

Written Submission on Regulation of Medical Devices (for use at the special meeting on 22nd March 2004)

Medical Esthetic Beautician Association

Dear Mr. Chairman and members of LegCo Panel on Health Services,

The Association at present has a membership of about 450, consisting of corporate members and employees from beauty and cosmetics industry. Amongst our corporate members, most of them provide Laser and Intense Pulsed Light (“IPL”) beauty treatments to their customers.

After reading the Consultation Document of the Regulation of Medical Devices and attending some forums convened by Department of Health (“DH”) and the Electrical and Mechanical Services Department (“EMSD”), we sensed that the government, by claiming to protect the safety of consumers, attempts to restrict non-medical professionals to operate Laser/IPL equipment. Worse still, many organisations and associations representing the interests of medical professionals, after the consultation document was published, disseminated messages to the general public that it is dangerous to let non-medical professionals to operate Laser/IPL equipment. For this reason, they requested the government to make legislation to prohibit non-medical professionals to operate these kinds of equipment. As far as our members know the personnel in the working group responsible for conducting the consultation and the making of legislation are from the DH and the EMSD only. The government did not invite representatives from the beauty and cosmetics industry (the “Industry”) to participate in the working group. Our members fear that in the coming consultation period, the government will only listen to medical professionals’ voices and disregarding opinion from the Industry. As it would have a long term effect and impact on the Industry, the Association represents our members to submit their view towards this matter.

We stress that our members have no objection to regulate the qualification and standard of the Laser/IPL equipment operators. Nevertheless, the pre-requisite is not to set unreasonably high requirements that the practitioners in the Industry can not meet. Meanwhile, we request to have representatives from the Industry to participate in the working group for making regulations, setting requirements, and sitting in the examination board. The number of seats in the working group should be at least the same number as the medical professionals have.

The following points are our members’ view on Laser/IPL equipment operated by medical professionals and non-medical professionals:-

	Laser/IPL equipment operated by medical professionals	Laser/IPL equipment operated by non-medical professionals
1. Safety of consumers		
Experience	Most of them started providing IPL beauty treatment only one year ago. Their experience in operating IPL equipment is much less than the IPL operators in the Industry. For providing Laser beauty treatment, medical professionals and non-medical professionals are more or less the same.	Most of them started providing IPL beauty treatment 2 to 3 years ago. They have abundant experience from operating Laser/IPL equipment on clients during these years. For providing Laser beauty treatment, medical professionals and non-medical professionals are more or less the same.
Knowledge of Laser/IPL beauty	When medical students studied at medical schools, they were not taught about beauty knowledge. The medical schools did not train students how to operate Laser/IPL equipment. Besides, not every medical professional is dermatologist. As such, it does not mean that we let only medical professionals to operate Laser/IPL equipment connote the meaning of safety to consumers.	All practitioners in the Industry have basic knowledge of providing beauty and skin care treatment and how to handle an incident in which skin has abnormal reaction after beauty and skin care treatment. They would take international recognised beauty courses to upgrade their knowledge, enhance their skill and keep practising. Furthermore, in the Industry, there is a common practice that only an experienced beautician with adequate training and practice, and passed her employer's test for operation of Laser/IPL equipment, can operate an Laser/IPL equipment.
Supplier to provide training	The operation manual and information of Laser/IPL equipment are provided by its manufacturer and/or supplier. Some suppliers told our members that doctors only study the operation manual themselves and would not take any course provided by the supplier.	The operation manual and information of Laser/IPL equipment are provided by its manufacturer and/or supplier. The employers would arrange their Laser/IPL operators to attend the courses provided by the supplier.
Laser/IPL treatment is an act for beauty, not an act for medical treatment	Laser/IPL treatment is not a surgical operation. Consumers undergo Laser/IPL treatment in hospital/clinic would not get pleasure and relaxation senses.	Laser/IPL treatment is a beauty treatment. Consumers want to get from a Laser/IPL treatment not only the result of the treatment, but also the pleasure and relaxation senses to them during the course of treatment which they could not enjoy in hospital/clinic.
Risk	The risk of performing Laser/IPL beauty treatment is very low. Besides, provision of Laser/IPL treatment, is not the main business of a hospital, a clinic or a doctor. Lost of reputation on the quality of Laser/IPL treatment would not give harmful impact on their revenue. Therefore, it is possible that some	Nowadays, the main source of income in the Industry is earning from providing Laser/IPL treatment. If a consumer were injured, the reputation of the beauty parlour would be damaged and the income would definitely be affected. Hence, they would handle each Laser/IPL treatment with extremely care.

