

立法會
Legislative Council

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LC Paper No. CB(2)2420/10-11
(These minutes have been seen
by the Administration)

Panel on Health Services

**Minutes of special meeting
held on Monday, 17 January 2011, at 10:45 am
in the Chamber of the Legislative Council Building**

- Members present** : Dr Hon LEUNG Ka-lau (Chairman)
Dr Hon Joseph LEE Kok-long, SBS, JP (Deputy 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
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** : Hon Cyd HO Sau-lan
Hon CHEUNG Kwok-che
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 Grant NG Wai-kit
Senior Pharmacist (Traditional Chinese Medicine)
Department of Health

Attendance by invitation : Chinese Medicine Merchants Association Ltd.

Mr KONG Chun-hung

Tsz Yan Tong Chinese Medicine Limited

Mr CHAN Sau-kut

Po Sau Tong Ginseng & Antler Association Hong
Kong Limited

Mr Karl CHAN
Chairman of the Supervisory Committee

Kowloon Chamber of Commerce

Mr CHENG Kwan-suen
Chairman

The Hong Kong Medicine Dealers' Guild

Mr WONG Ping-ming
Chairman

New York U.S.A. Yee Hing Pak Fow Oil Mfy.

Mr CHEUNG Yin-chuen

濟世中醫專科學院

Mr LI Ying-fai

Hong Kong Chinese Patent Medicine Manufacturers'
Association Ltd.

Mr TSE Kwok-cheong
Chairman

Hong Kong Registered Chinese Medicine
Practitioners Association Limited

Mr CHAN Wing-kwong
Vice-Chairperson

The Society of Hong Kong Professional Registered
Chinese Medicine Practitioners Limited

Mr LAM Ching
Chairman

Worldwide Chinese Medicine Modernization Alliance

Mr WONG Chun-fai

International General Chinese Herbalists and
Medicine Professionals Association Ltd.

Mr LO Ting-yu

香港中醫眼科中心

Ms LI Kam-fung

Tam Kam Medicament Manufacturing Factory

Miss LI Tsui-man

China Society of Practitioners of Chinese Medicine
Limited

Mr LAW Dao-bong
Chairman

Hong Kong Chinese Medicine Practitioners' Rights
General Union

Mr YU Kwok-wai

Chinese New Medicine Treatment Centre Co. Ltd.

Mr LAM Shiu-wing
Director

香港中國中醫針灸研究院

Mr David LUI Kwong-lam

Hong Kong Chinese Medicine Industry Association Ltd.

Mr LI Ying-sang
Chairman

TG BIO-TECH (International) Ltd.

Mr Eric SHIH
Director

The Hong Kong Acupuncturists Federation Ltd.

Mr CHEUNG Ka-hong
Chairman

Po Wo Tong Pharmaceutical Ltd

Mr GAN Pei-tzeng

The Hong Kong Professional Institute of Chinese
Medicine Medicated Meal Food

Mr PANG Chi-nung
Director General

Hong Kong Yee Yee Tong Chinese Medicine
Merchants Association Ltd.

Mr CHAN Wing-suen
Chairman

Chinese Medicine Informatics (Hong Kong) Ltd.

Mr KWONG Ping-nam
Director

The Hong Kong Society of Chinese Medicines Ltd.

Mr TSUI Kam-chuen
President

Mr CHENG Ping-kwan
Listed Chinese Medicine Practitioner

Tsuen Fung Shan Jong Chinese Medicine

Mr KONG Ka-fung
Staff

Han-Fang Chinese Medicine Co. Ltd.

