立法會
Legislative Council

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(These minutes have been seen by the Administration)

Panel on Health Services

Subcommittee on Issues Relating to the Development of Chinese Medicine

Minutes of the meeting
held on Tuesday, 16 December 2014, at 10:15 am
in Conference Room 1 of the Legislative Council Complex

Members present	:	Hon CHAN Han-pan, JP (Chairman) Hon Vincent FANG Kang, SBS, JP Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN Hon YIU Si-wing Dr Hon KWOK Ka-ki Dr Hon Elizabeth QUAT, JP Hon Christopher CHUNG Shu-kun, BBS, MH, JP
Member absent	:	Hon WONG Ting-kwong, SBS, JP Hon CHEUNG Kwok-che Hon Alice MAK Mei-kuen, JP
Public Officers attending	:	Professor Sophia CHAN Siu-chee, JP Under Secretary for Food and Health Miss Janice TSE Siu-wa, JP Deputy Secretary for Food and Health (Health) 1 Food and Health Bureau Dr Ronald LAM Man-kin Assistant Director (Traditional Chinese Medicine) Department of Health Mr Robert LAW Kwok-wai Senior Pharmacist (Traditional Chinese Medicine) 2 Department of Health

Attendance by invitation :

Tin Lee Medicine International Limited

Mr MAK Tin-lee
Director

Hong Kong Sun Chung Medical Centre University

Mr HOU Ping
Director

Po Sau Tong Ginseng & Antler Association Hong Kong Limited

Mr CHAN Tak-tai
Chairman

Hung Fai Company

Mr LEUNG Fu-wing
Proprietor

Hang Tai Trading Co. (Branch)

Mr CHAN Kit-tong
Manager

Medic-Pharm Technology (Int'l) Ltd.

Mr F S CHIU
Managing Director

HK Pharmaceutical Manufacturers Association

Mr Alex CHEUNG
Vice President

Smart Planning Ltd.

Mr CHENG Chung-ping
Director

Health Potential Culture Association

Ms NG Po-chu
Chairman

Lanway Ltd.

Mr WONG Yue-kam
Manager

Hong Kong Medicine Dealers' Guild

Mr WONG Ping-ming
Chairman

Hong Kong Chi Chun Tang Herbal Factory Limited

Mr Jason TSOI Chi-kong
Assistant of Director

Mr LI Tei-fat

Wai Fai Trading Co.

Mr YEUNG Fai Tsan
Owner

Nobility Herb & Medicine Company

Mr POON Po-sum
Proprietor

Mr WAN Shan-nam

新興製藥廠

Mr CHONG Yui
東主及註冊中醫師

Concern Group on Wholesale and Retail, Liberal Party

Mr Peter SHIU
Convenor

旺高國際發展有限公司

Mr CHEN Kok-en
Chinese Pharmacist Technician

Tak Cheong Ginseng Co.

Mr CHOW Kam-tim
註冊中醫(駐診)

Kwan Tung Pak Yuen Tong

Mr TAM Wing-yip
Project Manager

Worldwide Chinese Medicine Modernization Alliance

Ms Joanna MAK Wai-ching
Chairman

SGS Hong Kong Limited

Mr GOO Fei
Product Manager

Chinese Medicine Manufacturers' Group

Mr YIU Kai-wing
Committee Member

Hong Kong Chinese Medicine Industry Association

Ms TANG Mui-fun
Preisdent

Tsz Yan Tong Chinese Med. Manufacturing Co.

Mr CHAN Hau-kut
Managing Director

Wing On Medicine Co.

Mr NG Tai-loy
董事長總經理

H.K. Ma Sai Leung Tong Med. Mfy. Ltd.

