立法會
Legislative Council

LC Paper No. CB(2)2376/09-10
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Panel on Health Services

Minutes of meeting
held on Monday, 12 July 2010, at 8:30 am
in Conference Room A of the Legislative Council Building

Members present	:	Dr Hon Joseph LEE Kok-long, SBS, JP (Chairman) Dr Hon LEUNG Ka-lau (Deputy Chairman) Hon Albert HO Chun-yan Hon Fred LI Wah-ming, SBS, JP Hon CHEUNG Man-kwong Hon Andrew CHENG Kar-foo Hon Audrey EU Yuet-mee, SC, JP Hon Cyd HO Sau-lan Hon CHAN Kin-por, JP Hon CHEUNG Kwok-che Hon IP Kwok-him, GBS, JP Dr Hon PAN Pey-chyou Hon Alan LEUNG Kah-kit, SC
Member attending	:	Dr Hon Priscilla LEUNG Mei-fun
Members absent	:	Hon CHAN Hak-kan Hon Albert CHAN Wai-yip
Public Officers attending	:	Items II, III and IV Professor Gabriel M LEUNG, JP Under Secretary for Food and Health Items II and IV Dr Cindy LAI, JP Acting Deputy Director of Health

Item II only

Mr Thomas CHAN, JP
Deputy Secretary for Food and Health (Health) 2

Mr Bruno LUK
Principal Assistant Secretary for Food & Health (Health) 3

Item III only

Dr Amy CHIU
Assistant Director of Health (Traditional Chinese Medicine)

Items III and IV

Ms Shirley LAM
Principal Assistant Secretary for Food and Health (Health)1

Clerk in attendance	:	Miss Mary SO Chief Council Secretary (2) 5
Staff in attendance	:	Ms Maisie LAM Senior Council Secretary (2) 6 Ms Sandy HAU Legislative Assistant (2) 5

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I. Information paper(s) issued since the last meeting
(LC Paper No. CB(2)1874/09-10(01))

Members did not raise any queries on the Administration's reply dated 18 June 2010 to Hong Kong Doctors Union and The Practising Pharmacists Association of Hong Kong regarding the treatment provided by the Hospital Authority for wet aged-related macular degeneration patients.

II. Healthcare Service Reform - Primary Care Development Strategy
(LC Paper No. CB(2)1995/09-10(01))

2. Under Secretary for Food and Health ("USFH") briefed members on the latest progress of the primary care development strategy formulated based on the advice and recommendations of the Working Group on Primary Care ("WGPC"), details of which were set out in the Administration's paper (LC Paper No. CB(2)1995/09-10(01)). Principal Assistant Secretary for Food & Health (Health)3 then conducted a powerpoint presentation on the details of the three major areas of work for the

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development of better primary care services in Hong Kong as set out in the powerpoint materials (LC Paper No. CB(2)2053/09-10(01)) tabled at the meeting.

3. Whilst expressing support for the primary care development strategy, Mr CHAN Kin-por was of the view that the Administration should further enhance the primary care services for the elders. In particular, measures should be put in place to assist elders who had difficulty to use the telephone appointment service of the public general out-patient clinics ("GOPCs") and shorten the waiting time for the Elderly Health Centres ("EHCs"), which currently stood at about three years. Noting from paragraph 6.10 of the latest working version of the strategy document on primary care development ("the strategy document"), which was in the Appendix to the Administration's paper, that the Government had earmarked resources to support the development of pilot projects to, inter alia, improve dental care services of the needy elderly, Mr CHAN asked about the timetable for introducing the pilot projects.

4. Mr CHEUNG Kwok-che criticised the Administration for failing to provide any concrete information in the strategy document on how the strategies to strengthen primary care in Hong Kong would truly benefit the public in the primary care setting, such as shortening the waiting time for EHCs and providing comprehensive primary dental services for the needy elderly.