Ms TSE Choi-ying
Business Manager

Ms TUNG Tin-hung

Consumer Council

Ms Rosa WONG
Head, Research & Trade Practices Division

Mr HO Chi-fung

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

Staff in attendance : 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) to (16), CB(2)823/10-11(01) to (08) and CB(2)863/10-11(01) to (08))

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Attendance of the Administration

Mr Albert CHAN expressed grave dissatisfaction that neither the Secretary for Food and Health ("SFH"), the Under Secretary for Food and Health nor official from the Food and Health Bureau attended the meeting to receive views from deputations on the commencement of provisions related to proprietary Chinese medicines ("pCm") in the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance"). Dr Priscilla LEUNG also expressed deep regret with the non-attendance of SFH and the Under Secretary for Food and Health at the meeting. Mr LEUNG Yiu-chung considered that apart from bureau officials, representatives of the Chinese Medicine Council of Hong Kong ("CMC") should also attend the meeting to receive views from the trade. The Chairman sought clarification from the representatives of the Department of Health ("DH") whether they could speak on behalf of the Food and Health Bureau on the policy issues in relation to the mandatory registration of pCm.

2. Assistant Director (Traditional Chinese Medicine), DH ("AD(TCM), DH") stressed that the Administration attached great importance to the views of the trade on the subject of mandatory registration of pCm and had maintained communication with the trade in the legislative process. AD(TCM), DH further said that DH was responsible for implementing the registration of pCm and providing administrative and professional support to CMC. He was authorized by the Food and Health Bureau to explain the established policy and implementation details in relation to the registration regime in response to the views expressed by members and deputations attending the meeting.

3. The Chairman suggested and members agreed that SFH should be requested to attend the Panel's special meeting scheduled for 15 February 2011 to receive views from the other 22 deputations on the subject.

(Post-meeting note: The letter from the Chairman to SFH inviting him to the special meeting on 15 February 2011 and the Administration's reply were circulated to members vide LC Paper Nos. CB(2)1001/10-11 and CB(2)1055/10-11 on 11 and 17 February 2011 respectively.)

Views of deputations

4. At the invitation of the Chairman, the following 32 deputations presented their views on the commencement of the legislative provisions related to pCm -

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- (a) Chinese Medicine Merchants Association Ltd;
- (b) Tsz Yan Tong Chinese Medicine Limited;
- (c) Po Sau Tong Ginseng & Antler Association Hong Kong Limited;
- (d) Kowloon Chamber of Commerce;
- (e) The Hong Kong Medicine Dealers' Guild;
- (f) New York U.S.A. Yee Hing Pak Fow Oil Mfy.;
- (g) 濟世中醫專科學院;
- (h) Hong Kong Chinese Patent Medicine Manufacturers' Association Ltd.;
- (i) Hong Kong Registered Chinese Medicine Practitioners Association Limited;
- (j) The Society of Hong Kong Professional Registered Chinese Medicine Practitioners Limited;
- (k) Worldwide Chinese Medicine Modernization Alliance;
- (l) International General Chinese Herbalists and Medicine Professionals Association Ltd.;
- (m) 香港中醫眼科中心;
- (n) Tam Kam Medicament Manufacturing Factory;
- (o) China Society of Practitioners of Chinese Medicine Limited
- (p) Hong Kong Chinese Medicine Practitioners' Rights General Union;
- (q) Chinese New Medicine Treatment Centre Co. Ltd.;
- (r) 香港中國中醫針灸研究院;

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- (s) Hong Kong Chinese Medicine Industry Association Ltd.;
- (t) TG BIO-TECH (International) Ltd.;
- (u) The Hong Kong Acupuncturists Federation Ltd.;
- (v) Po Wo Tong Pharmaceutical Ltd.;
- (w) The Hong Kong Professional Institute of Chinese Medicine Medicated Meal Food;
- (x) Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Ltd.;
- (y) Chinese Medicine Informatics (Hong Kong) Ltd.;
- (z) The Hong Kong Society of Chinese Medicines Ltd.;
- (aa) Mr CHENG Ping-kwan;
- (ab) Tsuen Fung Shan Jong Chinese Medicine;
- (ac) Han-Fang Chinese Medicine Co. Ltd.;
- (ad) Ms TUNG Tin-hung;
- (ae) Consumer Council; and
- (af) Mr HO Chi-fung.

5. Members also noted the written submissions from the following organizations/individuals -

- (a) Shang Shan Medical Co.;
- (b) Mr YEUNG Wai-sing;
- (c) a member of the public; and
- (d) The Hong Kong Health Food Association.

