# *立法會*
# *Legislative Council*

LC Paper No. CB(2)2755/05-06
(These minutes have been
seen by the Administration)

Ref : CB2/PL/HS

**Panel on Health Services**

**Minutes of special meeting**
**held on Thursday, 27 April 2006 at 8:30 am**
**in the Chamber of the Legislative Council Building**

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| **Members present** | : | Dr Hon KWOK Ka-ki (Chairman)<br>Dr Hon Joseph LEE Kok-long (Deputy Chairman)<br>Hon Albert HO Chun-yan<br>Hon Mrs Selina CHOW LIANG Shuk-yee, GBS, JP<br>Hon CHAN Yuen-han, JP<br>Hon Andrew CHENG Kar-foo<br>Hon LI Fung-ying, BBS, JP<br>Hon Vincent FANG Kang, JP<br>Hon LI Kwok-ying, MH |
| **Members absent** | : | Hon Fred LI Wah-ming, JP<br>Hon Bernard CHAN, JP<br>Hon Mrs Sophie LEUNG LAU Yau-fun, SBS, JP<br>Dr Hon YEUNG Sum |
| **Public Officers attending** | : | Item I<br><br>Miss Susie HO, JP<br>Deputy Secretary for Health, Welfare and Food (Health)<br><br>Mr Jeff LEUNG<br>Principal Assistant Secretary for Health, Welfare and Food (Health) |

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Dr LEUNG Ting-hung, JP
Deputy Director of Health

Dr Gloria TAM, JP
Assistant Director of Health
(Health Administration and Planning)

Dr Monica WONG Man-ha
Principal Medical & Health Officer
Department of Health

**Deputations/ individual by invitation** : Item I

The Hong Kong Medical Association

Dr SHIH Tai-cho
Vice President

Dr Henry CHAN Hin-lee
Representative

Hong Kong Society of Plastic, Reconstructive & Aesthetic Surgeons

Dr Kenneth HUI
President

Dr C M HO
Council Member

Consumer Council

Mrs CHAN WONG Shui
Chief Executive

Ms Connie LAU Yin-hing
Deputy Chief Executive

Federation of Beauty Industry (H.K.)

Mr IP Sai-hung
Chairman

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Mr IP Wing-keung

Individual

Ms WONG Sin-man

**Clerk in attendance** : Ms Doris CHAN
Chief Council Secretary (2) 4

**Staff in attendance** : Miss Mary SO
Senior Council Secretary (2) 8

Miss Maggie CHIU
Legislative Assistant (2) 4

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**I. Use of PAAG for breast augmentation purpose**
(LC Paper Nos. CB(2)1840/05-06(01) to (04))

Mr Vincent FANG said that discussion on the use of Hydrophilic Polyacrylamide Gel (PAAG) for breast augmentation purpose would be biased if only the medical sector and the Consumer Council, and not the beauty trade, were invited to give views on the matter. Mrs Selina CHOW concurred.

2. The Chairman explained that the reason why he had only invited the medical sector and the Consumer Council, and not the beauty trade, on this occasion was due to the need to hold this special meeting within a very short period in view of the wide public concern over the use of PAAG for breast augmentation. The Chairman expressed his apology for not inviting the beauty trade to give views at the meeting. As it was unlikely that the discussion on the matter could be completed in one meeting, the beauty trade could be invited to give their views at a further meeting.

3. As some representatives of the beauty trade were already present in the public gallery to observe the meeting, Mrs Selina CHOW suggested and the Chairman agreed to allow them to attend the meeting to give views.

4. At the invitation of the Chairman, Deputy Secretary for Health, Welfare and Food (Health) (DSHWF(H)) briefed members on the follow-up actions taken by the Administration in response to the adverse reactions caused by PAAG for breast augmentation, as well as the measures taken by the Administration to prevent similar incidents from happening, details of which were set out in paragraphs

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10-17 of the Administration's paper (LC Paper No. CB(2)1840/05-06(01)). This was followed by a briefing by the Assistant Director of Health (Health Administration and Planning) (AD(HA&P)) on the risk of PAAG to users, details of which were set out in paragraphs 5-9 of the same paper.

Deputations' views

5. Representatives from the following organisations presented their views on the use of PAAG for breast augmentation, details of which were set out in their respective submissions -

(a) Hong Kong Medical Association (HKMA) (LC Paper No. CB(2)1840/05-06(02)); and

(b) Hong Kong Society of Plastic, Reconstructive & Aesthetic Surgeons (HKSPRAS) (LC Paper No. CB(2)1840/05-06(03)).

