立法會
Legislative Council

LC Paper No. CB(2)1947/16-17
(These minutes have been seen by the Administration)

Ref : CB2/PL/HS

Panel on Health Services

Minutes of meeting
held on Tuesday, 28 February 2017, at 10:30 am
in Conference Room 2 of the Legislative Council Complex

Members present	:	Prof Hon Joseph LEE Kok-long, SBS, JP (Chairman) Dr Hon Pierre CHAN (Deputy Chairman) Hon Tommy CHEUNG Yu-yan, GBS, JP Hon WONG Ting-kwong, SBS, JP Hon CHAN Kin-por, BBS, JP Hon Paul TSE Wai-chun, JP Hon LEUNG Kwok-hung Hon YIU Si-wing, BBS Hon CHAN Chi-chuen Hon CHAN Han-pan, JP Hon Alice MAK Mei-kuen, BBS, JP Dr Hon KWOK Ka-ki Dr Hon Fernando CHEUNG Chiu-hung Dr Hon Helena WONG Pik-wan Dr Hon Elizabeth QUAT, JP Hon POON Siu-ping, BBS, MH Hon CHU Hoi-dick Dr Hon Junius HO Kwan-yiu, JP Hon SHIU Ka-fai Hon YUNG Hoi-yan Hon Jeremy TAM Man-ho
Members absent	:	Hon Charles Peter MOK, JP Hon SHIU Ka-chun

[According to the Judgment of the Court of First Instance of the High Court on 14 July 2017, LEUNG Kwok-hung, Nathan LAW Kwun-chung, YIU Chung-yim and LAU Siu-lai have been disqualified from assuming the office of a member of the Legislative Council, and have vacated the same since 12 October 2016, and are not entitled to act as a member of the Legislative Council.]

Public Officers attending :	Items V to VII
	Prof Sophia CHAN Siu-chee, JP Under Secretary for Food and Health
	Item V
	Miss Fiona CHAU Principal Assistant Secretary for Food and Health (Health) Food and Health Bureau
	Dr Edwin TSUI Assistant Director of Health (Traditional Chinese Medicine) Department of Health
	Mr Stephen YUNG Senior Pharmacist (Traditional Chinese Medicine) Department of Health
	Item VI
	Mr Chris SUN Yuk-han, JP Head, Healthcare Planning and Development Office Food and Health Bureau
	Mr Bill LI Chi-pang Deputy Head, Healthcare Planning and Development Office Food and Health Bureau
	Dr Amy CHIU Pui-yin, JP Head, Office for Regulation of Private Healthcare Facilities Department of Health
	Dr FUNG Ying Principal Medical and Health Officer (Private Healthcare Facilities) 2 Department of Health

Item VII

Miss Amy YUEN
Deputy Secretary for Food and Health (Health) 2
Food and Health Bureau

Ms Wendy AU Wan-sze
Principal Assistant Secretary for Food and Health (Health) Special Duties 1
Food and Health Bureau

Dr Jeff LEE Pui-man
Head (Tobacco Control Office)
Department of Health

Clerk in attendance : Ms Maisie LAM
Chief Council Secretary (2) 5

Staff in attendance : Ms Janet SHUM
Senior Council Secretary (2) 5

Ms Priscilla LAU
Council Secretary (2) 5

Miss Maggie CHIU
Legislative Assistant (2) 5

Action

I. Information paper(s) issued since the last meeting

[LC Paper Nos. CB(2)644/16-17(01), CB(2)729/16-17(01), CB(2)806/16-17(01), CB(2)829/16-17(01), CB(2)839/16-17(01) and CB(2)876/16-17(01)]

Members noted the following papers issued since the last meeting:

(a) Letter dated 16 January 2017 from Dr KWOK Ka-ki suggesting the Panel to discuss the Recommended HIV/AIDS Strategy for Hong Kong (2017-2021) formulated by the Hong Kong Advisory Council on AIDS;

(b) Letter dated 25 January 2017 from Ms YUNG Hoi-yan concerning the financial and project management of the works

Action

projects of the Prince of Wales Hospital and the Administration's response to the issues raised therein;

(c) Letter dated 14 February 2017 from Dr Pierre CHAN requesting the Panel to discuss issues relating to the sexual assault cases of the psychiatric wards of the Hospital Authority;

(d) Information paper provided by the Administration in February 2017 on the Hospital Authority's annual report on the use of the $13 billion one-off grant for the carrying out of minor works projects for its facilities; and

(e) Referral memorandum from the Public Accounts Committee on the provision of health services for the elderly.

II. Items for discussion at the next meeting

[LC Paper Nos. CB(2)859/16-17(01) and (02)]

2. Members agreed to discuss the following items at the next regular meeting scheduled for 20 March 2017 at 4:30 pm:

(a) Policy on and drugs for rare diseases; and

(b) Hong Kong Code of Marketing of Formula Milk and Related Products, and Food Products for Infants & Young Children.

III. Matters arising from the special meeting on 13 February 2017

[LC Paper Nos. CB(2)859/16-17(03) to (05)]

3. The Chairman recapitulated that pursuant to the decision of the Panel at the special meeting on 13 February 2017, the three motions proposed by Dr Elizabeth QUAT, Dr Fernando CHEUNG and Mr SHIU Ka-fai respectively at the meeting under the agenda item "Proposed regulatory framework for medical devices" were carried forward to be dealt with at this meeting. Members noted Mr SHIU Ka-fai's amendment to his motion which was tabled at the meeting.

