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11 March 2004

The Hon Michael Mak
Panel Chairman
Panel of Health Services
Legislative Council
Hong Kong Special Administrative Region
of the People's Republic of China
Legislative Council Building
8 Jackson Road,
Central, Hong Kong

Dear Mr Mak

Re : Regulation of Medical Devices

The comments which follow represent the viewpoints of the Hong Kong Private Hospitals Association which has appointed me to represent the Association on this matter as well as my own, being the Chief Hospital Manager and Medical Director of Union Hospital.

First of all, we strongly support the principle of setting up regulatory mechanisms for medical devices in order to protect the public. However we would like to stress the following points:-

1. The GHTF recommendation that the imposition of regulatory controls should not place an unnecessary burden on the regulators or the trade should be underscored, especially with the latter.

2. We totally agree with the notion that assessment of low-risk devices by regulatory authority may not be necessary. The suggestion that the manufacturer can make a declaration that his product is safe and effective in this category is sound and appropriate (P4, 2.7 of Consultation Document).*

   * Similar parentheses in later text refer to the same document.

3. We feel that the chapter on local situation (Chapter 3) genuinely reflects our concerns on the present situation in Hong Kong.

4. As to the proposed framework, the classification according to the risk level of medical devices into four classes, hence ensuring that the level of regulatory

control be more stringent with increasing degree of risk, is accepted. However the definition of risk level has got to be reasonable and clearcut. We would welcome information on the list of devices included in the survey conducted by EMSD in early 2002 (P12, 4.8) and on how they were being classified as such, i.e. the arbitrarily defined difference between classes I and II and etc.

5. Some of the examples quoted in the table on the classification according to risk level may not be appropriate, e.g. surgical drill versus suction pump or transdermal stimulator in level I and II respectively (P11, 4.7). This serves to illustrate the necessity that the classification list is best handled by a body comprising representatives from all the stakeholders, i.e. users, suppliers and regulatory control body.

6. For product registration of Class II or above it would be difficult for the regulatory authority to assess products without overseas approval or certification by a recognized conformity assessment body, due to the lack of quality staff or resources. We can envisage problems with products from countries such as China, Korea and the like which may be a generic model with minor variation of a well proven or assessed product from western countries. We are wondering whether the regulatory authority would consider, as an alternative, assessment or endorsement from the ethics committee of the hospital which intends to 'import' or acquire such a product for its own use (P13, 4.16).

7. We agree with the various requirements for the registration of manufacturers, local representatives and/or importers. However the need to register overseas manufacturer or its local representative for Class II devices (low medium risk) is not evident (P15, 4.26). Probably they should be treated in the same category as Class I products.

8. On the 'Control on use and operation of selected high risk medical devices' we are of the opinion that the requirement should be 'to be operated by trained medical personnel only.' If the devices are intended for medical therapy then it is only appropriate that the personnel to be trained for that purpose should have medical knowledge, e.g. a doctor or a nurse (P16, 4.29). The types of selected devices and the category of trained medical personnel approved to operate them should be determined by the regulatory authority (P16, 4.30). Private clinics owned by individual or group of doctors should be subject to the same control as private hospitals.

9. The transitional measures to implement an administrative control system as outlined in Chapter 6 should be well received. We feel that some current devices being used in hospitals produced or imported by manufacturers or agents which have since become defunct will need special consideration, ? product registration to be exempted (P21, 6.5).

Finally we wish to reiterate strongly that public institutions should come under the same regulatory mechanism as private hospitals and clinics when relevant legislation has been introduced.

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Submitted by :

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