立法會
Legislative Council

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Panel on Health Services

Subcommittee on Issues Relating to the Development of Chinese Medicine

Minutes of the fourth meeting held on Monday, 8 June 2020, at 4:30 pm in Conference Room 1 of the Legislative Council Complex

Members present	:	Hon CHAN Han-pan, BBS, JP (Chairman) Hon CHAN Hoi-yan (Deputy Chairman) Prof Hon Joseph LEE Kok-long, SBS, JP Hon Alice MAK Mei-kuen, BBS, JP Dr Hon KWOK Ka-ki Dr Hon Helena WONG Pik-wan Hon Elizabeth QUAT, BBS, JP Hon SHIU Ka-fai, JP Hon SHIU Ka-chun Dr Hon Pierre CHAN
Member absent	:	Hon Mrs Regina IP LAU Suk yee, GBS, JP
Public Officers attending	:	Items I and II Dr CHUI Tak-yi, JP Under Secretary for Food and Health Dr CHEUNG Wai-lun, JP Project Director (Chinese Medicine Hospital Project Office) Food and Health Bureau

		Ms Ellen CHAN Sheung-man Principal Assistant Secretary for Food and Health (Health) 7/Head (Chinese Medicine Unit) Food and Health Bureau
		Dr NG Chi-sun Consultant Chinese Medicine Practitioner Food and Health Bureau
		Dr Christine WONG Wang Assistant Director of Health (Chinese Medicine) Department of Health
		Mr Robert LAW Kwok-wai Chief Pharmacist (Chinese Medicine) Department of Health
		Ms Rowena WONG Chief (Chinese Medicine Department) Hospital Authority
Clerk in attendance	**:**	Ms Maisie LAM Chief Council Secretary (2) 5
Staff in attendance	**:**	Miss Kay CHU Senior Council Secretary (2) 5
		Miss Maggie CHIU Legislative Assistant (2) 5

Action

I. Regulatory regime for Chinese herbal medicines and proprietary Chinese medicines and development of the industry
[LC Paper Nos. CB(2)1142/19-20(01) and (02)]

The Subcommittee deliberated (index of proceedings attached at **Annex**).

II. Development of the Government Chinese Medicine Testing Institute
[LC Paper No. CB(2)1142/19-20(03)]

Action

2. The Subcommittee deliberated (index of proceedings attached at **Annex**).

III. Any other business

3. The Chairman informed members that the next meeting would be the last meeting of the Subcommittee. Members agreed to discuss "Regulatory regime for and professional development of Chinese medicine practitioners" and "Latest progress of Chinese Medicine Development Fund" at the next meeting of the Subcommittee. The Chairman said that members would be informed of the meeting date and time in due course.

4. There being no other business, the meeting ended at 6:25 pm.

Council Business Division 2
Legislative Council Secretariat
28 October 2020

Annex

Proceedings of the fourth meeting of the Subcommittee on Issues Relating to the Development of Chinese Medicine on Monday, 8 June 2020, at 4:30 pm in Conference Room 1 of the Legislative Council Complex

Time marker	Speaker	Subject(s)/Discussion	Action required
Agenda item I: Regulatory regime for Chinese herbal medicines and proprietary Chinese medicines and development of the industry			
000603 - 000730	Chairman	Opening remarks	
000731 - 000832	Chairman Admin	Briefing by the Administration on the regulatory regime for Chinese herbal medicines and proprietary Chinese medicines ("pCms") and development of the industry [LC Paper No. CB(2)1142/19-20(01)].	
000833 - 001918	Chairman Admin	The Chairman was concerned that while the registration system for pCm had been implemented since 2003, as of March 2020, only 2 383 cases were issued with the "Certificate of registration" (or referred to as "HKC") and the number of cases being issued with the "Notice of confirmation of transition registration of pCm" (or referred to as "HKP") still stood at a high level of 5 863. He called on the Administration to consider creating a new registration group for those pCm products which had met the safety but no other registration requirements. The Administration advised that among the 5 863 HKP cases being processed, 356 cases (about 6%) had been approved by the Chinese Medicines Committee as HKC and the certificate would be issued subject to payment of relevant fees from the applicants. Another 2 167 HKP cases (about 37%) would be approved as HKC upon the completion of assessment of their product labels and inserts. In reply to the Chairman's follow-up enquiry, the Administration affirmed that the Chinese Medicines Board ("CMB") had implemented different measures to facilitate traders with transitional registration to obtain formal registration. For example, CMB allowed holders of HKP or product manufacturers, by way of statutory declaration, to clarify information on the packing specification, packing material, master formula and manufacturing method of the product submitted in the application for transitional registration. The Chairman enquired about the measures in place to facilitate the Chinese medicine drug sector to expand into the market of Guangdong-Hong Kong-Macao Greater Bay Area ("Greater Bay Area"). In response, the Administration advised that it would continue to liaise with the relevant Mainland authorities on facilitation measures given the different regulatory regimes for Chinese medicine drugs in the two places. The above apart, support would be provided under the Chinese Medicine Development Fund ("the CM Fund") to enhance the pCm quality and manufacturing system with regard to the Good Manufacturing Practices standards.	