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

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The Administration's response

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

- (a) the Administration was pleased to note that there was general support of the Chinese medicine trade for the mandatory registration of pCm, as its implementation was essential to safeguarding public health and consumer rights, as well as fostering the development of Chinese medicines in Hong Kong. Efforts had been and would continue to be made to maintain communication with the Chinese medicine trade to facilitate its understanding of the specific requirements on the product specification of pCm for the purpose of registration;
- (b) subsequent to the enactment of the Ordinance in July 1999, the Chinese Medicines Board ("CMB") under CMC had started to accept applications for registration of pCm since 19 December 2003. Over the past seven years, CMB and DH had made considerable efforts and carried out various activities, such as organizing briefing sessions, publication of the relevant requirements through newsletters and letters to all applicants for pCm registration, to prepare the Chinese medicine trade for the implementation of the mandatory registration of pCm. Regarding those applications for transitional registration of pCm which were rejected by CMB, the applicants had been informed that the products concerned would not be allowed for sale or import upon the commencement of section 119 of the Ordinance when being notified of the result of their applications;
- (c) the Panel had been advised of the Administration's plan to commence the legislative provisions relating to mandatory registration of pCm in 2010 when receiving the briefing from SFH on the 2009-2010 Policy Agenda on 16 October 2009. From late May to early July 2010, DH had held seven briefing sessions for the major trade associations to collect feedback of the trade/stakeholders on the subject. Chinese medicine students in tertiary education institutions had also been employed as ambassadors to promote to the Chinese medicine traders and listed sellers of poisons and dispensaries the statutory requirements relating to the selling

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of pCm. In addition, publicity programmes through the mass media and the Consumer Council were launched nearer the time of the commencement of the mandatory registration to raise public awareness in this regard. Given that the trade and the public should be well aware of the commencement of the provisions on 3 December 2010, the Administration did not see the need to suspend the implementation of the legislative provisions;

- (d) according to section 158(6) of the Ordinance, a pCm which was compounded by or under the supervision of a registered Chinese medicine practitioner ("CMP") or a listed CMP at the premises where he practised could be exempted from registration if, and only if, such pCm was being used for the purpose of administering or supplying to a patient under his/her direct care. CMB and DH had held a number of briefing sessions from 2000 to 2003 for CMPs to explain the implications of the mandatory registration of pCm including the above exemption requirement. The information was also published in the Newsletter from the Chinese Medicine Practitioners Board which was distributed to all CMPs;
- (e) details of the registration requirements including the requirement of excipient and definition of health-preserving medicines had been set out in the Application Handbook for Registration of pCm published by CMC in 2004. In case of doubt, deputations were welcomed to provide after the meeting details of individual cases for DH to follow-up;
- (f) the requirements of label and package inserts of pCm in prescribed manners as set out under sections 143 and 144 of the Ordinance would be commenced on 1 December 2011 to allow the trade to have adequate time to comply with the requirements. In the meantime, CMB and DH had started communicating with applicants for pCm registration on whether the labels and package inserts of their products had complied with the statutory requirements. A whole range of publicity programmes, such as visits of student ambassadors to the traders, roving exhibitions, announcements of public interest, would also be launched by DH in the coming months to enhance the understanding of the trade and the public on the requirements on labelling and package inserts; and

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- (g) former rejected cases for registration of pCm which had subsequently submitted the three acceptable basic test reports (i.e. test reports on heavy metals and toxic element, pesticide residues and microbial limit) would be further processed by CMB. When pCm's safety, quality and efficacy had been proven to the satisfactory of CMB, the product would be approved for registration.

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

Discussion

Registration regime for pCm

8. Mr Albert CHAN considered 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 medicines, which was formulated and implemented by officials trained in Western medicines, had failed to take into account these differences.

9. AD(TCM), DH advised that CMC was established under the Ordinance to, among others, develop and implement the regulatory measures on Chinese medicines in Hong Kong. The existing regulatory regime implemented by CMC, the membership of which comprised, among others, CMPs and representatives from the trade of Chinese medicines, emphasized self-regulation by the trade.