The motions

4. Dr Elizabeth QUAT moved the following motion:

Action

"本會要求政府設立包括政府、美容業界、儀器生產商及醫療業界組成的商議平台，並在美容業界佔不少於半數代表名額的前提下，重新將醫療儀器及美容儀器明確界定，在保障市民安全的同時，必須避免扼殺美容業界的生存空間。

此外，本會要求政府須為美容業界訂立獨立的監管制度及全面的產業發展政策，如規管美容儀器、推動美容師專業化、監管營商及銷售手法等，讓香港美容業可持續發展、及市民在使用美容服務時有更佳的保障。"

(Translation)

"This Panel requests the Government to, on the premise that at least half of the representatives are from the beauty sector, establish a deliberation platform comprising representatives from the Government, the beauty sector, manufacturers of devices and the medical sector to clearly define medical devices and cosmetic devices afresh so as to protect public safety without throttling the development of the beauty sector.

In addition, this Panel requests the Government to establish an independent regulatory regime for the beauty sector and formulate a comprehensive strategy for the industry's development, including, among others, the regulation of cosmetic devices, promoting the professionalization of beauticians, and the monitoring of trade and sales practices, so as to facilitate sustainable development of the beauty industry in Hong Kong and enhance the protection for the public in the use of beauty services."

5. Dr Fernando CHEUNG moved the following motion:

"本委員會贊同應盡快立法規管醫療儀器。目前本港對於醫療儀器的銷售和使用方面的規管相當落後，可是政府提出的立法文件非常粗疏，諮詢不足。本委員會促請政府重新設立規管醫療儀器立法的工作小組，成員應包括物理治療師、學者、醫生、以及其他相關專業人員等，清楚將儀器分類為醫療用途、美容，以及家用等，並盡快立法全面規管，以保障市民安全。"

Action

(Translation)

"This Panel agrees that legislation for regulating medical devices should be expeditiously introduced. At present, while Hong Kong falls far behind in respect of its regulation of the sale and use of medical devices, the paper provided by the Government on the relevant legislative proposals was prepared in a slipshod manner and without sufficient consultation. This Panel therefore urges the Government to establish afresh a working group to provide legislation for the regulation of medical devices, with particular emphasis on differentiation between medical devices and cosmetic devices. Members of the working group should comprise physiotherapists, academics, medical practitioners, and other relevant professionals, etc. The working group so set up should clearly categorize such devices into those for medical purposes, cosmetic purposes and for domestic use, so that legislation can be expeditiously introduced to put such devices under a comprehensive regulatory regime to protect public safety."

6. Mr SHIU Ka-fai moved the following motion:

"鑒於政府當局現時提交的《規管醫療儀器的建議架構》極為粗疏，嚴重扭曲醫療及美容行業的生態，實際執行的可行性存疑，本委員會要求當局暫停現時的有關立法計劃，並重新進行全面諮詢，及在保障公眾安全和不傾斜於任何一個業界的前提下，詳細研究將醫療用途和美容用途的儀器徹底分開規管，然後分別提交新的規管建議予本委員會審議。"

(Translation)

"Given that the proposed regulatory framework for medical devices currently provided by the Administration was prepared in an extremely slipshod manner, which will seriously distort the ecology of the healthcare and beauty sectors and the feasibility of its practical implementation is questionable, this Panel requests the Administration to withhold its current legislative plan, launch afresh a comprehensive consultation exercise, and, on the premise of protecting public safety without tilting in favour of any single sector, study in detail the adoption of two separate regulatory regimes for medical devices and cosmetic devices for the submission of new regulatory proposals respectively for these two types of devices for consideration by this Panel."

Action

7. The Chairman invited members' views on the motions before putting them to vote. Mr SHIU Ka-fai cast doubt as to whether the relevant legislation could be expeditiously introduced into the Legislative Council ("LegCo") as referred to in Dr Fernando CHEUNG's motion, as it took time for different stakeholders to deliberate on the refinements to the regulatory framework for medical devices currently proposed by the Administration.

8. In response to Mr YIU Si-wing, Dr Fernando CHEUNG elaborated that the other relevant professionals as referred to in his motion could include, among others, representatives from the beauty sector and manufacturers of devices, as well as optometrists. Mr WONG Ting-kwong held the view that beauty devices, medical devices and optometry devices should be subject to separate regulatory frameworks.

9. Dr Junius HO remarked that to improve the clarity of Dr Fernando CHEUNG's motion, the professionals as referred to by Dr Fernando CHEUNG in paragraph 8 above should be set out in the motion. In his view, representative of the beauty sector should form the majority of the relevant discussion platform. He noted that such requirement was set out in the motion moved by Dr Elizabeth QUAT. Dr Elizabeth QUAT explained that her motion was drawn up against the background that the use control currently proposed by the Administration only covered the devices for cosmetic purposes and the current proposal would stifle the development of the beauty industry. In her view, devices which were for cosmetic but not medical purposes should be regulated under a separate regime. Ms YUNG Hoi-yan was of a similar view. Dr KWOK Ka-ki expressed disappointment that the Administration had turned a deaf ear to the call for introducing a regulatory regime for the beauty industry. In the absence of the above, those medical devices for cosmetic purposes which would pose a high risk of serious injury or harm to the public if used inappropriately should be subject to regulation in order to safeguard public health. He would support Dr Fernando CHEUNG's motion.

10. Dr Fernando CHEUNG remarked that since the issues of concern covered different stakeholders, it would be difficult to determine which sector should have a greater representation in the relevant multi-party discussion platform. This apart, it should be noted that the aim of the regulatory framework was for regulating medical devices, albeit that these devices might be used for different purposes. Ms Alice MAK said that while she understood the concerns raised by Dr Fernando CHEUNG, past experience revealed that the concerns of the beauty sector could not be properly addressed when the medical and other healthcare professionals dominated the discussion of a multi-party working group.