Consumer Council

6. Mrs CHAN WONG Shui welcomed the measures taken by the Administration to prevent the use of PAAG for breast augmentation, and made the following suggestions to further safeguard consumers' interests -

(a) all materials for injection into the human body should only be performed by registered personnel and that these personnel should be held accountable to some extent for the safety of the materials used for injection into their clients;

(b) misleading or exaggerated claims relating to fat reduction/slimming, detoxification and regulation of the body immune system should be prohibited;

(c) advertisements relating to products and services for beautification purpose offered outside Hong Kong should be regulated. Reference could be drawn from the existing legislation regulating the advertising of real property or land offered for sale or to let in places outside Hong Kong; and

(d) referrals to unregistered doctors for treatment involving invasive procedures, including the use by needle, should be made an offence.

Federation of Beauty Industry (H.K.)

7. Mr IP Sai-hung said that the beauty trade supported the control of the

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import, sale and use of injectionable materials for breast augmentation and other beautification purposes. The beauty trade had never attempted, nor had any intention to perform invasive procedures on their clients. The beauty trade, however, considered it necessary for the Administration to make clear which types of registered personnel were eligible to perform invasive procedures, having regard to the wide-ranging professions covered by the meaning of registered personnel. Mr IP further said that the adverse reactions caused by the use of PAAG for breast augmentation could be avoided if doctors were allowed to advertise their services. Not only would this enable consumers to make an informed decision if they opted to undergo breast augmentation and other plastic procedures for beautification purpose, the beauty trade could avoid being used as a front for luring the public to undergo the procedures. He considered it regrettable that all fingers were pointing at the beauty trade for the use of PAAG for breast augmentation, with calls for the beauty parlours to be regulated to prevent incidents similar to the adverse reactions caused by PAAG from recurring. Mr IP also hoped that the Administration would first liaise with the beauty trade before announcing to the public that some skin care and cosmetic products contained polyacrylamide (PAA), a major component of PAAG, so as to enable the trade to better deal with enquiries from their clients.

8. Mr IP Wing-keung urged that the use of medical devices for beautification purpose should not be restricted to medical personnel, as to do so would adversely affect the livelihood of over 100 000 people working in the beauty trade.

Discussion

9. Mrs Selina CHOW noted from paragraph 13 of the Administration's paper that some 50 bottles of substance suspected to be containing PAAG were seized by the Customs and Excise Department (C&ED) in a beauty parlour on 13 April 2006, and that prosecution under the Trade Descriptions Ordinance (Cap. 362) was being considered. Mrs CHOW asked for the reason for such seizure, given that the import and use of PAAG was presently not subject to any direct regulation under existing legislation. Ms LI Fung-ying raised similar query.

10. AD(HA&P) responded that the seizure of the some 50 bottles of substance suspected to be containing PAAG in a beauty parlour by C&ED on 13 April 2006 was made in response to some breast augmentation advertisements containing a claim that PAAG had been registered for clinical use with the Department of Health (DH). AD(HA&P) further said that as of to date, the DH had received a total of 224 telephone enquiries. Of the 119 who said they had received PAAG injection for breast augmentation, 51 said that they had experienced adverse reactions. As it was suspected that illegal medical practice was involved in three cases, DH had referred them to the Police for follow-up action. DH had also

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referred one case involving professional misconduct by a doctor to the Medical Council of Hong Kong (HKMC) for action.

11. Responding to Mrs Selina CHOW's enquiry on whether the medical sector had carried out any investigation about the involvement of doctors in the use of PAAG for breast augmentation, Dr SHIH Tai-cho of HKMA said that if a doctor was found to have used PAAG for breast augmentation, he/she would be subject to disciplinary action by the HKMC.

12. Dr Joseph LEE said that the absence of any regulation on the use of PAAG for breast augmentation should not be an excuse for doctors and the beauty trade to use PAAG for breast augmentation because doctors should well understand the health hazards of PAAG and the beauty trade that they were not qualified to perform invasive procedures like PAAG injection. Notwithstanding, Dr LEE considered it necessary for the Administration to expedite the regulation of medical devices, as the current listing of medical devices had proved to be far from effective in protecting public health. In the meantime, the Administration should step up its work on educating the public about the safety and effectiveness of medical devices.

