Association • Hong Kong Pharmaceutical Manufacturers Association • Po Che Tong Poon Mo Un • 國際中醫藥研究學院 	<p>1. The deputations express grave concern about the inadequate laboratory support in Hong Kong. There is 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. Consideration should also be given to providing laboratory support to the trade through Government laboratories.</p>
Mandatory registration of pCm	
<ul style="list-style-type: none"> • Glory-In Chinese Medical Co. Ltd. 	<p>1. There is a view that mandatory registration should not be applied to concentrated pCm which are formulated according to ancient prescriptions and prescribed by CMPs. The deputation suggests that pCm for sale to the general public and pCm sold under prescription should be subject to a separate regulatory framework.</p>

Organization / individual	Major views and concerns
	<p>2. According to the Ordinance, a pCm which is compounded by or under the supervision of a listed or registered CMP at the premises where he practises can be exempted from registration if, and only if, such pCm is being used to a patient under his direct care. The deputation requests the Administration to consider extending such exemption to all patients under the direct care of listed or registered CMPs, as the same compounded pCm could be administered or supplied to a number of patients with similar medical needs.</p> <p>3. Consideration should also be given to extending the exemption to pCm compounded by licensed pCm manufacturers in accordance with prescription given by CMPs.</p>
Requirements of labels and package inserts	
<ul style="list-style-type: none"> • Hong Kong SME Development Association 	<p>1. Pointing out that imported pCm for the purpose of re-export can be exempted from the requirements of label and package inserts under the Regulation, the deputation urges the Administration to consider granting the same exemption to locally-produced pCm for the purpose of export.</p>
Regulation of Chinese medicine	
<ul style="list-style-type: none"> • Chinese Ancient Healings Medicines Conservation Association • Hong Kong Chinese Meridian Ligamentous Chinese Medical Research Institute • Modernized Chinese Medicine International Association Ltd. • Po Che Tong Poon Mo Un • 中國香港中醫急救協會 	<p>1. Given the characteristics and long history of Chinese medicines, the deputations consider it inappropriate to regulate Chinese medicines by adopting the Western medicines perspectives. They opine that the new regulatory system is not conducive to the development of Chinese medicines.</p> <p>2. The Government has proposed an initiative to introduce the standard of Good Manufacturing Practice ("GMP") in regulating Chinese medicines. Given the huge investment required, there is concern on the financial viability of the local small and medium-sized pCm manufacturers.</p>
Development of Chinese medicine	
<ul style="list-style-type: none"> • Chinese Ancient Healings Medicines Conservation Association • Pok Oi Hospital • South Natural Herbs Health Shop 	<p>1. The deputations make a number of suggestions with a view to fostering the development of Chinese medicines. The suggestions include setting up a new regulatory body to review and formulate policies regulating Chinese medicines, establishing a Chinese medicine hospital, training more CMPs, and setting up a fund</p>

Organization / individual	Major views and concerns
<ul style="list-style-type: none"> • Hong Kong Composite Materials and Technology Association • Hong Kong SME Development Association • Modernized Chinese Medicine International Association Ltd. 	<p>to support the local small and medium-sized pCm manufacturers.</p> <p>2. There is a lack of overall planning to support the development of Chinese medicines in Hong Kong. The Government should review the existing policy and formulate a long term strategy for the sustainable development of Chinese medicines and the training of CMPs and professionals in Chinese medicines.</p>
Others	
<ul style="list-style-type: none"> • Glory-In Chinese Medical Co. Ltd. 	<p>1. The deputation holds a view that some products, although containing Chinese herb, can still be regarded as food under certain circumstances. It urges the Administration to provide clearer definitions of and distinctions between food and pCm.</p>
<ul style="list-style-type: none"> • 國際中醫藥研究學院 	<p>1. In the deputation's view, members of the Chinese Medicine Council should be elected by the trade, so as to enhance the accountability of the Chinese Medicine Council and better reflect the views and interests of the trade in the formulation of policy and regulations on Chinese medicine.</p>
<ul style="list-style-type: none"> • Hong Kong Composite Materials and Technology Association • Hong Kong Wah Ha Medicine Association • Yuen Kut Lam Compant Ltd. • 國際中醫藥研究學院 	<p>1. The deputations request the Panel on Health Services to set up a subcommittee to review the mandatory registration of pCm and the policy regulating pCm.</p>

<u>Name of Organization / individual</u>	<u>Submission [LC Paper No.]</u>
Chinese Ancient Healings Medicines Conservation Association	LC Paper No. CB(2)776/10-11(17)
Glory-In Chinese Medical Co. Ltd.	LC Paper No. CB(2)1002/10-11(01)
The Hong Kong Association of Traditional Chinese Medicine Ltd.	LC Paper No. CB(2)1027/10-11(01)
Hong Kong Chinese Meridian Ligamentous Chinese Medical Research Institute	LC Paper No. CB(2)776/10-11(23)
Hong Kong Chinese Prepared Medicine Traders Association Limited	LC Paper No. CB(2)776/10-11(24)
Hong Kong Composite Materials and Technology Association	LC Paper No. CB(2)1054/10-11(02)
Hong Kong SME Development Association	LC Paper No. CB(2)1002/10-11(02)
Hong Kong Wah Ha Medicine Association	LC Paper No. CB(2)776/10-11(26)
Modernized Chinese Medicine International Association Limited	LC Paper No. CB(2)776/10-11(25)
Pok Oi Hospital	LC Paper No. CB(2)824/10-11(01)
Po Che Tong Poon Mo Um	LC Paper No. CB(2)776/10-11(18)
South Natural Herbs Health Shop	LC Paper No. CB(2)776/10-11(19)
Yuen Kut Lam Company Limited	LC Paper No. CB(2)776/10-11(21)
國際中醫藥研究學院	LC Paper No. CB(2)776/10-11(20)
中國香港中醫急救協會	LC Paper No. CB(2)776/10-11(22) LC Paper No. CB(2)1054/10-11(01) (<i>Further submission</i>)