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001919 - 002703	Chairman Dr Helena WONG Admin	Dr Helena WONG's enquiries on the following in respect of the market surveillance mechanism for monitoring the safety and quality of Chinese herbal medicines: (a) whether the sample number and scope of Chinese herbal medicines collected for testing could be increased, as only about 540 samples of the 605 types of Chinese herbal medicines listed in Schedules 1 and 2 to the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") were collected annually for the purpose; (b) the toxic element which was found in the Chinese herbal medicines sample to have exceeded the limit as referred to in paragraph 14 of LC Paper No. CB(2)1142/19-20(01); and (c) the regulation of the sulphur dioxide residue in Chinese herbal medicines. The Administration's advice that: (a) the Department of Health ("DH") had increased the number of samples collected for testing from the past level of 30 to 45 per month to 50 per month from January 2020 onwards, and would progressively increase the number to 70 samples per month by the end of 2020; (b) the types of Chinese herbal medicines to be collected from the market for testing would be based on a risk-based approach; and (c) it planned to introduce in June 2021 limits on sulphur dioxide residues in Chinese herbal medicines which would follow the relevant standard set out in the Pharmacopoeia of the People's Republic of China (2015 Edition) ("the Chinese Pharmacopoeia 2015").	
002704 - 003856	Chairman Mr SHIU Ka-fai Admin	Mr SHIU Ka-fai welcomed the Administration's proposal that in respect of the legislative exercise to amend the pCm definition and its relevant clauses under the Ordinance so as to impose more stringent regulation over those products, exemption clauses would be provided to specify that pCm did not include a product containing western medicine, customarily consumed as food or drink, or for use externally and exclusively for cosmetic purpose. On Mr SHIU Ka-fai's call for the Hong Kong Productivity Council, the implementation agent of the CM Fund, to shorten the application processing time under the pCm Registration Supporting Scheme and the Administration to enhance the training for Chinese medicine personnel, the Administration advised that it would continue to examine how to enhance the support for the Chinese medicine and Chinese medicine drug sectors under the CM Fund. In response to the Chairman and Mr SHIU Ka-fai's strong call for the Administration to put in place concrete measures to promote the brand image of Hong Kong's Chinese medicine drugs to facilitate the industry to expand into the market of Greater Bay Area, the Administration advised that it had relayed the views of the sector to the National Medical Products Administration in May 2019 for consideration and had followed up on the matter subsequently. While understanding that Hong Kong and the Mainland had in place different registration systems for the purpose of regulation of Chinese medicine drugs, the Chairman remarked that the	

