立法會 Legislative Council

LC Paper No. CB(2)2178/03-04 (These minutes have been seen by the Administration)

Ref: CB2/PL/HS

Panel on Health Services

Minutes of special meeting held on Monday, 22 March 2004 at 8:30 am in the Chamber of the Legislative Council Building

Members present

: Hon Michael MAK Kwok-fung (Chairman) Dr Hon LO Wing-lok, JP (Deputy Chairman)

Hon CHAN Yuen-han, JP

Hon Jasper TSANG Yok-sing, GBS, JP

Dr Hon YEUNG Sum

Hon Andrew CHENG Kar-foo Dr Hon LAW Chi-kwong, JP

Hon LI Fung-ying, JP

Members absent

: Dr Hon David CHU Yu-lin, JP

Hon Cyd HO Sau-lan

Hon CHAN Kwok-keung, JP

Hon Mrs Sophie LEUNG LAU Yau-fun, SBS, JP

Dr Hon TANG Siu-tong, JP

Members

: Hon LEE Cheuk-yan

attending

Hon Fred LI Wah-ming, JP Hon Albert CHAN Wai-yip

Public Officers: Mr Thomas YIU, JP

attending

Deputy Secretary for Health, Welfare and Food (Health)

<u>-</u> 2 -

Mr Jeff LEUNG

Principal Assistant Secretary for Health, Welfare and Food (Health) 1

Mr Freely CHENG

Assistant Secretary for Health, Welfare and Food (Health) 1

Dr T H LEUNG

Deputy Director of Health (2)

Dr Gloria TAM

Assistant Director of Health (Health Adm & Planning)

Dr Monica WONG

Principal Medical & Health Officer (1)

Deputations by invitation

: Hong Kong Chiropractors' Association

Dr Stanley LUM

Education Committee Chairman

Chiropractic Doctor's Association of Hong Kong

Dr FONG Hang Ethic Committee

Hong Kong Doctors Union

Dr WONG Bun-lap Council Member

Tsuen Wan Adventist Hospital

Mr Peter CHUK Kai-cheung Assistant Director of Nursing

Union Hospital

Dr Anthony K Y LEE

Chief Hospital Manager & Medical Director

Hong Kong Medical Association
The Hong Kong Society of Dermatology & Venereology
The University of Hong Kong

Dr Henry CHAN Hin-lee Chairman of the Hong Kong Society of Dermatology & Venereology Associate Professor & Chief of Dermatology of the University of Hong Kong

Hong Kong Dental Hygienists' Association

Ms Betty LEUNG Yin-bik President

Hong Kong Biomedical Scientists Association

Mr LI Wai-chun Secretary

Hong Kong Physiotherapy Association

Ms Polly LAU Mo-yee President

The Hong Kong Ophthalmological Society

Dr Christopher B O YU

Hong Kong Society of Audiology

Mr Ricky WONG Hong Kong Society for the Deaf Audiology Centre in Charge Members of Hong Kong Society of Audiology

The College of Ophthalmologists of Hong Kong

Dr Clement THAM

Hong Kong Association of Medical Laboratory Limited

Mrs Marianne LEUNG Chairman

Consumer Council

Ms Connie LAU Deputy Chief Executive

Mr Brian CHENG Chief Research & Trade Practices Officer

Medical Esthetic Beautician Association

Mr Edmond PANG Kin-man Legal Advisor

Beautiful Locations Ltd.