Miss MA Sze-lam
Manager

		The Hong Kong Federation of Chinese Medicine Sector Limited
		Mr LIN Hei-hing 副監事長
		Mr LAW Wai-keung
Clerk in attendance	:	Ms Joanne MAK Chief Council Secretary (2) 3
Staff in attendance	:	Ms Priscilla LAU Council Secretary (2) 5
		Mrs Fonny TSANG Legislative Assistant (2) 3

Action

I. Registration, testing and development of proprietary Chinese medicines ("pCms") and introduction of Good Manufacturing Practice requirements to pCms
[LC Paper Nos. CB(2)453/14-15(02), CB(2)322/14-15(01) and (03)]

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

2. The Subcommittee received views from 30 deputations on the registration, testing and development of pCms and the introduction of Good Manufacturing Practice ("GMP") requirements to pCms.

3. The Subcommittee noted the following major views expressed by the deputations -

(a) a number of deputations expressed grave concern on the implementation of GMP in pCm manufacture. As most of the local pCm manufacturers were small and medium enterprises ("SMEs"), they lacked the financial strength and expertise to build and operate GMP facilities. In their view, the adoption of GMP standards should be voluntary rather than a mandatory requirement so as to allow room for the survival of SME pCm manufactures. These deputations emphasized that the implementation of GMP in pCm

manufacture should be by phases, so as to allow sufficient time for pCm manufacturers to meet the requirements of hardware and software for GMP;

(b) apart from providing clear guidelines on GMP requirements for pCm manufacture, the Administration should also provide GMP training and technical consultation services to the trade as well as provision of GMP factory premises for pCm manufacturers under leasing arrangement. Consideration should also be given to further expanding the contract manufacturing services provided by the Hong Kong Institute of Biotechnology ("HKIB") to cover the production of additional dose forms of pCms, such as liniment and tablet, so that more SME pCm manufacturers could make use of this GMP product development and technical support platform;

(c) some deputations considered that the requirements for registration of pCms were too stringent and the processing time was too long. Many local pCm manufacturers had encountered great difficulties in fulfilling the testing requirements and were also very concerned about the expensive testing costs. There was a view that in considering an application for registration, whether or not the pCm concerned had got registered in Mainland China and/or Taiwan should also be taken into account. On the other hand, the Administration should step up efforts in combating the sale of unregistered pCms;

(d) some deputations were of the view that more time, say, two years (instead of only six months), should be allowed for the manufacturers or traders to print and replace new labels and package inserts for pCms (currently only issued with "Notice of confirmation of transitional registration of pCm" ("HKP")) for which formal registration had been approved with the "Certificate of registration of pCm" ("HKC") issued; and

(e) there was a view that the requirement of maintaining a complete transaction record (including the batch number of the processed herbal medicines ("中藥材飲片")) by retailers of Chinese herbal medicines had adversely affected their day-to-day operation.

4. In response to the major concerns expressed by the deputations, the Administration advised that -

(a) the GMP requirement in respect of pCms in Hong Kong was currently not mandatory. The Administration noted the trade's

concerns about the implementation of GMP in pCm manufacture. It would maintain close communication with the trade and actively engage them to work out a timetable for mandatory compliance with GMP for the manufacture of pCms;

(b) briefing and consultation sessions were organized by the Department of Health ("DH") to explain to pCm manufacturers the current GMP requirements, as well as to consult and discuss with them on relevant issues in order to assist them to implement GMP. Furthermore, under the support of the Innovation and Technology Commission, the Innovation and Technology Fund and The Hong Kong Jockey Club Charities Trust would jointly support HKIB to conduct a three-year project to set up a GMP product development and technical support platform for traditional oral solid pCm products. The project would also set up a GMP training platform on pCm manufacturing for Chinese medicines workers and students;

(c) DH had been holding regular briefing and consultation sessions for the trade on the registration requirements of pCm and for exchange of views on technical issues for establishment of quality specifications. Applicants who had encountered difficulties in the application process for registration were welcome to make appointment with DH to seek advice. Consideration would be given to including more case sharing in the briefing sessions in future;

