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Subject: Regulatory framework

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Proposed Regulatory Framework for Medical Devices ,LC paper No. CB(2)545/16-17(01)

Thank you for your kind e-mail dated 25 January 2017 inviting our views to the Government's proposed introduction of statutory regulatory framework for medical devices, and to attend the special meeting on 13 February.

In view of the complexity of this issue, we wish to expand on our earlier brief e-mail of 6 February and offer our members' views.

As you may know, ADAM is the largest organisation of Aesthetic Doctors in Hong Kong representing over 180 doctors practising (or interested in practising) in this field.

We fully understand that some stakeholders (ie. people in the beauty industry) are concerned about the impact such regulations would have on their livelihoods. We are concerned too, but patient lives and safety MUST come first above all commercial considerations.

We also understand there is a misconception among some that Lasers and other Medical Devices are safe because they are NON-INVASIVE. This is clearly not the case as the side-effects of such devices can include pain, bruising, burns and permanent scarring or disfigurement.

A more accurate representation is that procedures and devices that do not go beyond the epidermis can generally be considered safe and those below the epidermis can be considered potentially hazardous. (Scarring, for example, occurs when there is injury to the deep dermal layer).

As such, we are in full support of the government's attempts to classify risk, and correlate training according to risk levels.

We support high-risk procedures only being performed by doctors, as we believe they are the only ones qualified to do full medical assessments, know in-depth anatomy, identify relative and absolute contraindications, personalise treatment and handle complications should they arise (as well as know when NOT to treat, which is as important as when to treat).

We also support that non-medical personnel can be trained to operate medical device considered moderate-risk, and perform the treatments under the guidance and supervision of a medical doctor (similar to the system that currently exists for clinic assistants).

Beauty spa owners and managers who wish to continue providing these moderate-risk procedures to their clients need only send their therapists to the to-be-recommended government training courses.

We, at ADAM, believe this is the fairest scheme for all stakeholders in the market. It raises the standard of care for the provision, promotion and use of medical devices, avoids a monopoly by any one party and most importantly, provides a much higher level of protection for the public than currently exists.

We commend and fully support the Government in it's efforts to introduce measures to safeguard the public from further incidents as has been sadly seen in recent years.

Dr Edwin Lau
Chairman, ADAM