Mr David YIP Wing-keung President

Hong Kong Beauty and Hair Care Employees Association

Ms Kelly WONG Lai-ye Vice President I

Association of Professional Aestheticians International

Mrs Teresa TSOI Consultant

Federation of Beauty Industry (HK) Ltd

Mr IP Sai-hung Chairman

Better Hong Kong Movement Association

Dr Alexander YUAN Convenor

Hong Kong Hair Dressing and Make-up Trade Workers General Union

Ms WONG Chi-mei

Hong Kong Health & Beauty Business Union

Ms Ivy HO Man-yi Spokesman

Hong Kong Beauty Association

Ms Sandra TSOI Lai-ha

Chairman

Beautisky Int'l Ltd

Mr Jackie CHUNG General Manager

Professional Beauty Instructors Association of Hong Kong

Ms TAM Pui-ling

President

International CICA Association of Esthetics Limited

Ms LUK Wai-fong

Clerk in : Miss Mary SO

attendance Chief Council Secretary (2) 4

Staff in : Ms Amy LEE

attendance Senior Council Secretary (2) 8

I. Meeting with deputations and the Administration

(LC Paper Nos. CB(2)1180/03-04(06) to (09), CB(2)1765/03-04(01) to (21), CB(2)1802/03-04(01) and CB(2)1808/03-04(01))

Briefing by the Administration

At the invitation of the Chairman, <u>Deputy Director of Health</u> (DDH)

briefed members on the salient points of the proposed framework for regulation of medical devices, details of which were set out in the Administration's paper (LC Paper No. CB(2)1180/03-04(06)).

Views of the deputations

2. <u>The Chairman</u> invited the deputations to give their views on the proposed regulation of medical devices, details of which were set out in their respective written submissions (LC Paper Nos. CB(2)1180/03-04(08) to (09), CB(2)1765/03-04(01) to (16), CB(2)1903/03-04(01) and (03) issued on 31 March 2004 and CB(2)1918/03-04(01)) issued on 1 April 2004).

Discussion

- 3. <u>Mr Fred LI</u> asked the following questions -
 - (a) Whether the training of doctors and dentists included the use of laser and intense pulsed light (IPL) equipment or the training of the use of such was limited to dermatologists; and
 - (b) What was the number of complaints received by the Consumer Council on the use of laser and IPL equipment by doctors.
- 4. Responding to Mr LI's first question, Dr Henry CHAN, Associate Professor and Chief of Dermatology of the University of Hong Kong said that medical personnel needed training to use and operate laser equipment. Notably, the professional examinations for becoming a specialist in dermatology in Hong Kong included that on the use of laser equipment. In order to sit for the examination on the use of laser equipment, candidates had to undergo at least 48 hours of hands-on practical sessions with laser equipment and attend 48 hours of Such standards of training were based on those adopted by classroom session. the American Society for Laser Medicine and Surgery. Dr CHAN further said that it was important that the operators of laser/IPL devices were well versed in the study of dermatology. Such training started in the undergraduate teaching of medical schools and most doctors received clinical dermatology training during their post-graduation years. There were now well designed programmes for specialty trainees to receive the appropriate training in these technology before they were accredited to be a specialist and as a rule specialty training in medicine would take six years after completion of not only medical school but also internship.
- 5. As regards Mr LI's second question, <u>Ms Connie LAU of the Consumer Council</u> said that 26 and 14 complaints on laser and IPL treatments were received

by the Consumer Council in 2003 respectively. Amongst them, 28 complaints were associated with complications arising from these treatments. Of these 28 cases, 25 were conducted in beauty parlours and three were conducted in medical clinics. Ms LAU however pointed out that not all complaints on the use of laser and IPL equipment would be lodged with the Consumer Council. For instance, some people would resort to seek recourse from the service providers direct or openly express their dissatisfaction with the media. Ms LAU further pointed out that merely looking at the number of complaints against the improper use of laser and IPL equipment was not a reliable way to assess the risk associated with the use of such devices. In view of the rapidly rising and significant number of people patronising beauty parlours for laser and IPL treatments, Ms LAU hoped that the beauty trade could provide more information to the Government related to the operation of these treatments for the development of better training for the operators of laser and IPL equipment. Such information should include, say, the types of laser and IPL equipment being used by the beauty parlours, the number of beauty parlours offering laser and IPL treatments and the number of people engaged in the use and operation of laser and IPL equipment in the beauty parlours. Ms LAU added that the proposed regulation of medical device by the Government was not triggered by the Consumer Council, as alleged by some deputations. Government first unveiled its plan to regulate medical devices in May 2003, whilst the publication by the Consumer Council on the improper use of laser and IPL devices in its "Choice Magazine" was in December 2003.