5. USFH responded as follows -

(a) enhancing primary care was one of the proposals put forward in the Healthcare Reform Consultation Document "Your Health, Your Life" and received broad public support during the first stage public consultation conducted in March to June 2008. To take forward the initiative, WGPC had formulated a set of initial recommendations in 2009 for the development of better primary care services in Hong Kong through three main areas of work, i.e. development of primary care conceptual models and clinical protocols, development of a Primary Care Directory, and development of primary care service delivery models;

(b) the telephone appointment service was introduced by the Hospital Authority ("HA") in response to public demand for improving the crowded queuing conditions in GOPCs, with a view to saving patients with episodic illnesses the trouble from having to queue outside the clinic early in the morning, and making it easier for them to select their desired consultation timeslot and clinic. Having regard to some patients' need, some community organisations and social workers had been providing assistance to people who needed help in using the telephone appointment service. HA would also regularly review the operating mode of the telephone appointment system and consider introducing enhancement measures accordingly;

(c) the Department of Health ("DH") currently provided comprehensive primary care services, including health assessment, physical check-up, health education, individual counselling and curative treatment, to elders aged 65 or above through 18 EHCs in the territory. While the services

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provided by EHCs had been well received by the elders since their establishment, it should be pointed out that EHCs were not the only providers of primary care services for elders. At present, more than 80% of primary care services were provided by the private sector. With the launch of the Elderly Healthcare Voucher Pilot Scheme in January 2009, elders aged 70 or above were provided with five health care vouchers of $50 each annually to partially subsidise their use of private primary care services; and

(d) the Administration was in discussion with the dental professionals, including the Hong Kong Dental Association, to work out suitable programmes to enhance primary dental care, especially for the elderly in need. Details of the programmes would be announced by end of 2010.

6. Mr CHEUNG Man-kwong noted from paragraph 8 of the Administration's paper that an additional funding of more than $2.9 billion had been earmarked for the period 2009-2010 to 2012-2013 to implement various initiatives in line with the primary care development strategy. He was concerned about whether a considerable portion of the resources would be used on the development of the territory-wide electronic health record ("eHR") and staff cost of the Primary Care Office ("PCO"), whereas only a small percentage would be used in improving primary care services that directly benefit patients. Mr Andrew CHENG and Dr PAN Pey-chyou raised similar concern, and remarked that the benefits to be brought about by eHR, the primary care conceptual models and clinical protocols, as well as the Primary Care Directory to patients, if realised, were at best remote.

7. Dr LEUNG Ka-lau questioned the need for developing primary care conceptual model and clinical protocols, which in his view, would only serve as reference for private doctors participating in the Public-Private Chronic Disease Management Shared Care Programme in understanding the treatment provided by HA. Given that the public would usually choose the network doctors of their medical insurance schemes or neighbouring private doctors in the vicinity of their residence or working place, he further cast doubt on the need for setting up a Primary Care Directory to cover details of all primary care providers in the territory.

8. USFH responded as follows -

(a) the eHR sharing system would provide the essential infrastructural support on sharing patients' health records with patients' consent between different levels of care and between the public and private sectors. This would facilitate the provision of comprehensive, continuing and co-ordinated healthcare services in Hong Kong. It should be noted that the funding of some $2.9 billion earmarked for a series of initiatives to enhance primary care for the period 2009-2010 to 2012-2013 did not include the budget for implementing the First Stage eHR Programme (from 2009-2010 to 2013-2014), which was covered by separate funding;

(b) given that more than 80% of primary care services in Hong Kong were currently provided by the private sector, the implementation and

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monitoring of various initiatives to enhance primary care involved much co-ordination work which needed to be undertaken by a dedicated office. About $32 million would be used on staff cost of PCO for the period 2010-2011 to 2012-2013, which would only constitute less than 1% of the funding of some $2.9 billion;

(c) the primary care conceptual models and clinical protocols for chronic diseases and age-specific/sex-specific health problems would not only provide the public as well as the healthcare professionals in both the public and private sectors with a framework on what a comprehensive range of primary care services should cover, but also provide common reference to guide and co-ordinate the efforts of healthcare professionals across different sectors for the provision of continuing, comprehensive and evidence-based care for managing common chronic diseases in the primary care setting. The conceptual models and clinical protocols would also empower patients and their carers and raise the public's awareness on the importance of preventing and properly managing the major chronic diseases. It should be noted that clinical protocols were widely used internationally in different health systems, including that of the United States; and

(d) the development of a Primary Care Directory containing practice-based information of primary care professionals of various disciplines in the community was supported by patients and primary care practitioners. It was expected that the Directory would provide patients with adequate information to help them choose their primary care providers in the community on the one hand, and on the other hand facilitate the co-ordination among different primary care providers functioning as multi-disciplinary teams.