Action

11. Mr CHAN Chi-chuen said that he was in agreement with most of the views put forward by Dr Elizabeth QUAT in her motion. However, he would abstain from voting on the motion as he could not agree that representatives of the beauty sector should account for a greater proportion in the membership of a platform being set up for deliberating on the regulatory framework for medical devices. He considered the regulatory framework for medical devices currently proposed by the Administration slipshod. Hence, the current-term Government should not just leave out the use control of specified medical devices and introduce a bill focusing on the other parts of the regulatory regime for medical devices into LegCo in a hasty manner. Mr Paul TSE remarked that the current proposal of the Administration had failed to strike a proper balance.

12. Dr Junius HO moved the following amendments to Dr Fernando CHEUNG's motion:

"本委員會贊同應盡快立法規管醫療儀器。目前本港對於醫療儀器的銷售和使用方面的規管相當落後，可是政府提出的立法文件非常粗疏，諮詢不足。本委員會促請政府重新設立規管醫療儀器立法的工作小組，***特別是將醫療儀器和美容儀器區分。***成員應包括物理治療師、學者、醫生、***美容業界、儀器生產商、視光師***，以及其他相關專業人員等，清楚將儀器分類為醫療用途、美容，以及家用等，並盡快立法全面規管，以保障市民安全。"

(Translation)

"This Panel agrees that legislation for regulating medical devices should be expeditiously introduced. At present, while Hong Kong falls far behind in respect of its regulation of the sale and use of medical devices, the paper provided by the Government on the relevant legislative proposals was prepared in a slipshod manner and without sufficient consultation. This Panel therefore urges the Government to establish afresh a working group to provide legislation for the regulation of medical devices***, with particular emphasis on differentiation between medical devices and cosmetic devices***. Members of the working group should comprise physiotherapists, academics, medical practitioners, ***the beauty sector, manufacturers of devices, optometrists***, other relevant professionals, etc. The working group so set up should clearly categorize such devices into those for medical purposes, cosmetic purposes and for domestic use, so that legislation can be expeditiously introduced to

Action

put such devices under a comprehensive regulatory regime to protect public safety."

(*Note*: The amendment is marked in ***bold and italic type***)

13. The Chairman then put each of the motions to vote. At members' request, the Chairman ordered that the voting bell be rung for five minutes to notify Panel members of the voting. At Dr Pierre CHAN's request, the Chairman ordered that a division would be taken on each of the motions.

Voting on the motions

14. The Chairman put Dr Elizabeth QUAT's motion to vote.

The following 10 members voted in favour of the motion:

Mr CHAN Kin-por, Mr Paul TSE, Mr YIU Si-wing, Mr CHAN Han-pan, Ms Alice MAK, Dr Elizabeth QUAT, Mr POON Siu-ping, Dr Junius HO, Mr SHIU Ka-fai and Ms YUNG Hoi-yan.

The following three members voted against the motion:

Dr KWOK Ka-ki, Dr Fernando CHEUNG and Dr Pierre CHAN.

The following member abstained:

Mr CHAN Chi-chuen.

15. The Chairman declared that that the motion was carried.

16. The Chairman put the motion moved by Dr Fernando CHEUNG and as amended by Dr Junius HO to vote.

The following 11 members voted in favour of the motion:

Mr CHAN Kin-por, Mr Paul TSE, Mr YIU Si-wing, Mr CHAN Chi-chuen, Mr CHAN Han-pan, Dr Fernando CHEUNG, Dr Elizabeth QUAT, Mr POON Siu-ping, Dr Junius HO, Mr SHIU Ka-fai and Ms YUNG Hoi-yan.

No member voted against the motion.

The following three members abstained:

Ms Alice MAK, Dr KWOK Ka-ki and Dr Pierre CHAN.

Action

17. The Chairman declared that the motion as amended was carried.

18. The Chairman put Mr SHIU Ka-fai's motion to vote.

The following 10 members voted in favour of the motion:

Mr CHAN Kin-por, Mr Paul TSE, Mr YIU Si-wing, Mr CHAN Chi-chuen, Mr CHAN Han-pan, Dr Elizabeth QUAT, Mr POON Siu-ping, Dr Junius HO, Mr SHIU Ka-fai and Ms YUNG Hoi-yan.

The following three members voted against the motion:

Dr KWOK Ka-ki, Dr Fernando CHEUNG and Dr Pierre CHAN.

The following member abstained:

Ms Alice MAK.

19. The Chairman declared that the motion was carried.

Admin

20. The Chairman directed that the Administration be requested to provide a written response to the motions.

IV. Proposal for setting up a joint subcommittee under the Panel on Health Services and the Panel on Commerce and Industry on issues relating to the regulation of devices and development of the beauty industry

[LC Paper No. CB(2)793/16-17(01)]

21. Members raised no objection to the proposal from Mr SHIU Ka-fai for setting up a joint subcommittee under the Panel and the Panel on Commerce and Industry ("the CI Panel") on issues relating to the regulation of devices and development of the beauty industry, and the terms of reference and work plan of the joint subcommittee set out in the proposal.

22. Members noted that there were currently 10 subcommittees on policy issues appointed by Panels or the House Committee in operation, which had reached the maximum number of such subcommittees that might be in operation at any one time. The joint subcommittee would be put on the waiting list of subcommittees on policy issues to be activated. The Chairman said that the CI Panel had suggested that a joint meeting of the two Panels should be held in the interim to discuss issues relating to the regulation of devices and development of the beauty industry. Members

Action

agreed. Dr KWOK Ka-ki remarked that any discussion on issues relating to devices of the beauty industry would only be meaningful if the Administration had decided on how it would take forward the legislative proposal on regulating medical devices.