13. Mr Andrew CHENG considered the Administration's plan to introduce legislative amendment to control the import of PAAG not going far enough to protect public health, and asked whether consideration could be given to banning the use of PAAG for breast augmentation until more knowledge of the long-term effect of its use on humans was known, as suggested by the HKMA. Ms LI Fung-ying, Mr Vincent FANG and Mr LI Kwok-ying expressed similar view. Mr CHENG further asked whether the Administration had any plan to regulate all orally-consumed products and implant materials for beautification purpose. The Chairman also asked the Administration to respond to two other suggestions made by the HKMA, namely, all invasive procedures, including the use of needle and equipment such as laser, should be done by trained doctors, and all materials for injection or implantation into the human body must be registered and that the burden of proof of their safety should be placed on the manufacturers.

14. DSHWF(H) responded as follows -

(a) the control of the import of PAAG could prevent the use of PAAG for breast augmentation, as the ability of DH to trace where PAAG was sold by importers could deter people from using the substance for breast augmentation;

(b) there was a need to tackle the problem of using PAAG for breast augmentation swiftly, and introducing a legislative amendment to control the import of PAAG was the fastest way to achieve it;

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(c) to ban the use of PAAG for breast augmentation might require the enactment of a new piece of legislation, the legislative process of which would entail a much longer time than the introduction of a legislative amendment to control the import of PAAG;

(d) in view of the public concern about the safety of medical devices in the wake of the PAAG incident, the Administration was actively considering expediting the implementation of a statutory system of registration and would accord priority to the regulation of medical devices with higher risk. Views of the relevant trade would be sought by end 2006/early 2007;

(e) another reason for not regulating the use of PAAG was because the decision of how PAAG should be used should best be left to the professional judgement of doctors, as the substance was sometimes used by doctors for dermal filling;

(f) all orally-consumed products containing medicines, regardless of whether they were western or Chinese medicine, were already regulated or being regulated under existing legislation. As regards materials for injection or implantation into the human body, they would be considered under the planned regulation of medical devices;

(g) no decision had yet been made on whether the use of devices, such as lasers and intense pulsed light (IPL) equipment, should be restricted to doctors through legislation if the use of such was for beautification purpose and by personnel who had met the prescribed training requirements; and

(h) effort on educating the public on the safety and effectiveness of medical devices would be stepped up.

15. Dr SHIH Tai-cho was adamant that the Administration should come up with a stance on the use of PAAG, instead of leaving the matter to doctors to decide. Dr SHIH pointed out that although the use of PAAG had been approved by the authorities in the European Union (EU) for dermal filling, PAAG was totally banned for injection into the human body in the United States (US).

16. Mr Vincent FANG urged that in regulating medical devices, due regard should be given to differentiating what were medical devices and beauty devices, as well as those devices which could be used by doctors and the beauty trade in a complementary manner, so as not to hamper the development of the beauty trade.

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Mr FANG also urged the Administration to step up raising public awareness about the risk of novel beauty and slimming procedures to avoid incidents similar to that of the PAAG from recurring.

17. DSHWF(H) noted Mr FANG's views on the regulation of medical devices, and further assured members that work would be stepped up to raise public awareness about the safety and effectiveness of novel beauty and slimming procedures.

18. Mr LI Kwok-ying asked why the use of PAAG was still allowed when it was mentioned in the HKSPRAS' submission that the residual monomer acrylamide in PAAG was toxic to human nervous system and was classified by the International Agency for Research on Cancer as a probable carcinogen.

19. Dr C M HO of HKSPRAS responded that it was very difficult to determine at this stage that the use of PAAG should be banned, as there was no conclusive evidence that a small amount of acrylamide, a residue found during the production of PAA, absorbed by the human body was cancer-causing, and in most instances, the amount of this chemical substance absorbed by humans was in small quantity. For instance, the amount of PAA that could be used in the water treatment in the United States was strictly controlled. Apart from the fact that residues of acrylamide could be found during the production of PAA, this chemical substance was also found in most food cooked at high temperature, such as potato chips. To date, studies had revealed that acrylamide might be carcinogenic but in animals only. The World Health Organisation and many developed countries had therefore stepped up study on the health hazards of acrylamide. Dr HO further said that the reason why HKSPRAS considered it necessary to ban the use of PAAG for breast augmentation was because of the large amount of PAA contained in the PAAG, not to mention that PAAG injected into the body could not be removed completely afterwards and would make diagnosis of breast cancer difficult.