10. The Chairman urged the Administration to allay the concerns of deputations that there were currently no elected representatives from the Chinese medicine trade in CMC.

Implementation of section 119 of the Ordinance

11. Mr Albert HO expressed concern about the long time required by CMB to vet the applications for pCm registration. Taking into account the fact that quite a lot of pCm were already on sale and in frequent use for quite a long period of time, Mr HO asked whether the Administration would accede to the request of the deputations for suspending the implementation of section 119 of the Ordinance for one year to give more time for the traders to comply with the registration requirements.

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12. AD(TCM), DH advised that the progress of the commencement of the legislative provisions was smooth. Since the commencement of the legislative provisions on 3 December 2010, about six surprise inspections to Chinese medicine traders were conducted by DH per day and no violation of regulation for selling unregistered pCm had been found so far. Ms Audrey EU disagreed with the view that the commencement of the legislative provisions was smooth. She considered that quite a number of problems arising from the implementation of the registration regime as pointed out by the deputations attending the meeting would need to be resolved.

13. On the processing time of applications for registration of pCm, AD(TCM), DH advised that given that Chinese medicines had a long history, there was a certain degree of complexity in processing individual applications. On average, more than 60% of applications were vetted two to five times. In some cases, applicants were required to provide supplementary information for their applications in the vetting process. AD(TCM), DH further said that for more than half of the cases, applicants still failed to furnish the requisite information despite the issuance of three rounds of reminders.

14. Dr Priscilla LEUNG pointed out that many pCm which were formulated according to well-known prescriptions and had been in frequent use by the public for years had failed the registration assessment due to the applicants' inability to provide the required information. Dr LEUNG asked whether DH could exercise flexibility in enforcement so that these pCm would continue to be made available to the public.

15. AD(TCM), DH replied in the negative, pointing out that the full implementation of the statutory requirement for mandatory registration of pCm was essential to safeguarding public health. He further advised that among the 5 800 applications which were rejected for registration due to failure to furnish sufficient information, more than 4 000 cases had failed to submit the three acceptable basic test reports.

16. Noting that some pCm had already been granted approval for transitional registration or registration, Ms Audrey EU held the view that it would be difficult for the Administration to either suspend the implementation of section 119 under the Ordinance or adopt a flexible approach in enforcement as this would be at variance with the principle of ensuring a level playing field for all pCm traders. Ms EU considered that a better approach was to create a new category of pCm which had been in use for many years but failed to comply with the requirements of the

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three acceptable basic test reports. The continued sale of such pCm would be allowed on the condition that such information was specified on their sales pack to provide a wider choice to the public.

17. AD(TCM), DH advised that at present, those applications for transitional registration in respect of which documentary proofs showing that the pCm under application was, on 1 March 1999, manufactured, sold or supplied for sale in Hong Kong by the applicant would be issued with the "Notice of confirmation of transitional registration of pCm". For applications of non-transitional registration in respect of which three acceptable basic test reports had been submitted, CMB would issue a "Notice of confirmation of (non-transitional) registration application of pCm". All these pCm were allowed to continue to be sold in Hong Kong, 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.

18. Dr PAN Pey-chyou pointed out the difficulties of some Chinese medicine 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. In the light of this, the Administration should exercise some degrees of flexibility in assessing the eligibility of these pCm for transitional registration.

19. Mr LEUNG Yiu-chung urged the Administration to face squarely the concerns raised by the deputations about the lack of transparency and objectivity of the assessment criteria and procedure for the registration of pCm. AD(TCM), DH reiterated that efforts had been and would continue to be made to maintain communication with the trade.

Assistance to pCm traders

20. Dr Priscilla LEUNG expressed concern that many small and medium-sized pCm traders had difficulties, in terms of technical and financial viability, in proving the product's safety, efficacy and quality when applying for registration of pCm. She asked the Administration whether consideration could be given to providing assistance to the trade in meeting the testing requirements for the purpose of registration of pCm. Dr PAN Pey-chyou raised a similar concern.