[At this juncture, the Chairman decided that the meeting be extended for 15 minutes beyond its appointed time.]

V. Legislative proposal for conferring power on the Director of Health to issue recall order under the Chinese Medicine Ordinance (Cap. 549)

[LC Paper Nos. CB(2)859/16-17(06) to (09)]

23. Under Secretary for Food and Health ("USFH") briefed members on the legislative proposal for conferring power on the Director of Health ("DoH") under the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") to make decision to order any person to recall from the market any proprietary Chinese medicines ("pCm") or Chinese herbal medicines under specified circumstances ("the legislative proposal on Chinese medicines"), details of which were set out in the Administration's paper (LC Paper No. CB(2)859/16-17(06)).

24. Members noted the following papers on or relevant to the subject under discussion:

(a) information note entitled "Legislative proposal for conferring power on the Director of Health to issue recall order under the Chinese Medicine Ordinance (Cap. 549)" prepared by the LegCo Secretariat (LC Paper No. CB(2)859/16-17(08));

(b) the Administration's information paper entitled "Regulation of pesticide residues and heavy metals in Chinese herbal medicines" (LC Paper No. CB(2)859/16-17(07)); and

(c) background briefs entitled "Regulation of pesticide residues and heavy metal in Chinese herbal medicines" prepared by the LegCo Secretariat (LC Paper No. CB(2)859/16-17(09)).

The recall order

25. Mr CHAN Han-pan welcomed the legislative proposal on Chinese medicines which could fill the lacuna in the Ordinance as set out in paragraph 8 of the Administration's paper which he had long called for.

Action

Expressing support for the legislative proposal on Chinese medicines, Mr CHAN Kin-bor sought elaboration about the grounds for issuing a recall order and the mechanism for appealing against a recall decision.

26. USFH advised that under the legislative proposal on Chinese medicines, DoH would order any person (regardless of whether the person was a licensed trader under the Ordinance or not) who had supplied Chinese herbal medicines, pCm and/or intermediate product generated in the course of manufacturing a pCm ("intermediate product") to recall the product concerned from the market and to withdraw the same from being supplied should DoH had reasonable cause to believe, at the time of making the recall decision, that such products were dangerous or injurious to health, or unfit for use by human being; or the order was necessary to prevent or reduce a possibility of danger to public health, or to mitigate any adverse consequence of a danger to public health; or the products were being sold or distributed in contravention of the Ordinance, such as Chinese herbal medicines being sold or distributed without licence, unregistered pCms being sold, pCms being sold without a package insert which complied with the prescribed requirements, and pCms being sold were in a package not being labelled in the prescribed manner.

27. Noting that DoH currently did not have the statutory power to make decision on recalling Chinese herbal medicines or pCms from the market, Mr CHAN Kin-bor enquired about the actions to be taken by DoH in the interim should the products concerned were found meeting the above criteria for the issuance of a recall order. USFH advised that the existing law had provided for the restriction on sale of Chinese herbal medicines and pCms under specified circumstances.

28. Ms Alice MAK expressed support for the legislative proposal on Chinese medicines. However, she noted that some Chinese herbal medicines traders had grave concern about the operation details of the recall. She called on the Administration to fully communicate with the trade before introducing this legislative proposal into LegCo.

29. USFH advised that in January 2017, DH had conducted a meeting with 16 Chinese medicines traders associations and six sessions of briefing forums for licensed Chinese medicines traders on the legislative proposal on Chinese medicines. Assistant Director of Health (Traditional Chinese medicine) ("ADoH(TCM)") supplemented that 164 members of the trade had participated in the above activities. Separately, the submissions DH received during the public consultation exercise on the legislative proposal on Chinese medicines which ended on 26 February 2017 were all in support of the proposal. While the licensed Chinese medicine traders

Action

supported in principle the proposal as they had already been required under the Chinese Medicines Regulation (Cap. 549F) to set up and maintain a system of recall of Chinese herbal medicines and pCms, DH would continue to communicate with the traders on the operation details of the proposed recall order.

30. Mr SHIU Ka-fai remarked that members of the Chinese medicines traders associations supported in principle the legislative proposal on Chinese medicines. However, they had concerns on various operational issues such as the time to be given for the traders to recall the products concerned; whether products that had been supplied to places outside Hong Kong would be subject to recall; whether licensed wholesalers of Chinese medicines products would be held liable if the retailers concerned did not return all their stock on hand; and the maximum penalty for non-compliance which was proposed to be a fine at level 6 (i.e. $100,000) and imprisonment for two years. ADoH(TCM) advised that a Chinese medicine trader bound by a recall order should recall, to the extent reasonably possible, the products already supplied. As was the case under the recall system set up and maintained by the trade, the wholesalers concerned should report the progress of recall, including whether the retailers concerned had returned all the recalled products, to DH. It should also be noted that the proposed level of penalty for non-compliance was in line with the existing level of penalty for most of the other offences under the Ordinance. Ms YUNG Hoi-yan opined that it should be provided for in the relevant bill that a person committed an offence in this regard only if the person, without reasonable excuse, failed to comply with the recall order.

31. Expressing support to the legislative proposal on Chinese medicines, Mr YIU Si-wing sought clarification as to whether a recall order would be applied on those retailers selling the pCm concerned but were not licensed traders under the Ordinance. USFH replied in the positive.

