

Hong Kong Dental Hygienists' Association

Dear Mr. Mak (Panel Chairman),

Re: views on the proposed regulation of medical devices

We are please of being invited and offering the chance to give views on the proposed regulation of medical devices. We have discussed the above issue with our council members of Hong Kong Dental Hygienists' Association. As one of the operators in Hong Kong's dentistry, we definitely support the need to regulate the supply and use of medical devices.

Our responses are as follows:

- 1/ currently, the decision of using any devices is very objective. There is the situation; decision is made depending on the budget and the profit rate. It also means that it put patient's safety in hazard.
- 2/ those un-ethical or non-moral professions could be restricted by setting regulation. It will guarantee patients to obtain internationally accepted services.
- 3/ by regulate the user of the medical device could protect patients obtaining the appropriate professional services rather than practically operated by any untrained personnel. On the other it will favor patients' need and minimize any negative or unexpected results.
- 4/ Pre-market control is needed which could prohibit any fake and non-standard devices being used in the market. And Post-market control could give us valuable data on that device for further evaluation.

An example in the market: there is a dental device called "Dental Cleaner" which is sold in the market. It is claimed to be made in Germany with rotation 15000 per min and effective on removing the calculus, stains...It costs HK\$100. The salesman showed the audiences that it removed the color printing on a plastic bag and the ages stains on a coin. For a layman, he/she most likely will buy it and use it by himself/herself at home as it is cheaper than scaling or polishing being provided in the dental clinic. Since the device has not been regulated, we will query the mechanism...and we will foresee there is certain hazard being created on tooth tissue.

We are sure that once the regulation on medical device is launched, consumer will be greatly benefited and professional standard will be more utilized.

Thank you for processing the matter!

Yours sincerely,

Betty Leung
President
Hong Kong Dental Hygienists' Association