	<p>medical professionals might not pay attention to every Laser/IPL treatment, accident might easily happen.</p> <p>For the above reasons, one can see that a medical professional, without knowledge of dermatology and training on operating Laser/IPL equipment on consumers, would not be safer than a well-trained non-medical professional.</p>	<p>One can see from the above, an experienced and trained beautician is able to provide safe Laser/IPL treatment on consumers.</p>
2. Protection for injured consumers	<p>Since medical professionals are not bound to take out professional negligence insurance for their patients, the injured consumers would not get extra protection from medical professionals.</p>	<p>The employers in the Industry would take out a public liability insurance to cover treatment risk. Injured consumers may also claim compensation against the Laser/IPL operator and her employer.</p>
3. Choice Magazine's Report (15.12.03)	<p>The report quoted a complaint from a consumer after receiving several IPL treatments in a clinic.</p> <p>However, the report did not provide the cardinal number of Laser/IPL treatment which medical professionals and non-medical professionals did.</p> <p>We believe that the number of times which medical professionals underwent Laser/IPL treatment were less than one-tenth of the Industry in the last year.</p>	<p>The report also quoted complaints from consumers after receiving Laser/IPL treatment in beauty parlours.</p> <p>The report mixed up the complaints about the services provided and the charges of the treatments instead of separating the injured consumers' complaint. The report did not give a fair analysis to the public.</p> <p>We estimate that Laser/IPL equipment operators had done over hundred thousand Laser/IPL treatment last year.</p>
4. Whole Industry be responsible for one single incident?	<p>Medical professionals providing Laser/IPL treatment on consumers also had accidents before. Does that mean, no doctor is allowed to provide Laser/IPL treatment because of other medical professionals' fault?</p>	<p>In fact, only a few accidents happened arising from Laser/IPL treatment. Therefore, the government should not prohibit trained non-medical professionals to operate Laser/IPL equipment.</p>
5. Upsurge in unemployment rate	<p>The medical professionals - doctors – can continue to practise in their professional, should they want to quit of beauty industry any time in the future.</p>	<p>The non-medical professionals – Laser/IPL equipment operators – will become unemployed.</p>
6. Impede local investment	<p>At present, most of the medical professionals provide Laser/IPL beauty treatments only and do not provide other kind of facial treatments. Thus the contribution towards investment in Hong Kong is not as much as the Industry did.</p>	<p>During these years, Laser/IPL treatments are very prominent and yielding more money for people to expand their businesses. As a result of the expansion, it creates many job opportunity for Hong Kong citizens, especially for the young. Due to the uncertainty of this matter, our members and most proprietors in the Industry slow down the paces of expansion to see the</p>