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21. AD(TCM), DH advised that in line with international practice, the primary responsibility fell on the pCm manufacturers to ensure that the products they produced were safe, efficacious and of good quality by means of laboratory testing. The fee of testing would have to be borne by the manufacturers. The Chairman requested the Administration to provide information on the number of applications for registration of pCm which had met the safety and/or quality requirements but were rejected for registration due to their failure to comply with the efficacy requirements at the next special meeting of the Panel on 15 February 2011.

Way forward

22. Ms Audrey EU proposed to appoint a subcommittee under the Panel to follow up the subject of mandatory registration of pCm. The Chairman said that the Panel would further discuss the proposal at the next regular meeting on 14 February 2011.

23. To facilitate members' further consideration of the subject at the next special meeting on 15 February 2011, Mr Albert CHAN requested the Research Division of the Legislative Council Secretariat to provide information on the registration of pCm in Macao, Taiwan and the Mainland, particularly relating to how these places addressed the major concerns raised by the attending deputations.

24. There being no other business, the meeting ended at 1:10 pm.

Council Business Division 2
Legislative Council Secretariat
19 July 2011

Panel on Health Services

Special meeting on Monday, 17 January 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"> • Chinese Medicine Merchants Association Ltd. • Consumer Council • Hong Kong Chinese Medicine Industry Association Ltd. • Hong Kong Chinese Patent Medicine Manufacturers' Association Ltd. • Hong Kong Registered Chinese Medicine Practitioners Association Ltd. • Po Sau Tong Ginseng & Antler Association Hong Kong Ltd. • Po Wo Tong Pharmaceutical Ltd. • Mr YEUNG Wai-sing, Eastern District Council Member 	<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") and the requirements of label and package inserts in the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") and the Chinese Medicines Regulation (Cap. 549F) ("the Regulation") in December 2010 and December 2011 respectively. They consider that the regulatory regime could help safeguard public health and consumer rights, enhance the safety of pCm and public confidence in the usage of pCm as well as foster the further development of Chinese medicines. 2. Pointing out that the registration of pCm has started to commence since 2003, the deputations consider that the Chinese medicine trade should be well aware of and prepared for the enforcement of mandatory registration. Nevertheless, the deputations request the Administration to strengthen communication with the trade concerning the legislative and testing requirements for the registration of pCm.
<ul style="list-style-type: none"> • Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Ltd. 	<ol style="list-style-type: none"> 1. The deputation expresses support for the implementation of mandatory registration of pCm in December 2010. It considers that the requirement for mandatory registration of pCm could help safeguard public health and consumer rights, as well as enhance the safety of pCm in the long run. 2. As regards the requirements of label and package inserts, the deputation holds the view that the relevant provisions should be commenced one year after the Administration has completed the vetting process of the label and package inserts of pCm, so that the trade would have sufficient time to replace labels and inserts for their products.