Testing of Chinese herbal medicines

32. Dr KWOK Ka-ki expressed support for the legislative proposal on Chinese medicines. Noting that there were some 4 660 licensed retailers and 930 licensed wholesalers of Chinese herbal medicines in Hong Kong, he called on the Administration to increase the number of samples of Chinese herbal medicines drawn from the market for testing of pesticide residues (including organochlorine pesticide residues) and heavy metals contents in tandem with the conferring of power upon DoH for issuance of recall order under the Ordinance. He sought information about the current numbers in this regard and the proportion of these numbers to the total

Action

number of Chinese herbal medicines sold in Hong Kong. Dr Helena WONG was in supportive of the legislative proposal on Chinese medicines. Noting that the proposal would confer statutory power on DoH to order any person to recall from the market, among others, any Chinese herbal medicines which might pose threats to public health, she enquired about the measures being put in place to monitor the quality and safety of Chinese herbal medicines imported from the Mainland into Hong Kong.

33. ADoH(TCM) advised that various regulatory controls were imposed on the 605 types of Chinese herbal medicines listed in Schedules 1 and 2 to the Ordinance. For instance, all the 31 types of Chinese herbal medicines listed in Schedule 1 and five Chinese herbal medicines listed in Schedule 2 were subject to import and export control. Any person who engaged in retail and wholesale business of Chinese herbal medicines had to obtain a licence from the Chinese Medicines Board and comply with the relevant practising guidelines, which included ensuring that the Chinese herbal medicines traded by them were of good quality and suitable to be used. It was noted that all Chinese herbal medicines manufacturing facilities in the Mainland should meet the Good Manufacturing Practice standards. At present, around 300 out of these 605 types of Chinese herbal medicines were commonly being sold in Hong Kong. DH had already increased the targeted number of market surveillance samples of Chinese herbal medicines, at both wholesale and retail levels, from 30 to 45 per month, with a view to covering all Chinese herbal medicines commonly available for sale in local market within a year. At the request of the Chairman, USFH agreed to provide after the meeting a written response on the information requested by Dr KWOK Ka-ki.

Admin

34. Referring to Annex I to LC Paper No. CB(2)859/16-17(07), Dr Helena WONG expressed concern that the organophosphorus pesticide residues in Chinese herbal medicines being tested by DH only covered 17 types, and were different from the types of organophosphorus pesticide residues in food being tested by the Centre for Food Safety.

35. ADoH(TCM) advised that standards for pesticide residues and heavy metal contents in Chinese herbal medicines were not the same as that provided for food. The standards used for testing of these contents in Chinese herbal medicines sold in Hong Kong, which covered 37 pesticide residues (including 20 organochlorine pesticides and 17 organophosphorus pesticides) and four heavy metal contents, were formulated by the Chinese Medicine Council of Hong Kong with reference to other international standards, including those of the World Health Organization and those set by different countries or regions for herbs or raw materials of natural plant preparations. In selecting these 37 contents for testing, due consideration

Action

had been given to their toxicity, residual effect, popularity and prohibition or restriction in import, export and usage internationally. Dr Helena WONG considered that the Panel should further discuss the safety standard and surveillance of pesticide residues and heavy metal in Chinese herbal medicines at a future meeting. Members raised no objection.

Scope of the current legislative exercise

36. Mr CHAN Han-pan considered that the Administration should take the opportunity of this legislative exercise to introduce a new category in the existing pCm registration system to cover pCms with proven safety and quality only; to allow applicants for formal registration of pCms to change those active ingredients in the master formula that were banned or no longer available; to provide a longer transitional period for pCms being approved to migrate from transitional registration to formal registration; and to regulate those products not consisted solely of Chinese medicine materials and were currently regarded as "health food products".

37. USFH advised that the focus of the current legislative exercise was confined to confer powers on DoH to prohibit, in specified circumstances, the sale of Chinese medicines and other substances or compounds generated in the course of manufacture of pCms and to recall, in specified circumstances, the medicines, substances or compounds that had been sold. DH would continue to address the other concerns of the trade on the registration and regulation of pCms. ADoH(TCM) supplemented that at present, around 7 700 pCm products had been issued with a "Notice of confirmation of transitional registration of pCm". To facilitate the application for formal registration of pCms, DH had regularly held exchange sessions to help the trade to understand the requirements for registration and exchange views on technical difficulties in establishing product specifications.

Motion

38. Mr SHIU Ka-fai moved the following motion:

"本委員會原則上支持政府當局今次提出的修例建議，以更有效地禁止銷售未經註冊的中成藥或存在安全問題的中藥產品，惟要求當局在草擬法例修訂條文時，能顧及業界的關注和憂慮，包括：

Action

1. 業界接獲衞生署署長發出"中藥安全命令"會否有足夠時間處理回收工作；

2. 如何界定在"合理可能的範圍內"將已供應的產品回收；

3. 供應商向客戶發出回收通知後，若有客戶未把產品退回，相關的違法責任誰屬；及

4. 當局建議的罰則(罰款100,000元及監禁兩年)過分嚴厲，希望當局能作適當調減。"

(Translation)

"This Panel, while supporting in principle the Administration's current legislative amendment proposal to more effectively prohibit the trading of unregistered proprietary Chinese medicines or Chinese medicine products having safety problems, requests the Administration to take into account the concerns and worries of the trade in drafting the amendments to the provisions of the legislation which include:

1. whether there will be sufficient time would be provided for the trade to recall the products concerned after receiving "Chinese Medicine Safety Order" from the Director of Health ;

2. how the criterion "to the extent reasonably possible" will be defined in recalling products that have already been supplied;

3. which party is to be held liable for the breach if customers, after receiving a recall notice from suppliers, have failed to return the products concerned; and

4. given that the penalty proposed by the Administration (i.e. a fine of $100,000 and imprisonment for two years) is too harsh, it is hoped that the Administration will lower the penalty to an appropriate level."