9. Mr CHEUNG Man-kwong requested a breakdown of the funding of some $2.9 billion earmarked for the various initiatives for the period 2009-2010 and 2012-2013 in writing; as well as the timetable, the priority accorded and resources allocated by the Administration for the implementation of each of the eight major strategies and the nine initiatives/pilot projects to enhance primary care in Hong Kong, and the six areas that required further development as set out in Box 3, Table 1 and Chapter 7 of the strategy document respectively, for without which the strategies were merely slogans.

10. USFH explained that based upon the advice of WGPC and taking reference from international experience, the eight major strategies set out in Box 3 of the strategy document targeted at improving the attributes of a good primary care system, supported by a well-equipped primary care workforce and built-in infrastructure. While it would be practically difficult to specify the timeframe, priority accorded to and resources allocated for the implementation of each strategy, the initiatives/pilot projects set out in Table 1 of the strategy document were the specific measures in the pipeline to take forward these strategies to enhance primary care in Hong Kong.

11. In response to Dr LEUNG Ka-lau's enquiry on the scope and definition of the term "primary care" under the overall strategy for primary care development in Hong

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Kong, USFH said that the range of services covered by "primary care" was set out in paragraph 1.2 of the strategy document. The strategy document focused more on the enhancement of the provision of primary medical care which mainly referred to the provision of first contact healthcare services by doctors and other healthcare professionals.

12. Dr LEUNG remarked that many chronic disease patients would prefer to be followed up in the public healthcare system, even if they had a regular private primary care doctor. However, the subsidies provided under the Elderly Healthcare Voucher Pilot Scheme and the Public-Private Chronic Disease Management Shared Care Programme were far from adequate to provide an incentive to patients to receive care in the private sector, so as to relieve the existing problem of over-reliance on the public healthcare system. He asked about the unit cost per attendance of chronic disease patients at public clinics.

13. USFH responded that the unit cost per attendance of chronic disease patients would depend on whether the patient was receiving treatment at the public GOPCs or specialist out-patient clinics and the drugs prescribed.

14. Mr CHEUNG Kwok-che was concerned about the lack of representation of the patient groups in WGPC and its Task Forces.

15. USFH advised that the Vice-chairperson of the Alliance for Patients' Mutual Help Organizations, an umbrella organisation representing some 40 mutual support groups for patients with various chronic diseases, was a member of WGPC, the Task Force on Conceptual Model and Preventive Protocols and the Task Force on Primary Care Delivery Models. In addition, the Chief Executive of the Consumer Council was also a member of WGPC and the Task Force on Primary Care Delivery Models. USFH stressed that the representatives of the public and private healthcare sectors in WGPC were committed to seeing that the future development of primary care in Hong Kong was in the best interest of patients and the public.

16. Noting that the development of feasible service models to deliver enhanced primary care services in the community was recommended by WGPC as one of the three major areas of work for primary care development in Hong Kong, Mr Andrew CHENG asked how health promotion and disease prevention services, primary dental services for the elderly, as well as mental health services in the primary care setting would be enhanced.

17. USFH pointed out that the community health promotion and disease prevention services for various population sub-groups had been strengthened through different services under DH, including, inter alia, Family Health Service (for babies and young children from birth to five years of age and women at or below 64 years of age), Student Health Service and Elderly Health Service. When devising the feasible service delivery models to deliver enhanced primary care services in the community, consideration would be given to strengthening the health promotional function.

18. USFH further said that as mentioned earlier at the meeting, details of the programme to enhance primary dental care for the elderly in need would be

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announced by end of 2010. To strengthen the mental health services in the primary care setting, HA had set up Common Mental Disorder Clinics to provide patients with common mental disorders with more timely assessment and consultation services. HA would introduce a pilot Integrated Mental Health Programme at the Family Medicine Specialist Clinics and GOPCs in the second half of 2010-2011. Under the Programme, HA patients with stabilised and milder mental health conditions would be referred to the Family Medicine Specialist Clinics and GOPCs for further management by family medicine specialists and general practitioners working in multi-disciplinary teams.