Organization / individual	Major views and concerns
<ul style="list-style-type: none"> • Chinese Medicine Informatics (Hong Kong) Ltd. • Chinese Society of Practitioners of Chinese Medicine Ltd. • Chinese New Medicine Treatment Centre Co. Ltd. • The Hong Kong Acupuncturists Federation Ltd • Han-Fan Chinese Medicine Co Ltd. • Hong Kong Chinese Medicine Practitioners' Rights General Union • The Hong Kong Medicine Dealers' Guild • The Hong Kong Professional Institute of Chinese Medicine Medicated Meal & Food • The Hong Kong Society of Chinese Medicine Ltd. • International General Chinese Herbalists and Medicine Professionals Association Ltd. • Kowloon Chamber of Commerce • New York U.S.A. Yee Hing Pak Fow Oil Mfy • The Society of Hong Kong Professional Registered Chinese Medicine Practitioners Ltd • Tam Kam Medicament Manufacturing Factory • TG BIO-TECH (International) Ltd. • Tsz Yan Tong Chinese Medicine Manufacturing Co. • Worldwide Chinese Medicine Modernization Alliance • 香港中國中醫針灸研究院 • 香港中醫眼科中心 • 濟世中醫專科學院 • Mr CHENG Ping-kwan • Mr HO Chi-fung 	<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. In their view, government consultation and communication with the trade are inadequate; the trade has not fully understood the legislative requirements; and there is a lack of government support for assisting the trade in complying with the requirements. 2. The deputations also consider that the mandatory registration of pCm would threaten the survival of local pCm manufacturers who are mainly small- to medium-sized firms. They strongly urge the Administration to defer the implementation of the relevant provisions and provide a transition period, say one year, for the trade to register their pCm, and to print and replace the labels and package inserts. There is a suggestion that pCm which have passed the three basic tests of heavy metals and toxic element, pesticide residues and microbial limit should be allowed to continue to be sold in Hong Kong during the transition period. 3. The deputations also propose that provisions relating to the requirements of label and package inserts should only be commenced when the vetting of label and package inserts of pCm has been completed by the relevant authority. 4. Noting the excessively high cost involved in the registration of pCm, some Chinese medicine practitioners ("CMP") are worried that under the new regulatory regime, some pCm they have been using would no longer be available as the Chinese medicine traders might not be willing to incur the high registration cost for these products.
Registration procedure of pCm	
<ul style="list-style-type: none"> • Chinese Medicine Informatics (Hong Kong) Ltd. • Chinese Medicine Merchants Association Ltd. • Chinese New Medicine Treatment Centre Co. Ltd. • Hong Kong Chinese Medicine Practitioners' Rights General Union • The Hong Kong Society of Chinese Medicine Ltd. • International General Chinese Herbalists and Medicine 	<ol style="list-style-type: none"> 1. The deputations urge the Chinese Medicines Board ("CMB") and the Department Health ("DH") who provides administrative support to CMB 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. There is also a view that pCm should be deemed to have registered in accordance with the Ordinance if their three basic test reports on heavy metals and toxic element, pesticide residues and microbial limit have been submitted to the relevant authority.

Organization / individual	Major views and concerns
Professionals Association Ltd. <ul style="list-style-type: none"> • Tam Kam Medicament Manufacturing Factory • TG BIO-TECH (International) Ltd. • Tsuen Fung Shan Jong Chinese Medicine • Tsz Yan Tong Chinese Medicine Manufacturing Co. • Ms TUNG Tin-hung • A member of the public 	<ol style="list-style-type: none"> 2. The deputations express discontent with the lack of transparency and the slow processing of the registration applications of pCm. Some deputations point out that applicants are not provided with sufficient time to supply additional information or test reports since CMB and DH have taken a long time to process their applications. They urge CMB and DH to provide performance pledges for the processing of applications of registration.
Registration requirements of pCm	
<ul style="list-style-type: none"> • Chinese medicine Informatics (Hong Kong) Ltd. • The Hong Kong Health Food Association • The Hong Kong Medicine Dealers' Guild • The Hong Kong Professional Institute of Chinese Medicine Medicated Meal & Food • The Hong Kong Society of Chinese Medicine Ltd. • New York U.S.A. Yee Hing Pak Fow Oil Mfy • Shang Shan Medical Co. • TG BIO-TECH (International) Ltd. • Ms TUNG Tin-hung • Mr YEUNG Wai-sing, Eastern District Council Member 	<ol style="list-style-type: none"> 1. The deputations express great difficulties, in terms of technical and financial viability, in proving the product safety, efficacy and quality when applying for registration of pCm. They opine that the requirements for registration are too stringent. There are substantial differences between Chinese medicines and Western medicines, but the existing regulatory system for Chinese medicines fails to take into account these differences as well as the past practice of the trade. 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. 3. In assessing the registration applications, due regard should be given to those pCm which have already been registered in the Mainland and/or Taiwan.
Inadequate laboratory support	
<ul style="list-style-type: none"> • Chinese Medicine Informatics (Hong Kong) Ltd. • Hong Kong Chinese Medicine Practitioners' Rights General Union • The Hong Kong Professional Institute of Chinese Medicine Medicated Meal & Food • The Hong Kong Society of Chinese Medicine Ltd. 	<ol style="list-style-type: none"> 1. The deputations express grave concern about the inadequate laboratory support in Hong Kong. Some traders have to use the laboratory services in the Mainland. Owing to the different laboratory testing standards between Hong Kong and the Mainland, some test reports certified by the laboratories in the Mainland might not be able to satisfy the requirements of CMB, hence causing delay and incurring greater costs in the application process.