39. The Chairman ruled that the motion was related to the agenda item under discussion, and invited members to consider whether the motion should be proceeded with at this meeting. Members agreed.

Action

40. Mr CHAN Han-pan said that he would support the motion. He urged the Administration to address the concerns of the trade as set out in the motion. Dr Helena WONG said that she could not support the last item in the motion as it was necessary to have the penalty set at a level which could achieve sufficient deterrent effect to safeguard public health. Dr Fernando CHEUNG said that he would abstain from voting on the motion as he could not judge at this stage whether the proposed level of penalty was too severe.

41. Dr Junius HO moved the following amendments to the motion:

"本委員會原則上支持政府當局今次提出的修例建議，以更有效地禁止銷售未經註冊的中成藥或存在安全問題的中藥產品，惟要求當局在草擬法例修訂條文時，能顧及業界的關注和憂慮，~~包括：~~***特別是衞生署署長***：

1. ***在***~~業界接獲衞生署署長~~發出"中藥安全命令"~~會否有~~***時應給予業界***足夠時間處理回收工作；

2. ~~如何~~界定在"合理可能的範圍內"~~將~~***只適用於***已供應的產品回收；

~~3. 供應商向客戶發出回收通知後，若有客戶未把產品退回，相關的違法責任誰屬；及~~

4. ~~當局建議~~***將***罰則~~(罰款100,000元及監禁兩年)過分嚴厲，希望當局能~~作適當調減***低，目前罰款10萬元及監禁兩年太嚴苛***。"

(Translation)

"This Panel, while supporting in principle the Administration's current legislative amendment proposal to more effectively prohibit the trading of unregistered proprietary Chinese medicines or Chinese medicine products having safety problems, requests the Administration to take into account the concerns and worries of the trade in drafting the amendments to the provisions of the legislation, and ~~such concerns and worries include:~~ ***in particular, the Director of Health should***:

Action

1. ~~whether there will be~~ ***provide*** sufficient time for the trade to recall the products concerned ~~after receiving~~ ***when issuing*** a "Chinese Medicine Safety Order"~~ from the Director of Health~~;

2. ~~how~~ ***specify that*** the criterion "to the extent reasonably possible" ~~will be defined in recalling~~ ***is only applicable to the recall of*** products that have already been supplied; ***and***

~~3. which party is to be held liable for the breach if customers, after receiving a recall notice from suppliers, have failed to return the products concerned; and~~

4. ~~given that the penalty proposed by the Administration (i.e. a fine of $100,000 and imprisonment for two years) is too harsh, it is hoped that the Administration will~~ lower the penalty to an appropriate level ***as the current penalty of a fine of $100,000 and imprisonment for two years is too harsh."***

(*Note*: The amendment is marked in ***bold and italic type*** or with deletion line)

42. The Chairman put the motion as amended to vote. Five members voted for and one member voted against the motion as amended, and three members abstained from voting. The Chairman declared that the motion as amended was carried.

43. The Chairman directed that the Administration be requested to provide a written response to the motion.

Way forward

44. Mr SHIU Ka-fai suggested that the Panel should invite interested parties to give views on the legislative proposal. Pointing out that members present at the meeting were all in principle supportive of the legislative proposal and the Administration had agreed to further communicate with the Chinese medicines trade to address their concerns on the operation issues of the proposed recall order, the Chairman remarked that it would be more appropriate for the bills committee to be set up to scrutinize the relevant bill to invite public views on the details of the proposed recall order. Members raised no objection.

Action

VI. Legislative proposals for regulation of private healthcare facilities

[LC Paper Nos. CB(2)845/16-17(01), CB(2)859/16-17(10) and CB(2)896/16-17(01)]

45. USFH briefed members on the legislative proposals for strengthening regulation of private healthcare facilities ("PHFs") ("the PHF legislative proposals"), details of which were set out in the Administration's paper (LC Paper No. CB(2)845/16-17(01)).

46. Members noted the background brief entitled "Legislative proposals for regulation of private healthcare facilities" prepared by the LegCo Secretariat (LC Paper No. CB(2)859/16-17(10)); and a submission on the proposal.

Types of PHFs to be regulated

47. Mr SHIU Ka-fai sought clarification as to whether beauty centres would be subject to regulation under the PHF legislative proposals. USFH advised that the new regulatory regime for PHFs would cover hospitals, day procedure centres, clinics, and health services establishments. For day procedure centres, they were referring to premises that were used for carrying out, in an ambulatory setting, those medical procedures of higher risks to be set out in a schedule to the relevant bill. Ms Alice MAK asked whether the use of a medical device for beauty purposes would be a factor to be taken into consideration in deciding whether a premises should be regarded as a day procedure centre. USFH replied in the negative.

48. Dr Pierre CHAN expressed support for the direction of strengthening regulation of PHFs. Noting that those high-risk medical procedures that could be performed in day procedure centres would be set out in a schedule to the relevant bill, he considered that any amendments to the schedule should be subject to the positive vetting procedure under section 35 of the Interpretation and General Clauses Ordinance (Cap. 1) such that Members would have sufficient time to examine the amendments.

49. Head, Healthcare Planning and Development Office, Food and Health Bureau ("H(HPDO)") advised that the Administration's intention was for the relevant schedule be subject to the negative vetting procedure under section 34 of the Interpretation and General Clauses Ordinance, as this would facilitate amendments more efficiently when regulatory need arose so as to safeguard public health. That said, the Administration would consider any views that members might have in the bills committee to be set up to scrutinize the relevant bill.