19. Dr PAN Pey-chyou was of the view that the Administration should set down performance indicators/targets to measure the effectiveness of the reform initiatives.

20. Whilst expressing support for the development of primary care in Hong Kong, Ms Audrey EU echoed Dr PAN's view, and considered that the Administration should also assess the long-term demand for various primary care services for the next five and ten years and set out how the primary care system would be reformed to ensure an adequate supply of services to meet the estimated demand.

21. USFH responded that the Government would work with independent assessment bodies to measure the effectiveness of various reform initiatives. In addition, some macro indicators, such as life expectancy, could also be used to indirectly reflect the effectiveness of the development of primary care.

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22. In closing, the Chairman requested the Administration to provide after the meeting information on how the pilot projects to enhance primary care in Hong Kong would be evaluated as well as the resources earmarked for various primary care initiatives.

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

(LC Paper Nos. CB(2)1995/09-10(02) and (03), CB(2)1915/09-10(01) and (02), CB(2)2006/09-10(01), CB(2)2024/09-10(01), CB(2)2038/09-10(01) to (04) and CB(2)2503/09-10(02))

23. USFH briefed members on the Administration's plan to commence in phases from December 2010 the provisions in the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") and the Chinese Medicine Regulation (Cap. 549F) ("the Regulation") related to the mandatory registration of proprietary Chinese medicines ("pCm"), and the requirements of label and package inserts, details of which were set out in the Administration's paper (LC Paper No. CB(2)1995/09-10(02)). USFH then conducted a powerpoint presentation on the application procedures for registration of pCm as set out in the powerpoint material (LC Paper No. CB(2)2503/09-10(02)) tabled at the meeting.

24. Members noted the submissions from the following organisations -

(a) International General Chinese Herbalists and Medicine Professionals Association Ltd (LC Paper No. CB(2)2038/09-10(03));

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(b) Worldwide Chinese Medicine Modernization Alliance (LC Paper No. CB(2)2038/09-10(04));

(c) International General Chinese Herbalists and Medicine Professionals Association Ltd. (LC Paper No. CB(2)2024/09-10(01));

(d) The Hong Kong Society of Chinese Medicines (LC Paper No. CB(2)2006/09-10(01)); and

(e) Hong Kong Medicine Dealers' Guild (LC Paper Nos. CB(2)1915/09-10(01) and (02)).

25. Dr Priscilla LEUNG expressed concern that given the past practice that some sales pack of pCm might not contain full and complete information of the master formula to avoid being replicated, some applicants for transitional registration had difficulties to provide documentary proofs showing that the pCm under application was, on 1 March 1999, manufactured, sold or supplied for sale in Hong Kong, albeit that they had already spent several hundred thousand dollars to perform the heavy metals and toxic element test, the pesticide residues test and the microbial limit test and submitted the test reports to the Chinese Medicine Board ("CMB") as required. As such, their applications for transitional registration were rejected and they had to opt to apply for non-transitional registration. Some traders had reflected to her that they did not have sufficient time to furnish the required information, in particular documents to prove the efficacy of the pCm, in order to be issued with the certificate of registration of pCm before section 119 of the Ordinance came into effect in December 2010 that the sale, import or possession of unregistered pCm in Hong Kong would be an offence by then. In the light of this, Dr Priscilla LEUNG suggested inviting the trade to give views on the proposal to commence the relevant legislative provisions in December 2010.

26. USFH advised that CMB started to accept applications for registration of pCm since 19 December 2003 and applications for pCm registration under transitional arrangement were accepted up to end June 2004. In determining an application for registration of a pCm, CMB would consider the safety, quality and efficacy of the pCm concerned. The requirements included measures of heavy metal, pesticide, non-adulteration of western medicines and endangered species, toxicity and stability, etc. While the fee and time needed for testing the pCm varied from product to product, there should be no question of having insufficient time to prepare for the documents, as applicants could submit by phases the necessary test reports for non-transitional registration. A "Notice of confirmation of (non-transitional) registration application of pCm", which contained a serial number with the format of "HKNT-XXXXX", would be issued for applications for non-transitional registration in respect of which the three acceptable basic test reports, i.e. acceptable test reports on heavy metals and toxic element, pesticide residues and microbial limit, had been submitted. These pCm, as well as those which met the eligibility criteria for transitional registration and had been issued with the "Notice of confirmation of transitional registration of pCm", which contained a serial number with the format of "HKP-XXXXX", would continue

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be allowed to be sold in Hong Kong after section 119 of the Ordinance came into operation in December 2010 until the pCm was formally registered, or until the application for its registration was subsequently refused, or the date as specified and promulgated by the Secretary for Food and Health, whichever date was the earliest.