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		Administration should be more proactive to explore with the Mainland authorities on how to enable both online and offline sale of Hong Kong's registered pCms in the market of Greater Bay Area.	
003857 - 004725	Chairman Dr Helena WONG Admin	In reply to Dr Helena WONG's enquiries, the Administration advised that countries around the world had not yet come up with a standardized set of limits for heavy metal contents in Chinese herbal medicines. The Chinese Medicine Council of Hong Kong ("CMCHK") had formulated the general limits of four heavy metals which were known to be more toxic to human beings (i.e. arsenic, cadmium, lead and mercury) with reference to other relevant international standards for application on all the 605 types of Chinese herbal medicines listed in Schedules 1 and 2 to the Ordinance. As a reference, the Chinese Pharmacopoeia 2015 had set out the specified heavy metal limits for individual types of Chinese herbal medicines. Dr Helena WONG was of the view that more heavy metal contents should be tested to safeguard public health. In response, the Administration advised that according to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and the Substance Priority List compiled by the Agency for Toxic Substances and Disease Registry under the Department of Health and Human Services of the United States, arsenic, cadmium, lead and mercury were amongst the top toxic substances that would pose significant potential threat to the health of humans through medication.	
004726 - 005336	Chairman Ms CHAN Hoi-yan Admin	Ms CHAN Hoi-yan asked whether the approved application for subsidy for launching the research study on the certification system of Chinese medicine pharmacists under the Chinese Medicine Applied Studies and Research Funding Scheme of the CM Fund would help set out the qualifications and academic requirements under the certification system such that accredited personnel would become available upon the commencement of service of the Chinese Medicine Hospital. The Administration advised that the said research study was expected to be completed in about two years and it would formulate the way forward in respect of such policies on the basis of the findings and the industry's views so as to, among others, support the development of the Chinese Medicine Hospital which was expected to commence operation by phases from end-2024.	
005337 - 010632	Chairman Dr Helena WONG Admin	While expressing appreciation that the Administration planned to introduce in June 2021 limits on sulphur dioxide residues in Chinese herbal medicines, Dr Helena WONG asked why the measure could not be introduced at an earlier time to better protect public health and the reasons for having a one-year grace period (i.e. from 1 June 2021 to 31 May 2022) before the measure took full effect.	

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		The Administration advised that the Government Laboratory ("GL") and the industry required time to prepare for the method of testing sulphur dioxide residues contained in Chinese herbal medicines under the market surveillance mechanism. As regards the quality standard for the limits of sulphur dioxide residues in Chinese herbal medicines, it would follow the standards of the Chinese Pharmacopoeia 2015 that except otherwise specified, the sulphur dioxide residues in all Chinese herbal medicines (except minerals) should not exceed 150 mg/kg. The sulphur dioxide residue in the specified types of Chinese herbal medicines (such as Radix Asparagi and Radix Codonopsis) should not exceed 400 mg/kg. During the one-year grace period, DH would request the Chinese medicine drug traders concerned to recall from the market those Chinese herbal medicines which were found in market surveillance to contain sulphur dioxide residues at a level exceeding the above limits and prosecution and appropriate actions would be conducted if the residues were found to be unfit for human consumption. The Chairman asked whether the Administration would assist the trade to progressively switch to from applying sulphur dioxide to applying gamma rays radiation from a cobalt-60 source for the preservation of Chinese herbal medicines in tandem with the introduction of the new measure. The Administration advised that the Chinese Medicine Warehouse Management, Logistics and Services Improvement Funding Scheme under the CM Fund would provide funding for eligible wholesalers and retailers of Chinese herbal medicines to purchase related equipment to enhance the efficiency and safety of the handling, storage and transportation of Chinese herbal medicines. Separately, it would continue to step up public education on the precautions for the purchase and decoction of Chinese herbal medicines.	
Agenda item II: Development of the Government Chinese Medicine Testing Institute			
010633 - 010752	Chairman Admin	Briefing by the Administration on its work and progress in establishing the Government Chinese Medicines Testing Institute ("GCMTI") [LC Paper No. CB(2)1142/19-20(03)]	
010753 - 011618	Chairman Admin	The Chairman cast doubt about whether GCMTI should continue its function in formulating reference standards for Chinese medicine drugs under the Hong Kong Chinese Materia Medica Standards ("HKCMMS"), as the local Chinese medicine drug industry had widely followed the relevant standards set out in the Chinese Pharmacopoeia. He opined that resources should instead be allocated for GCMTI to provide testing services of pCms. The Administration advised that the issue would need to be thoroughly considered having regard to the fact the Chinese Pharmacopoeia 2015 provided regulatory standards for Mainland drug industry, whereas HKCMMS offered reference standards to Hong Kong Chinese medicines trade and testing industry. The Administration also elaborated on the facilities to be provided in the permanent GCMTI building for	