- 6. Mr Fred LI further asked about the percentage of revenue of the beauty trade generated by laser and IPL treatments, and the number of personnel engaged in performing such treatments. Mr LI also sought the views of the beauty trade on the proposal to set up a licensing system to restrict the possession of class 3B and 4 lasers and to limit their use to only doctors and dentists.
- 7. Mr IP Sai-hung of the Federation of Beauty Industry (Hong Kong) responded that it was difficult to provide an exact figure on the number of personnel in the beauty trade engaged in the operation of laser and IPL equipment. Mr IP surmised that the number could be in the region of several thousands, having regard to the number of such devices being sold to the beauty parlours. Mr IP further said that although he did not know the percentage of revenue of the beauty trade generated by laser and IPL treatments, it had become apparent that these treatments were fast becoming the dominant source of income for the beauty parlours. The average cost per treatment ranged between \$2,000 and \$3,000, and a full course of treatment ranged from over \$10,000 to \$20,000 on average. On the Government's proposal to set up a licensing system to restrict the possession of class 3B and 4 lasers and to limit their use to only doctors and dentists, Mr IP said that this should not be a major concern of the beauty trade as only a small number of beauty parlours possessed class 3B laser and the number of beauty parlours

possessing class 4 should be negligible. Nevertheless, <u>Mr IP</u> was of the view that the proposed regulation of medical devices would affect the beauty trade given the wide definition of what would constitute a medical device. If the Government's intent was to restrict the use of class 3B and 4 lasers to the medical personnel, then its regulation should only target at such devices.

- 8. Mr Fred LI expressed concern that there was no mention in the Administration's paper on the implication of the proposed regulation of medical devices on the beauty trade, and requested that this be done.
- 9. <u>Mr LI Cheuk-yan</u> expressed concern that consumers would suffer a lack of choice and high fee if the possession and use of class 3B and 4 lasers were limited to only doctors and dentists. <u>Mr LI</u> further said that he disagreed with the medical sector's view that a medical personnel was more qualified than non-medical personnel who nevertheless had undergone recognised training to use and operate laser and IPL equipment.
- 10. <u>Dr Henry CHAN</u> gave the following reasons why the medical sector considered it necessary that the use and operation of high powered lasers and IPL equipment should be by qualified doctors and/or dentists or their authorised persons -
 - (a) Doctors and dentists specialists in the relevant field were best equipped to diagnose disease and offer treatment options other than laser. For instance, patients with skin cancer should be treated with excision rather than laser;
 - (b) Doctors and dentists specialists in the relevant field were also best equipped to determine the clinical end point achieved by laser and IPL equipment. For instance, dermatologists would be able to assess the appropriate clinical end point achieved by a laser device designed for the treatment of the skin conditions. This was important, as excessive energy could lead to inappropriate end point thus giving rise to complications such as permanent scarring;
 - (c) Laser surgery, similar to other forms of surgical procedure, was associated with known complications. Medical and dental specialists in the relevant field would be able to detect and manage the complications in a competent manner. This would in turn lead to a better clinical outcome and reduce the morbidity associated with the complications;
 - (d) Inappropriate observation of laser safety when using class 3B and 4