Action

50. Noting that it was proposed that those private clinics which involved only solo or small group practice, say, operated by not more than three/four/five registered medical practitioners or registered dentists, would be exempted under the new regulatory regime on PHFs, Dr Helena WONG sought information about the number of private clinics involved.

51. Head, Office for Regulation of Private Healthcare Facilities, DH ("H(ORPHF)") advised that DH was conducting a survey in this regard. According to the preliminary data, there were around 6 000 medical and/or dental ambulatory facilities in Hong Kong. Around 70% of the medical and/or dental clinics were small practice clinics being operated by not more than three registered medical practitioners or registered dentists. The corresponding figure would be increased to around 80% if those clinics being operated by four to five registered medical practitioners or registered dentists were included into the calculation. In response to Mr SHIU Ka-fai's enquiry as to whether day procedure centres operated by less than three registered medical practitioners would likewise be exempted under the new regulatory regime on PHFs, USFH replied in the negative.

Admin

The Chairman requested the Administration to provide in the LegCo brief on the bill the information sought by Dr Helena WONG and the estimated number of day procedure centres performing high-risk medical procedures in the territory.

52. Mr Tommy CHEUNG noted that the new piece of legislation for implementing the new regulatory regime for PHFs, if enacted, would repeal, among others, the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165). He sought explanation as to the reason why nursing homes providing care for elderly persons, which were currently registered under the above Ordinance, would not be regulated under the new regime for PHFs.

53. H(ORPHF) advised that residents of these registered nursing homes did not require continuous and round-the-clock medical care. The great majority of them received treatment from visiting medical practitioners and/or dentists when needed. Hence, these nursing homes for the elderly were not medical facilities and should not be regarded as such under the new regulatory regime. Under the PHF legislative proposals, these nursing homes would be transferred to be regulated under the Residential Care Homes (Elderly Persons) Ordinance (Cap. 459) and its subsidiary legislation.

Action

Regulatory standards for PHFs

54. Dr Pierre CHAN called on the Administration to ensure that the regulatory standards for clinics to be drawn up by DH and the Hong Kong Academy of Medicine would not be pitched at such a high level that clinics of small and medium sizes would find it difficult, if not impossible, to comply with. USFH assured members that the Administration would consult the stakeholders including, among others, registered medical practitioners in private practice in the drafting of the regulatory standards for clinics.

Proposed requirements on licensee and chief medical executive of a PHF

55. Mr POON Siu-ping expressed support for the direction of strengthening regulation of PHFs. Noting that the licensee of a PHF would be required to appoint a chief medical executive to take charge of the day to day administration of the facility, he asked whether the licensee and the chief medical executive had to be two separate persons. USFH advised that for private hospitals, the licensee and the chief medical executive had to be different persons. This requirement did not apply to other PHFs.

Proposed requirements on complaints management

56. Referring to the two-tier complaints management system to handle complaints against PHFs to be regulated under the new regime, Ms Alice MAK asked what would constitute unresolved complaints at service delivery level for taking up by the independent Committee on Complaints against PHFs ("Complaints Committee"). USFH advised that under the proposed two-tier complaints management system, the first-tier should be at the service delivery level at which PHFs should manage complaints at source. Complaint cases which could not be resolved at the first-tier level would be handled by the Complaints Committee which would make recommendations to the Director of Health on whether the complaint (or a part of the complaint) was substantiated or not. Dr Pierre CHAN considered that an appeal mechanism should be put in place under the complaints management system. H(HPDO) responded that the second-tier Complaints Committee could provide an appropriate check and balance.

57. Mr SHIU Ka-fai noted that it was proposed that at least half of the members of the Complaints Committee would be lay persons. Expressing concern about whether representatives from the beauty sector could serve as lay members of the Complaints Committee, he sought elaboration on the sectors these lay persons would be belonged to. H(HPDO) advised that the

Action

lay members had to be persons who were neither registered medical practitioners nor registered dentists. The Administration's initial thought was that these persons might include representatives from patients groups and the Consumer Council, as well as members of other professions or business sectors.

Proposed requirements on price transparency

58. Mr POON Siu-ping noted that under the PHF legislative proposals, licensees of private hospitals would be required to, among others, put in place a budget estimate system, and publish historical statistics on fees and charges in respect of the treatments and procedures specified by DoH for enhancing price transparency. To try out these price transparency measures, a pilot programme had been rolled out by the Administration, together with the Hong Kong Private Hospitals Association, in October 2016. He sought information about the implementation of the pilot programme. Mr Tommy CHEUNG considered it of utmost importance to expeditiously enhance the price transparency of private hospitals.

59. H(ORPHF) advised that as of December 2016, about 50% of the inpatient admission cases for receiving the specified common and non-emergency operations or procedures were provided with budget estimates before admission. At the suggestion of members at the Panel meeting in November 2016, DH was in the course of developing a webpage to provide the list of common operations or procedures for provision of budget estimates, as well as enabling patients to have convenient access to the historical bill sizes statistics released by private hospitals on their respective websites.

Legislative timetable

60. Mr Tommy CHEUNG expressed concern that according to the 2016-2017 Legislative Programme provided by the Administration to the House Committee (LC Paper No. CB(2)20/16-17(01)), there were four pieces of legislation which the Health Branch of the Food and Health Bureau planned to introduce into LegCo in the remainder of the 2016-2017 legislative session. He urged the Administration to introduce the relevant bill on regulating PHFs into LegCo as early as possible. Mr SHIU Ka-fai expressed a similar view.