20. Dr SHIH Tai-cho remarked that the explanation given by Dr HO in paragraph 19 above had aptly illustrated the urgent need to enact legislation to regulate medical devices to protect public health. Dr SHIH hoped that the Administration would not drag its feet in regulating medical devices, as the longer it took to implement such, the more financial damage it would cause to the beauty trade. As a result of the free rein over the use of lasers and IPL equipment, there were at present several thousand such equipment being used by beauty parlours in Hong Kong. It was understandable that the beauty trade was very concerned about the adverse financial impact on their businesses if the use of laser and IPL equipment was restricted to trained medical personnel.

21. Mr IP Sai-hung said that the beauty trade disagreed that laser and IPL

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equipment used for beautification purpose should be classified as medical devices and hence the operation of them should be restricted to medical personnel. Mr IP pointed out that a lot of work had been done by the trade and DH in the past two years to strengthen the control on the use of devices like laser and IPL equipment and to facilitate the continued use of such devices by operators with no medical training. A case in point was that an examination developed by the Vocational Training Council to provide an avenue for IPL operators, including beauticians, to obtain accreditation, would be held within this year. Operators would be regarded as trained practitioners if they passed the examination, and certificates would be granted to them. Veteran practitioners might opt for sitting for the examination directly. The ultimate objective was to ensure that IPL operators would have received some forms of training and to enhance better consumer protection. Mr IP reiterated that the only way to stamp out misuse of medical devices was to allow doctors to advertise their services, so as to prevent people from using beauty parlours as a front to attract clients to undergo procedures using these devices.

22. Noting that PAA was also generally used in the manufacture of cosmetic products, Ms LI Fung-ying asked about the measures taken to ensure the safety of the products.

23. Ms Connie LAU of Consumer Council advised that the safety standards of cosmetic products offered for sale in Hong Kong were governed by the Consumer Goods Safety Ordinance (Cap. 456).

24. Miss CHAN Yuen-han asked whether consideration could be given to regulating the import of all materials for injection and implantation into the human body in its forthcoming legislative amendment, apart from PAAG. Miss CHAN further asked about the standards which would be adopted by the Administration in the regulation of medical devices.

25. DSHWF(H) responded that the Administration would consider including other high risk materials for injection and implantation into the human body in its forthcoming legislative amendment, after consulting with the DH. The Administration hoped to introduce the legislative amendment into the Legislative Council (LegCo) within the current legislative session.

26. As regards Miss CHAN's second question, Deputy Director of Health said that the Administration planned to follow the recommendations of the Global Harmonization Task Force, a group formed by representatives from regulatory authorities and medical device industries in the EU and US, etc., by classifying medical devices into four classes based on their risk to patients and users in the future regulation of medical devices in Hong Kong. In fact, the existing medical devices listing system had largely followed such recommendations.

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27. The Chairman opined that it would be more practical for the Administration to expedite the enactment of legislation to regulate medical devices, instead of introducing legislative amendment to control the import of medical devices. The Chairman considered that the time needed to draw up a bill to regulate medical devices should not be too long, as there was already an international framework for controlling medical devices. The Chairman further requested the Administration to take the following actions -

(a) expeditiously regulate misleading or exaggerated claims relating to fat reduction/slimming, detoxification and regulation of body immune system, as well as the advertising of products and services for beautification purpose offered outside Hong Kong; and

(b) implement a licensing scheme for beauty parlours.

28. DSHWF(H) responded as follows -

(a) the Administration could do away with introducing legislative amendment to control the import of PAAG and focus on formulating the legislative proposals to regulate medical devices if so wished by members. However, the introduction of the relevant bill into LegCo would still not be possible within a short time;

(b) as mentioned by the Secretary for Health, Welfare and Food on several occasions, the Administration would review the need to regulate the claims relating to fat reduction/slimming, detoxification and regulation of body immune system, after the registration of Chinese proprietary medicine had largely been completed;

(c) the Administration would examine the feasibility of regulating the advertising of products and services for beautification purpose (if such products and services posed public health threats to the local population) offered outside Hong Kong, by drawing reference from the Broadcasting Ordinance (Cap. 562); and

(d) prior to considering the implementation of a licensing scheme for beauty parlours, it was necessary to sort out whether the objective was to protect public health or consumers' interests.

Conclusion

Admin 29. In closing, the Chairman requested the Administration to revert to members in June 2006 on the scope and contents of the legislative amendment to control the

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import of PAAG and the implementation timetable for the regulation of medical devices.

30. There being no other business, the meeting ended at 10:36 am.

Council Business Division 2
Legislative Council Secretariat
14 July 2006