(d) in accordance with the Chinese Medicine Ordinance ("CMO") (Cap. 549), as well as the Practising Guidelines for both wholesalers and retailers of Chinese herbal medicines issued by the Chinese Medicines Board, wholesalers and retailers of Chinese herbal medicines were required to maintain a complete transaction record including the batch number of Chinese herbal medicines provided by the suppliers. It would facilitate source tracing and recall of any problematic products where necessary to protect public health; and

(e) DH would take appropriate actions against those unregistered pCm products with improper health claims. In addition to complying with CMO and the Pharmacy and Poisons Ordinance (Cap. 138) respectively, applicants for registration of pCm and pharmaceutical product should also ensure that their products would comply with the requirements of other legislation, such as the Undesirable Medical Advertisements Ordinance (Cap. 231), the Public Health and Municipal Services Ordinance (Cap. 132), the Trade Descriptions Ordinance (Cap. 362), the Trade Marks Ordinance

(Cap. 559) and so forth.

5. Members noted that about 40 more deputations would give views on the same subject at the next meeting to be held on Monday, 26 January 2015 at 10:45 am.

II. Any other business

6. There being no other business, the meeting ended at 12:15 pm.

Council Business Division 2
Legislative Council Secretariat
14 January 2015

Annex

Proceedings of the meeting of the Subcommittee on Issues Relating to the Development of Chinese Medicine on Tuesday, 16 December 2014, at 10:15 am in Conference Room 1 of the Legislative Council Complex

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
Agenda item I - Registration, testing and development of proprietary Chinese medicines ("pCms") and introduction of Good Manufacturing Practice ("GMP") requirements to pCms			
000858 - 001240	Chairman	Opening remarks	
001241 - 001455	Chairman Tin Lee Medicine International Limited	Presentation of views [LC Paper No. CB(2)506/14-15(01)]	
001456 - 001615	Chairman Hong Kong Sun Chung Medical Centre University	Presentation of views [LC Paper No. CB(2)466/14-15(01)]	
001616 - 001802	Chairman Po Sau Tong Ginseng & Antler Association Hong Kong Limited	Presentation of views	
001803 - 001922	Chairman Hung Fai Company	Presentation of views	
001923 - 002035	Chairman Hang Tai Trading Co. (Branch)	Presentation of views	
002036 - 002334	Chairman Medic-Pharm Technology (Int'l) Ltd.	Presentation of views	
002335 - 002704	Chairman HK Pharmaceutical Manufacturers Association	Presentation of views	
002705 - 002959	Chairman Smart Planning Ltd.	Presentation of views	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
003000 - 003338	Chairman Health Potential Culture Association	Presentation of views [LC Paper No. CB(2)506/14-15(02)]	
003339 - 003457	Chairman Lanway Ltd.	Presentation of views	
003458 - 003826	Chairman Hong Kong Medicine Dealers' Guild	Presentation of views [LC Paper No. CB(2)506/14-15(03)]	
003827 - 003832	Chairman Hong Kong Chi Chun Tang Herbal Factory Limited	No view was presented	
003833 - 003912	Chairman Mr LI Tei-fat	Presentation of views	
003913 - 003917	Chairman Wai Fai Trading Co.	No view was presented	
003918 - 004410	Chairman Nobility Herb & Medicine Company	Presentation of views [LC Paper No. CB(2)466/14-15(02)]	
004411 - 004542	Chairman Mr WAN Shan-nam	Presentation of views [LC Paper No. CB(2)453/14-15(01)]	
004543 - 004911	Chairman 新興製藥廠	Presentation of views	
004912 - 005221	Chairman Concern Group on Wholesale and Retail, Liberal Party	Presentation of views	
005222 - 005401	Chairman 旺高國際發展有限公司	Presentation of views [LC Paper No. CB(2)466/14-15(03)]	
005402 - 005652	Chairman Tak Cheong Ginseng Co.	Presentation of views	
005653 - 005923	Chairman Kwan Tung Pak Yuen Tong	Presentation of views	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
005924 - 010151	Chairman Worldwide Chinese Medicine Modernization Alliance	Presentation of views [LC Paper No. CB(2)466/14-15(04)]	
010152 - 010501	Chairman SGS Hong Kong Limited	Presentation of views	
010502 - 010808	Chairman Chinese Medicine Manufacturers' Group	Presentation of views	
010809 - 011134	Chairman Hong Kong Chinese Medicine Industry Association	Presentation of views [LC Paper No. CB(2)506/14-15(04)]	
011135 - 011510	Chairman Tsz Yan Tong Chinese Med. Manufacturing Co.	Presentation of views [LC Paper No. CB(2)506/14-15(05)]	
011511 - 011622	Chairman Wing On Medicine Co.	Presentation of views	
011623 - 011952	Chairman H.K. Ma Sai Leung Tong Med. Mfy. Ltd.	Presentation of views [LC Paper No. CB(2)466/14-15(05)]	
011953 - 012234	Chairman The Hong Kong Federation of Chinese Medicine Sector Limited	Presentation of views [LC Paper No. CB(2)506/14-15(06)]	
012235 - 012545	Chairman Mr LAW Wai-keung	Presentation of views	
012546 - 014049	Chairman Administration	Administration's initial responses to the views and concerns expressed by the deputations	
014050 - 014950	Chairman Mr Vincent FANG Administration	Mr Vincent FANG highlighted the deputations' concern that the implementation of mandatory GMP compliance might lead to closure of some pCm manufacturers, especially the small and medium enterprises ("SMEs"). He also expressed	