27. In response to the Chairman's enquiry as to whether the trade had been consulted on the proposal to commence section 119 of the Ordinance in December 2010, Assistant Director of Health (Traditional Chinese Medicine) ("AD(TCM)") said that strengthening the regulation of Chinese medicine with the full implementation of pCm and enhancing inspections of Chinese medicine traders had been set out in the Policy Agenda of the 2009-2010 Policy Address. At the policy briefing on 16 October 2009, the Panel was briefed on the Administration's plan to commence the operation in 2010 the remaining provisions under the Ordinance relating to mandatory registration of pCm. To prepare the Chinese medicines trade for the full implementation of the mandatory registration of pCm, CMB and DH had held a number of briefing sessions in 2009 to inform the trade that the Government planned to commence the legislative provisions related to the mandatory registration of pCm shortly, and also through attending meetings of the Retail Task Force under the Business Facilitation Advisory Committee reported the progress of the pCm registration regularly. Representatives of CMB and DH had also attended meetings of Chinese medicines traders associations to facilitate the trade in understanding the pCm registration requirements. In addition, seven briefing sessions had been held for the major trade associations and the traders from late May to early July 2010 to collect the trade/stakeholders' feedback on the commencement of the legislative provisions, who had indicated their support to the implementation plan and the related timeframe.

28. Dr Priscilla LEUNG maintained the view that the Panel should invite views from the trade on the difficulties they encountered in complying with the registration requirements.

29. Mr CHEUNG Man-kwong shared the view of Dr LEUNG that the trade should be invited to give views on the Administration's proposal to commence section 119 of the Ordinance in December 2010. Noting from paragraph 5 of the Administration's paper that about 4 610 out of the some 14 100 applications for transitional registration of pCm (i.e. 33%) were rejected, Mr CHEUNG sought information on the number of rejected cases due to the reason of exceeding the permitted level of heavy metals or toxic element, pesticide residues and microbial limit. Mr CHEUNG further said that for applicants who had provided the basic product safety information but needed more time to furnish the necessary documents for CMB's assessment, they should be given the opportunity to have their applications be reviewed if the documents could then be submitted within a specific period of time, say, six months.

30. AD(TCM) advised that under the transitional registration system for pCm, applicants were required to submit within one year from the deadline of application for transitional registration, i.e. by June 2005, the three acceptable basic test reports. About 3 000 applications for transitional registration were rejected by CMB for failing to furnish the test reports even though the applicants had been reminded several times of the need to submit the relevant information for CMB's assessment. The remaining

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applications were rejected mainly due to the reason of not fulfilling the definition of a pCm. AD(TCM) further said that according to section 140 of the Ordinance, any person aggrieved by the decision of CMB regarding registration of pCm might request, within 14 days after the receipt of the notification of decision, for review of such decision. About 920 of the some 4 610 rejected cases had applied for review and about 360 applications for review were being further processed as the required information had been furnished.

31. Holding the view that strengthening the regulation of Chinese medicine was of utmost importance to protect public health, Mr CHEUNG Man-kwong considered that information of those pCms proved to be unfit for human consumption should be made known to the public and measures should be put in place to prohibit the sale of these products to protect public health.

32. Referring to the some 3 000 rejected applications where the applicants had not provided the three basic acceptable basic test reports for safeguarding public health, Ms Audrey EU asked whether the pCm concerned were still available on the market, and if so, whether the Administration would announce the details to the public.