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		conducting Chinese medicine drug testing and related work, which included various dedicated laboratories, a Chinese medicines herbarium laboratory, a digitalized database of Chinese medicines, an international collaboration and training centre, an outdoor medicinal plant garden, laboratories for the Chinese Medicines Section of GL, the macroscopic and microscopic identification laboratory of DH and a laboratory for conducting proficiency test schemes and producing reference materials as detailed in paragraph 11 of LC Paper No. CB(2)1142/19-20(03).	
011619 - 012036	Chairman Dr Helena WONG Admin	In reply to Dr Helena WONG's enquiries, the Administration advised that the testing services to support the regulatory work in respect of Chinese medicine drugs were provided by, among others, the laboratories for the Chinese Medicines Section of GL. These laboratories would be moved to the permanent GCMTI building which was expected to commence operation in phases together with the Chinese Medicine Hospital.	
012037 - 013653	Chairman Mr SHIU Ka-chun Admin Dr Helena WONG	Pointing out that some Chinese herbal medicines could be taken directly after being grounded into powder, Mr SHIU Ka-chun relayed the concern of some members of the Chinese medicine sector over the method employed by GL for testing samples of Chinese herbal medicines under the market surveillance mechanism whereby preliminary tests were conducted on Chinese medicine decoction pieces in the first stage of testing. Dr Helena WONG was of the view that the second-stage testing of residues in the decoctions of the Chinese herbal medicines concerned had narrowed the net. The Administration advised that the tests on Chinese medicine drugs undertaken by GL had been accredited. Under the market surveillance mechanism, GL would first conduct primary testing on the samples of Chinese herbal medicines. If excessive pesticide residues and/or heavy metals and toxic elements were detected in the samples, second-stage testing, i.e. testing for pesticide residues in the decoctions of the Chinese herbal medicine samples concerned (not applicable if the Chinese herbal medicines concerned could be directly taken after being grounded into powder), would be carried out. The testing of the Chinese herbal medicines concerned in the form of a decoction was considered by international experts to be a closer simulation of condition under which such medicines were consumed and which was more appropriate for health risk assessment. It should be noted that the regulatory standards adopted by the Chinese Pharmacopoeia had also taken into account, among others, the transfer rate of heavy metal and toxic elements as well as pesticide residues from the Chinese herbal medicines into the decoctions to assess the intake impacts on human beings. The limits of heavy metals and toxic elements and pesticide residues in Chinese herbal medicines set by CMCHK were made available on the website of CMCHK. The Administration had also maintained communication with the Chinese medicine industry in this regard.	

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013654 - 015743	Chairman Admin	The Chairman's views that (a) the proposed setting up of an outdoor medicinal plant garden in the permanent GCMTI might have little value in setting benchmarks to pave way for the internationalization of Hong Kong's Chinese medicine drug industry; and (b) the proposals that the permanent GCMTI would house a digitalized database on Chinese medicines to form a database on knowledge, research and application of Chinese medicine drugs, as well as an international collaboration and training centre to promote the transfer of technical know-how of Chinese medicine drug testing to the Chinese medicine drug sector might duplicate the work of the academic sector in this regard; and (c) the positioning of the permanent GCMTI should be targeted at fostering the development of the local Chinese medicine drug industry. The Administration elaborated on how the functions of the three facilities of GCMTI cited by the Chairman would meet the mission of the permanent GCMTI of developing reference standards for Chinese medicine drugs through scientific research and their uniqueness when compared to other similar facilities. The Administration further assured members that it would take into account views from members and stakeholders, and further consult the Advisory Committee on GCMTI, which was set up to advise the Government on the development strategy and priority areas of GCMTI, in taking forward the establishment of the permanent of GCMTI. In reply to the Chairman's follow-up enquiry, the Administration advised that its plan was to seek the funding approval for the permanent GCMTI from the Finance Committee in the 2020-2021 legislative session.	
Agenda item III: Any other business			
015744 - 015850	Chairman	Closing remarks Arrangement for the next meeting	

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