



中華人民共和國香港特別行政區政府總部食物及衛生局

Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Our ref: L/M to FH CR6/3921/09 Pt.2

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16 December 2010

Ms Elyssa Wong
Clerk to Panel
Panel on Health Services
Legislative Council
8 Jackson Road
Central

Dear Ms Wong,

Proposed regulatory framework of medical devices

I refer to item 6 of the Appendix VI to LC Paper No. CB(2)/10-11(02). At the Panel meeting held on 8 November 2010, the Administration was requested to provide explanation for not making the purchase of liability insurance against negligence claims arising from the improper use of medical devices a mandatory requirement.

To prevent unnecessary harm or complications arising from the improper use of medical devices, we have proposed control over the use and operation of certain medical devices by those who are not statutorily registered healthcare professionals. It is proposed that the business operators of this group of medical devices should apply for a licence to use the devices and undertake to comply with a set of licensing conditions. For example, the business operators must ensure that the device is operated by trained and competent personnel, who have undergone training and passed the trade test run by reputable institutes such as Vocational Training Council.

Similar to the practice of the registered medical practitioners, liability insurance is not a mandatory requirement. Liability insurance provides protection to the patient/consumer as well as the business operators against whom negligence claims are made. Business

operators should assess the risks of their business, their ability to pay the potential compensation awards and the legal costs of defending the claims, and obtain proper insurance coverage where appropriate.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Estrella', written in a cursive style.

(Estrella CHEUNG)

for Secretary for Food and Health

cc.

DH

(Attn : Dr Heston Kwong)

(Attn : Dr Teresa Li)