Paper No. CB(2)1808/03-04(01)

March 18, 2004

Ms Amy Lee
Senior Council Secretary (2) 8
Legislative Council Secretariat
3/F Citibank Tower
3 Garden Road
Central, H.K.

Dear Ms Lee,

Panel on Health Services
Regulation of Medical Devices

Thank you for your letter of March 5, 2004. While I am unable to attend the special meeting of the Panel scheduled for March 22, 2004, my written submissions are as follows:

1. In principle, I support that there should be control from the Government in use of medical devices in Hong Kong.

2. The suggestion of setting a Conformity Assessment Body (CAB) to carry out product assessment is sound in principle. The classification of I – IV classes is also reasonable.

3. In practice, care must be taken. It is difficult, up to this point, to set up an assessment body for so many medical devices because such work is multi-disciplinary. The workload is anticipated to be large. There should be no conflict of interest in carrying out jobs of the consultants/assessors in assessing the various aspects of the commercial medical devices. For class II – III devices it would be therefore very difficult to set up a workable, fair assessment system up to the present time, so that there is no unreasonable hold up of registration with assessment. It is my personal opinion that overseas countries might encounter such problems.

4. If an assessment system is enforced, many of the products produced in the third world would have to be registered in the "advanced countries" (being sold back to the third world countries) where assessment process is going on and be recognized by the HKSAR Government in order to sell their products in Hong Kong.

5. Is it possible to set up an assessment system in the third world as majority of the users are in the third world; can HK/China play a leading role in this joint effort?

6. Setting up the control system for Class IV medical devices is a must. The number of devices is not too large in this class and they are mainly manufactured in advanced countries where assessment is recognized by our

Government, and it is workable to set up a workable assessment system which can be carried out in Hong Kong.

7. In the meantime, it is urgent that we set up a registration system suggested by the Consultation Document for Class I, II, III, devices and set up a reporting organization for recording officially incidents of complaints, accidents. If unsatisfactory consequences arising from Class I, II, III devices, we must be able to trace back the producers and the operating companies for action if necessary. Class IV device has its own entry stated in (6).

8. In my personal opinion, we cannot put all (some is inevitable and advisable) the operational work of medical devices on the shoulders of medical doctors, but a good system as monitored by the Government should be set up to train up the operators (in operating devices) during this transient period while we consider to solve the problems outlined in item (4).

As requested, a soft copy of this letter can be found in the diskette enclosed.

Yours sincerely,

Professor SK Lam
Dean

SKL/LT/al
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Encl.