Time marker	Speaker(s)	Subject(s) / Discussion	Action required
		concern about the need for a pCm manufacturer to disclose the pCm master formula to the Hong Kong Institute of Biotechnology ("HKIB") under the GMP contract manufacturing arrangements. He suggested that the Administration should set up GMP factory premises for use by pCm manufacturers under leasing arrangement. The Administration advised that - (a) the Administration was aware of the key concerns of the industry and their need for hardware and technical support for GMP implementation. In fact, the Science Park under The Hong Kong Science and Technology Parks Corporation was providing the industry with research infrastructure, including the two biotechnology buildings established in Science Park Phase Two as well as laboratory facilities for the pCm manufacturing companies in the Science Park. The biotechnology industry (including Chinese medicine and western pharmaceuticals) would be further promoted in the Phase Three development; and (b) the arrangements set out in paragraph 21 of the Administration's paper (LC Paper No. CB(2)453/14-15(02)) would be adopted to address the intellectual property problems of pCm manufacturers arising from contracting out the manufacturing process to other GMP manufacturers.	
014951 - 015544	Chairman Mr YIU Si-wing Hong Kong Medicine Dealers' Guild Nobility Herb & Medicine Company	Mr YIU Si-wing sought the deputations' views on whether they would make use of the GMP contract manufacturing services provided by HKIB in the future. Representatives of Hong Kong Medicine Dealers' Guild and Nobility Herb & Medicine Company responded that different pCm manufacturers had their unique way of production of their pCm products. The standardized production workflow adopted by GMP manufacturing service providers might not be able to cater for the specific production requirements for different products.	
015545 - 015806	Chairman Dr Elizabeth QUAT	While the implementation of GMP requirement aimed at enhancing the safety and quality of pCms, Dr Elizabeth QUAT expressed concern that the implementation of GMP would threaten the survival of SME pCm manufacturers. She urged the Administration to strengthen support to the industry in moving towards GMP.	

015807 - 020022	Chairman Administration	The Chairman requested the Administration to take note of a deputation's concerns that the operation of retailers of Chinese herbal medicines had been affected by the requirement that they had to maintain complete transaction record including the batch number of the processed herbal medicines. The Administration advised that the requirement was not new and its purpose was to facilitate source tracing and recall of any problematic batches in the event of incidents.	
Agenda item II – Any other business			
020023 - 020209	Chairman Administration	Closing remarks	

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