33. USFH and AD(TCM) responded as follows -

(a) according to the Import and Export Ordinance (Cap. 60), an import licence issued by the Director of Health must be obtained for each consignment of pCm imported into Hong Kong. For pCm imported for local consumption, the provision of the re-confirmation receipts to applicants who had submitted the required documents for registration was required. Hence, pCm of the cases being rejected for application of transitional registration due to the failure to furnish the three acceptable basic test reports would not be issued with the import licence;

(b) for pCm that was manufactured locally, pCm manufacturers in Hong Kong were required to apply for a licence with CMB. Licensed pCm manufacturers had to observe the law and the requirements of practising guidelines, which included the need to make sure that the pCm manufactured met the requirements as to their quality;

(c) DH would conduct market surveillance by collecting samples of pCm (irrespective of whether such products had been registered or not) from the market on a regular basis for testing. If any problem was detected (e.g. adulteration with western medicines, exceeding the limits for heavy metals), DH would conduct investigation and take appropriate actions in accordance with the relevant regulations. If necessary, DH might order the importers or manufacturers to recall the products in question; and

(d) upon the commencement of section 119 of the Ordinance in December 2010, unregistered pCm, except those in respect of which the three acceptable basic test reports, i.e. acceptable test reports on heavy metals and toxic element, pesticide residues and microbial limit, had been

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submitted for registration, could not be sold in the market until they had obtained registration status. This would not only make the regulation of Chinese medicines more comprehensive, but also provide a legal basis for combating more effectively the selling of unregistered pCm.

34. Ms Audrey EU noted from the submission of the International General Chinese Herbalists and Medicine Professionals Association Ltd. that the briefing sessions for the Association to collect the trade/stakeholders' feedback on the commencement of the legislative provisions related to registration of pCm were held on 21 and 23 June 2010. However, the consultation was ended on 23 June 2010. She expressed concern about whether the Administration had made reasonable efforts to consult the trade on the proposed commencement of the legislative provisions. Mr Andrew CHENG expressed similar concern. They considered it necessary for the Panel to invite the trade to give views on whether members of the trade were ready for the commencement of the mandatory registration.

35. USFH advised that taking into account that pCm had a long history, the Administration had taken a phased approach for the transition from no regulation in the past to implementation of comprehensive regulation after the passage of the Ordinance in 1999. The traders had also been consulted extensively on the registration requirements before the commencement of the registration system for pCm. USFH further said that as mentioned earlier at the meeting, CMB and DH had made considerable effort and carried out a number of consultation activities to prepare the trade for the full implementation of the mandatory registration of pCm since the announcement in the 2009-2010 Policy Agenda of the policy objective of strengthening the regulation of Chinese medicine with the full implementation of pCm, amongst others. The statutory requirements of pCm registration were also published in the "Chinese Medicine Traders Newsletter" which was distributed to all licensed Chinese medicine traders and trader associations. In addition, a letter was issued by DH on 6 May 2010 to all applicants for pCm registration to inform them of the Administration's plan to commence the provisions in the Ordinance and the Regulation related to the mandatory registration of pCm shortly, and the requirements of label and package inserts. Seven briefing sessions had also been held for the major trade associations from late May to early July 2010 to collect the feedback of the trade/stakeholders on the commencement of the legislative provisions. Having regard to the views of the trade, the consultation with the trade and stakeholders on the commencement of the legislative provisions through the electronic platform was extended by two weeks to end on 6 July 2010.

36. Dr LEUNG Ka-lau enquired about the assessment of CMB in respect of the efficacy of a pCm under application for registration.

37. AD(TCM) responded as follows -

(a) under the registration system, pCm would, base on its composition, usage and sales history, be classified into one of the three classification categories, namely, the "Established medicines category", the "Non-established medicines category" (included two sub-categories: "Health-

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preserving medicines" and "Single Chinese medicine granules") and the "New medicines category";

