

(Translation)

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2 February 2007

Miss Mary SO
Clerk to Panel
Panel on Health Services
Legislative Council
8 Jackson Road
Central
Hong Kong

Dear Miss So,

At the meeting of the Legislative Council Panel on Health Services on 19 July 2005, Members discussed the regulation of medical devices in Hong Kong. In light of the discussion, this letter briefs the Panel on the progress of the regulation of medical devices and matters relating to assisting the industry members to prepare for the certification examination.

The Department of Health (DH) has implemented by phases the Medical Device Administrative Control System on a voluntary basis, which includes listing of medium and high risk medical devices; setting up of a reporting system for adverse incidents related to medical devices; safety alert and recall arrangements; and recognition of Conformity Assessment Bodies. DH is consulting the relevant parties on the listing

of local manufacturers and intends to launch the scheme in the first quarter of 2007. Separately, DH will begin the consultation on the listing system for importers of medical devices in due course.

DH is also working with the Efficiency Unit and the Economic Analysis and Business Facilitation Unit on the preparatory work for a regulatory impact assessment. The assessment will commence upon selection of the consultant. The consultant will examine the direct and indirect impact that the proposed regulatory model would have on various stakeholders. In the process, relevant stakeholders will be consulted.

A working group comprising representatives of DH, the Education and Manpower Bureau, the Vocational Training Council (VTC), the Consumer Council, medical practitioners and beauticians, resolved that VTC would provide trade test for operators of Intense Pulse Light (IPL) devices who have not received any professional training in medical care. The objective is to enhance the safety awareness of the operators and reduce the risk caused by improper use of the devices to industry members and consumers. VTC has set up the scope of the test for reference of the candidates. It is understood that training programmes will be run by some organizations to assist operators of IPL devices to pass the trade test. The first trial written and practical tests were conducted in September and November 2006 respectively. VTC will launch the comprehensive trade test in March this year.

Yours sincerely,

(Miss Pamela LAM)
for Secretary for Health, Welfare and Food