Organization / individual	Major views and concerns
<ul style="list-style-type: none"> • International General Chinese Herbalists and Medicine Professionals Association Ltd. • Tsuen Fung Shan Jong Chinese Medicine • 香港中醫眼科中心 • Ms TUNG Tin-hung 	<ol style="list-style-type: none"> 2. 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.
Mandatory registration of pCm	
<ul style="list-style-type: none"> • Han-Fan Chinese Medicine Co Ltd. • The Hong Kong Acupuncturists Federation Ltd • Hong Kong Chinese Medicine Practitioners' Rights General Union • The Society of Hong Kong Professional Registered Chinese Medicine Practitioners Ltd 	<ol style="list-style-type: none"> 1. 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 deputations request 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. 2. 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 deputations suggest that pCm for sale to the general public and pCm sold under prescription should be subject to a separate regulatory framework.
Requirements of labels and package inserts	
<ul style="list-style-type: none"> • Chinese Medicine Merchants Association Ltd. • Chinese Medicine Informatics (Hong Kong) Ltd. • Hong Kong Chinese Patent Medicine Manufacturers' Association Ltd. • The Hong Kong Medicine Dealers' Guild • The Hong Kong Society of Chinese Medicine Ltd. • Kowloon Chamber of Commerce • Tsuen Fung Shan Jong Chinese Medicine • Worldwide Chinese Medicine Modernization Alliance • Ms TUNG Tin-hung 	<ol style="list-style-type: none"> 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 deputations urge the Administration to consider granting the same exemption to locally-produced pCm for the purpose of export to ensure fairness in trade. Moreover, the local requirements for labels and package inserts may not be the same as those of the exporting countries, requiring the trade to comply with both sets of requirements would only have adverse impact on the trade.
Possession of pCm	
<ul style="list-style-type: none"> • The Chinese Medicine Informatics (Hong Kong) Ltd. • Chinese Society of Practitioners of Chinese Medicine Ltd. 	<ol style="list-style-type: none"> 1. With the commencement of the mandatory registration of pCm, the sale, import or possession of unregistered pCm is an offence. To prevent the general public from

Organization / individual	Major views and concerns
<ul style="list-style-type: none"> • Hong Kong Chinese Medicine Practitioners' Rights General Union • The Hong Kong Society of Chinese Medicine Ltd. • The Society of Hong Kong Professional Registered Chinese Medicine Practitioners Ltd • Worldwide Chinese Medicine Modernization Alliance 	<p>breaking the law unknowingly by purchasing unregistered pCm, it is suggested that the definition of "possession of pCm" in section 119 of the Ordinance should be amended as "possession for the purpose of sale".</p>
Regulation and development of Chinese medicines	
<ul style="list-style-type: none"> • Chinese New Medicine Treatment Centre Co. Ltd. • Chinese Medicine Informatics (Hong Kong) Ltd. • The Hong Kong Acupuncturists Federation Ltd • Hong Kong Chinese Medicine Practitioners' Rights General Union • The Hong Kong Health Food Association • The Hong Kong Medicine Dealers' Guild • The Hong Kong Professional Institute of Chinese Medicine Medicated Meal & Food • The Society of Hong Kong Professional Registered Chinese Medicine Practitioners Ltd • TG BIO-TECH (International) Ltd. • Worldwide Chinese Medicine Modernization Alliance • 濟世中醫專科學院 	<ol style="list-style-type: none"> 1. Given the characteristics and long history of Chinese medicines, it is inappropriate to regulate Chinese medicines by adopting the Western medicines perspectives. The deputations call for a review of the existing regulation system of pCm, as well as greater involvement of Chinese medicine experts in the formulation of the regulatory policy and framework. A new regulatory body should also be set up to review and formulate the policy for the development of Chinese medicines. 2. Other suggestions are proposed for the further development of Chinese medicines. They include setting up of a Chinese medicine hospital and revitalizing old industrial buildings to support the local pCm manufacturing industry.
Others	
<ul style="list-style-type: none"> • Han-Fan Chinese Medicine Co Ltd. 	<ol style="list-style-type: none"> 1. The deputation holds the view that some products, although containing Chinese herb, can still be regarded as food under certain circumstances. They request the Administration to provide clearer definitions of and distinctions between food and pCm.
<ul style="list-style-type: none"> • Hong Kong Chinese Medicine Practitioners' Rights General Union • Mr CHENG Ping-kwan 	<ol style="list-style-type: none"> 1. The number of representatives from the trade in the Chinese Medicine Council should be increased in order to reflect their views in the Council. There is also a suggestion that members of the Chinese Medicine Council should be elected by the trade.