		<p>development and outcome of the consultation. This would affect the job opportunity for the public and our economy.</p> <p>The flourishing of the Industry can stimulate internal expenditure, create more job opportunity. And the trend in the Industry is that all future advanced beauty equipment will apply advanced light energy. Preventing non-medical professionals to operate Laser/IPL equipment or other advanced devices would impede the Industry's marching towards high technology beauty service era.</p>
7. Resources wrongly allocated	<p>The government using taxpayers' money is to educate a medical student to become a doctor, not a beautician. Providing Laser/IPL beauty treatment by doctors is a commercial act and is not a medical behaviour. As such, it is not right to request the government to make regulations to prohibit non-medical professionals to operate Laser/IPL equipment, letting the medical professionals monopolize the Laser/IPL beauty services. Medical professionals' mission is to cure people of disease, sickness, injury not to provide beauty treatment.</p>	<p>The practitioners get entry to the Industry by starting as beautician trainees, many with certificates of international recognized beauty courses. They, without the assistance of the taxpayers' money, spent their leisure time and savings to study beauty courses with a view to paving their way to become a professional, though not a medical professional, Laser/IPL equipment operator. It is unfair and unacceptable for our society to make laws to deprive the rights of those aspiring beauticians.</p>
8. Transparency of handling complaint organization	<p>Medical Council of Hong Kong The council will not reveal the figures of complaints about Laser/IPL treatment it received.</p>	<p>Consumer Council It will publish the figures of complaints about Laser/IPL treatment it received.</p>
9. The Government's control	<p>Almost every personnel in the Department of Health are medical professionals. We suspect the independency of the government when making the law and regulations.</p>	<p>If representatives in the Industry have half number of seats in the regulatory body and examination board, our members will not object the making of such regulation. Otherwise, we suggest a self-regulatory system should be envisaged and manage by members of the Industry. In fact, members of the Industry have formed a working group for this purpose.</p>
10. Conflict of Interest	<p>At present, many private hospitals and doctors in private practice provide Laser/IPL treatment. It seems to us that some medical professionals requesting for a piece of legislation to protect their own interest but not for the consumers' interest.</p>	<p>The practitioners in the Industry have never objected medical professionals to enter the Industry, as this is common in the commercial world. However, it is unfair and reasonable that some medical professionals by relying on their influential power over the government despotize us in order to monopolize the advanced technology beauty industry.</p>

<p>11. Deprivation of the consumers' right of choice</p>	<p>At all times, Laser/IPL beauty treatments are for beauty purpose only. If non-medical professionals are forbidden to operate Laser/IPL equipment, consumers will have to go to hospital or clinic to undergo beauty treatment.</p> <p>Regarding the price of Laser/IPL treatments, medical professionals' charge is 40% higher than the usual price in the Industry and the price is not flexible.</p>	<p>Receiving Laser/IPL treatment at beauty parlours, the practitioners would provide extra skin cleaning and mask to consumers before and after treatment but hospital/clinic would not provide such services.</p> <p>Flexible charges in the Industry ranging from \$800 – 1,800.</p>
<p>12. Difficulty to carry on</p>	<p>As a result of the proposed registration system, the operating costs of hospitals/clinics will increase a lot but they can afford to pay the extra costs.</p>	<p>According to the definitions stated in the consultation document, almost every beauty equipment and instruments (for examples infrared slimming light devices, slimming massage devices, ultra sound facial devices, electro muscle stimulators, macular needles etc.,) will become medical devices which would not be found in the hospitals/clinics.</p> <p>Many beauty parlours are small businesses. In order to lower the operating costs, owners of beauty parlours usually go to the mainland and other countries to buy cheap but with good quality beauty equipment for their business. Should the proposed regulation be implemented, they will become importers of medical devices. They need to register their status, ask the manufacturer or its agent for product confirmation, envisage and manage labelling and product recall system, submit a list of imported medical devices of Class II and above annually.</p> <p>At present, many manufacturers of beauty equipment, especially in the Mainland, do not prepare technical documentation and clinical evaluation/trial data. This complicated procedures and requirements causing owners of beauty parlours difficulties to import good and cheap beauty equipment from the Mainland for their own use. Consequentially, consumers' right to enjoy cheap and good quality beauty services is deprived.</p> <p>There are many kinds of beauty equipment which are within the definition of medical device. The owners need to register a lot</p>

		<p>of items under the proposed regulation. The owners just bought beauty equipment for their own use. They are not selling the beauty equipments in Hong Kong. Because of the proposed regulation, they become importers of beauty equipment. Our members hope that the government would make this category of importers as an exception.</p>
<p>13. Other countries' control</p>	<p>No</p>	<p>Sub-clause 2.10 of page 5 of the consultation document states that except UK and some states of the USA require registration of premises where medical lasers are used and some other states of the USA, and Singapore, require operators of medical lasers must obtain a certificate or a licence from the regulatory authority, other countries do not control the operators of medical devices. The document is silent on whether there is control over the operators of Laser/IPL equipment for beauty purposes in other countries.</p> <p>Why should Hong Kong be the pioneer to make regulation to restrict non-medical professionals to operate IPL equipment?</p>