lasers could lead to blindness, burn injury and even fire; and

- (e) Clients seeking laser/IPL treatment from medical/dental practitioners were better safeguarded, as the latter were subject to professional regulations and codes of practice and had purchased professional indemnity.
- 11. Mr LI Cheuk-yan was not convinced by the reasons given by Dr CHAN in paragraph 10 above, as evidenced by fact that three complaints against improper use of laser/IPL equipment by doctors were received by the Consumer Council last year. Mr LI pointed out that given the number of laser/IPL treatments performed by beauty parlours (about 500 000 as indicated by some deputations), 25 cases against the improper use of laser/IPL devices by beauty parlours recorded last year were on the low side comparing with similar cases against doctors.
- 12. <u>Dr Henry CHAN</u> responded that the small number of complaints against beauty parlours on the use and operation of laser/IPL devices was because estheticians generally used a very low power on their clients for fear of any complications. This could explain why clients would not see any results for, say, hair removal, despite underwent up to a dozen treatments.
- 13. <u>Miss CHAN Yuen-han</u> urged the Administration to make clear to the beauty trade whether its personnel could continue to use and operate laser and IPL equipment for beauty treatment, such as hair removal and skin rejuvenation, under the proposed framework; if so, under what conditions would they be permitted to do so. <u>Miss CHAN</u> also urged the Administration to assume an active role in the working group to be formed with representatives from the medical professions, beauty trade and concerned groups to implement the recommendations on the control and use of selected medical devices. <u>Miss CHAN</u> pointed out that as the Administration only provided secretarial support to the Chinese Medicine Council of Hong Kong, numerous disputes on the regulation of Chinese medical practitioners had sprung up.
- 14. <u>Ms LI Fung-ying</u> asked whether the Administration had assessed the impact of the proposed regulation of medical devices on the beauty trade and whether a transitional period would be given to allow the affected personnel to undergo recognised training. <u>Ms LI</u> further said that she could not see why non-physicians should be allowed to operate and use laser/IPL devices under the authorisation of doctors/dentists, whereas this should not be the case for people working in the beauty parlours who had undergone recognised training.
- 15. <u>Dr YEUNG Sum</u> suggested the setting up of an examination system to test whether non-medical personnel could operate and use the medical devices before

allowing them to use such devices on humans. In the light of concerns expressed by deputations on the adverse impact of the proposed regulation of medical devices on their business, <u>Dr YEUNG</u> was of the view that the Administration should further distinguish what were medical and beauty devices.

- 16. <u>Dr LO Wing-lok</u> was of the view that in order to strike a balance between safeguarding public safety and the development of the beauty trade, the Administration should clarify what procedures would constitute medical and beauty procedures. <u>Dr LO</u> disagreed with the views that non-medical personnel should be allowed to perform procedures best delivered by medical professionals if the former had received training on the operation and use of the medical device for the reasons already given by Dr CHAN in paragraph 10 above. <u>Dr LO</u> hoped that members, in respecting the views of the minority, would not loose sight on the views of the majority who welcomed the regulation of medical devices to safeguard their health and safety.
- 17. Having regard to the views made by members and the deputations, <u>Deputy Secretary for Health</u>, <u>Welfare and Food</u> (DSHWF) said that the proposed regulatory framework was aimed at safeguarding the health and safety of patients, users and public on the one hand, whilst ensuring continued access to new technologies on the other. The regulatory controls should be proportional to the level of risk associated with the medical devices. At the same time, the regulatory control should not place an unnecessary burden on regulators or on the trade and industry, nor deter the introduction of new products that would benefit the public.
- 18. <u>DSHWF</u> clarified that it was not the Administration's intention to use the proposed regulation of medical devices to regulate a particular trade or to shift any services now provided through the use and operation of medical devices from one sector to another. <u>DSHWF</u> pointed out that as a first step, the Administration planned to implement an administrative control system in order to facilitate the transition to long-term statutory control. The administrative control would pave the way and lay the foundation for the legislative system. Manufacturers, importers and local representatives were invited to list their medical devices on a voluntary basis. The listing would be made public for consumers' reference. An adverse incident reporting system for medical devices would also be set up. The Administration would consider all the views expressed by deputations and members in drawing up the administrative control system.
- 19. <u>DSHWF</u> further said that the Administration would see to it that the proposed regulation of medical devices would not undermine the business or the development of the beauty trade. The Administration's thinking was that beauty parlours should be allowed to continue to use certain high risk medical devices

they presently possessed, provided that their personnel had received recognised training to use and operate such devices. <u>DSHWF</u> also said that the Administration would consider liaising with the Vocational Training Council in providing training programmes for people working in the beauty trade with a view to raising their standards in using medical devices.

- 20. On closing, the Chairman requested representative of the Hong Kong Medical Association to provide additional information on the training required to operate and use high risk medical devices. The Chairman also requested the Administration to provide a written response to the views expressed by deputations and members.
- 21. There being no other business, the meeting ended at 10:46 am.

Council Business Division 2
<u>Legislative Council Secretariat</u>
27 April 2004