(b) applicants for registration of pCm were required to provide sufficient documents to support the product efficacy for CMB's assessment. For pCm classified into the "Established medicines" category and was formulated according to an ancient prescription; a modified ancient prescription or pharmacopoeia prescription; or any other prescriptions originated from the National Drug Standards of the People's Republic of China, the applicant had to submit copies of relevant materials from Chinese medicines bibliography, Pharmacopoeia or any other National Drug Standards of the People's Republic of China. For "Health-preserving medicines" in the "Non-established medicines category", the claimed functions had to be supported by research studies, or the functions of which had been described in health care literatures compiled by Chinese medicines professionals. For "Single Chinese medicine granules" in the "Non-established medicines category", copies of relevant materials from Chinese medicines bibliography or Pharmacopoeia should be submitted. Based on the information submitted by the applicants, the specialists of the Chinese Medicine Division of DH would assess and recommend to CMB on whether the selected prescription had clearly defined indications or functions, reasonable formulation, correct composition and appropriate dosages for the purpose for which the medicine was proposed to be administered; and

(c) as regards products classified into the "New medicines category", the submission of reports on pharmacodynamic studies, pharmacological studies and clinical trials were necessary as their compositions, routes of administration, indications or dose forms were different from traditional use and scientific evidence was essential to ensure their efficacy.

38. Given the substantial differences between Chinese medicines and Western medicines in terms of their principles, Mr Andrew CHENG urged the Administration to look at the issue of regulation of Chinese medicines from the perspective of Chinese medicine, rather than adopting a Western medicine perspective. He then asked whether members of CMB as well as staff of the Chinese Medicine Division of DH possessed the necessary expertise and qualifications for discharging their duties.

39. AD(TCM) responded that CMB was a statutory body established under the Chinese Medicine Council of Hong Kong ("CMC") to vet the applications for pCm, amongst others. It was chaired by the Director of Health and comprised 13 members. Amongst these members, five were representatives from the trade in Chinese medicine and two were Chinese medicine practitioners. As regards the Chinese Medicine Division of DH, Chinese medicine experts from the Mainland as well as local qualified personnel were employed to support its work on the enforcement of the Ordinance; providing professional and administrative support to CMC; and the development of standards for some commonly used Chinese Materia Medica.

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40. Whilst supporting the implementation of the mandatory registration of pCm to safeguard public health, Dr PAN Pey-chyou said that the trade should be invited to present views on their difficulties in complying with the registration requirements. Taking into consideration that pCms manufactured locally might be made from imported ingredients, Dr PAN asked whether there was any mechanism to ensure the safety and quality of the imported Chinese medicine raw materials.

41. USFH responded that with effective from 11 January 2008, any person who wished to import or export any of the 31 toxic Chinese herbal medicines specified in Schedule 1 of the Ordinance and the five Chinese herbal medicines specified in Schedule 2 of the Ordinance must first apply for an import or export licence. In manufacturing pCm, testing had to be conducted by manufacturers on their pCm as to whether they met the safety and quality standards.

42. Ms Cyd HO noted that with the commencement of the legislative provisions relating to the package insert requirements in December 2011, the package inserts of pCm should include information such as the ingredients, dosage and method of usage, indications, contra-indications, side-effects and toxic effects of the pCm and the precautions to be taken regarding its use. She asked the Administration whether it would conduct laboratory tests on pCm to verify the particulars being set out in the package inserts.

43. AD(TCM) responded that CMB had formulated the "Guidelines on labels of proprietary Chinese medicines" and "Guidelines on package inserts of proprietary Chinese medicines". These Guidelines had been uploaded on the website of CMC for traders' reference. Where necessary, staff of DH could provide relevant advice for individual product. CMB and DH had also held a number of briefing sessions in 2009 to facilitate the trade to have a better understanding of the guidelines on labels and package inserts of pCm. AD(TCM) further said that there were laboratory facilities in Hong Kong to conduct various tests on pCm and it was the responsibility of the applicant to submit the test results for CMB's assessment.

44. In closing, the Chairman said that he saw no urgency for holding a special meeting before the end of this legislative session to receive views from the trade on the subject matter. Where necessary, the Panel could decide in the new legislative session whether a special meeting should be convened to revisit the matter and receive views from the trade. Members did not raise any queries.

IV. Issues related to health services under the Framework Agreement on Hong Kong/Guangdong Co-operation

(LC Paper No. CB(2)1995/09-10(04))

45. In view of the time constraint, members agreed to defer the discussion of the item to a future meeting.

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V. Any other business

46. There being no other business, the meeting ended at 10:43 am.

Council Business Division 2
Legislative Council Secretariat
13 October 2010