61. USFH advised that the Administration planned to introduce the bill into LegCo in the first half of 2017. This apart, it would introduce the bills on amendments to the Chinese Medicine Ordinance and the Medical Registration Ordinance (Cap. 161) in the second quarter of 2017. It also

Action

planned to focus efforts on the legislative exercise for "pre-market control" and "post-market control" of medical devices, while the part on use control for selected medical devices would be revisited later.

Way forward

62. Mr Tommy CHEUNG suggested the Panel to invite stakeholders to give views on the PHF legislative proposals. Ms Alice MAK considered it more appropriate for the bills committee to be set up to scrutinize the relevant bill to receive views on the details of the bill. Dr Helena WONG expressed a similar view. Ms Alice MAK requested that a vote be taken on Mr Tommy CHEUNG's proposal. At the request of Mr SHIU Ka-fai, the Chairman ordered that the voting bell be rung for five minutes to notify Panel members of the voting; and that a division would be taken.

63. The Chairman put to vote the question that the Panel should receive public views on the PHF legislative proposals.

The following three members voted in favour of the question:

Mr Tommy CHEUNG, Mr YIU Si-wing and Mr SHIU Ka-fai.

The following six members voted against the question:

Dr Helena WONG, Dr Fernando CHEUNG, Ms Alice MAK, Mr CHU Hoi-dick, Dr Pierre CHAN and Mr Jeremy TAM.

The following member abstained:

Mr POON Siu-ping.

64. The Chairman declared that the question was not supported.

VII. Further discussion on the proposal to amend the health warnings on packets and retail containers of tobacco products

[LC Paper Nos. CB(2)742/16-17(01), CB(2)859/16-17(11) to (14), CB(2)880/16-17(01), CB(2)888/16-17(01) to (02), CB(2)896/16-17(02), CB(2)899/16-17(01) to (03) and CB(2)900/16-17(01) to (05)]

65. USFH briefed members on the supplementary information provided by the Administration on issues raised by members and the deputations in the previous discussions concerning its proposal to amend the health

Action

warnings on packets and retail containers of tobacco products ("the health warning legislative proposal"), details of which were set out in the Administration's paper (LC Paper No. CB(2)859/16-17(12)).

66. Members noted the updated background brief entitled "Proposals to amend the health warnings on packets and retail containers of tobacco products" prepared by the LegCo Secretariat (LC Paper No. CB(2)859/16-17(13)). Members also noted a letter dated 3 February 2017 from Dr Pierre CHAN and 13 submissions on the subject under discussion.

67. While expressing support for the health warning legislative proposal which had been in discussion at LegCo since 2015, Ms Alice MAK called on the Administration to allow the seals on soft pack cigarette packets to partly overlay the areas of the health warning, as was the practice adopted in Thailand. USFH advised that according to paragraph 3(7) of the Smoking (Public Health) (Notices) Order (Cap. 371B) ("the Order"), no health warning and indication of tar and nicotine yields shall appear in such a manner that it was obscured by any affixture to the packet or retail container, the wrapping of the packet or retail container or any affixture to the wrapping of the packet or retail container. The trade might consider using transparent seals on soft pack cigarette packets or making the seal blend in with the design of the space for displaying the brand name.

68. While expressing support for enlarging the coverage of the health warning on the packet or retail container of the tobacco products, Mr SHIU Ka-fai considered that the current proposal to drastically increase the area of the health warning from covering at least 50% at present to at least 85% of the two largest surfaces of the packet or retail container concerned would result in intensification of the trade of counterfeit and illicit tobacco products. This would also amount to unlawful deprivation of intellectual property rights. USFH advised that the tobacco trade could still display the trademark on the remaining areas (i.e. 15% of the two largest surfaces) as well as the lateral surfaces of the packet or retail container in a way that did not alter the distinctive character of the trademark. An increasing number of developed countries had implemented plain packaging. There was no evidence suggesting that increasing the size of health warnings would lead to intensification of illicit cigarette trade.

69. Ms Alice MAK expressed concern that the Administration's proposal to require the indication of tar and nicotine yields to appear on a surface of a cigarette packet and retail container other than the surfaces bearing the health warning would make the information on the tar and nicotine yields to stand out more clearly. This might in turn create misleading perception concerning the health risks of consuming one product as compared to

Action

another. USFH responded that the Administration considered it necessary to retain the indication of tar and nicotine yields to make the public aware of the existence of such substances that were harmful to health.

70. Mr SHIU Ka-fai urged the Administration to provide a response to the various legal questions raised by the trade in their submissions. He expressed dissatisfaction that the Administration did not conduct public consultation on the health warning legislative proposal. USFH advised that the Administration had provided detailed responses to address the concerns raised by members and the tobacco trade in its paper for the meeting. According to a survey conducted by the Hong Kong Council on Smoking and Health, more than 70% of respondents supported increasing the coverage of health warning on tobacco products.

71. Mr SHIU Ka-fai sought explanation from the Administration as to the reason why the proposed amendment to the Order would be subject to the negative vetting procedure under section 34 of the Interpretation and General Clauses Ordinance. Deputy Secretary for Food and Health (Health)2 explained that under section 18 of the Smoking (Public Health) Ordinance (Cap. 371), the Secretary for Food and Health might by order in the Gazette prescribe matters relating to the form of any health warning and any indication of tar and nicotine yields and the manner in which such matters were to be displayed, and introduce the amendments into LegCo for negative vetting.

72. In view of the time constraint, members agreed that discussion of the subject would be continued at the March regular meeting.

VIII. Any other business

73. There being no other business, the meeting ended at 1:30 pm.

Council Business Division 2
Legislative Council Secretariat
20 July 2017