<u>Name of Organization / individual</u>	<u>Submission [LC Paper No.]</u>
China Society of Practitioners of Chinese Medicine Limited	LC Paper No. CB(2)776/10-11(10)
Chinese Medicine Informatics (Hong Kong) Ltd.	LC Paper No. CB(2)863/10-11(08)
Chinese Medicine Merchants Association Ltd.	LC Paper No. CB(2)863/10-11(01)
Consumer Council	LC Paper No. CB(2)823/10-11(08)
Han-Fang Chinese Medicine Co. Ltd.	LC Paper No. CB(2)823/10-11(06)
The Hong Kong Acupuncturists Federation Ltd.	LC Paper No. CB(2)863/10-11(06)
Hong Kong Chinese Medicine Industry Association Ltd.	LC Paper No. CB(2)776/10-11(12)
Hong Kong Chinese Medicine Practitioners' Rights General Union	LC Paper No. CB(2)776/10-11(11)
Hong Kong Chinese Patent Medicine Manufacturers' Association Ltd	LC Paper No. CB(2)776/10-11(05)
The Hong Kong Health Food Association	LC Paper No. CB(2)776/10-11(16)
The Hong Kong Medicine Dealers' Guild	LC Paper No. CB(2)863/10-11(03)
The Hong Kong Professional Institute of Chinese Medicine Medicated Meal & Food	LC Paper No. CB(2)863/10-11(07)
Hong Kong Registered Chinese Medicine Practitioners Association Limited	LC Paper No. CB(2)823/10-11(02)
The Hong Kong Society of Chinese Medicines Ltd.	LC Paper No. CB(2)823/10-11(04)
Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Ltd.	LC Paper No. CB(2)823/10-11(03)
International General Chinese Herbalists and Medicine Professionals Association Ltd.	LC Paper No. CB(2)776/10-11(07)
Kowloon Chamber of Commerce	LC Paper No. CB(2)863/10-11(02)
New York U.S.A. Yee Hing Pak Fow Oil Mfy.	LC Paper No. CB(2)776/10-11(04)
Shang Shan Medical Co.	LC Paper No. CB(2)776/10-11(13)
The Society of Hong Kong Professional Registered Chinese Medicine Practitioners Limited	LC Paper No. CB(2)776/10-11(06)
Tam Kam Medicament Manufacturing Factory	LC Paper No. CB(2)776/10-11(09)
TG BIO-TECH (International) Ltd.	LC Paper No. CB(2)863/10-11(05)
Tsuen Fung Shan Jong Chinese Medicine	LC Paper No. CB(2)823/10-11(05)

Name of Organization / individual

Tsz Yan Tong Chinese Medicine Limited

Worldwide Chinese Medicine Modernization Alliance

香港中醫眼科中心

濟世中醫專科學院

Ms TUNG Tin-hung

Mr YEUNG Wai-sing, Eastern District Council Member

A member of the public

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LC Paper No. CB(2)776/10-11(08)

LC Paper No. CB(2)823/10-11(01)

LC Paper No. CB(2)823/10-11(07)

LC Paper No. CB(2)776/10-11(14)

LC Paper No. CB(2)776/10-11(15)

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