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24th April, 2004

By fax and mail

Panel on Health Services
Legislative Council
Legislative Council Building
8 Jackson Road
Central, Hong Kong
Attn: Ms. Amy Lee
Clerk to Panel

Dear Sir / Madam,

Re: Consultation on Regulation of Medical Devices in Hong Kong

“I will prescribe regimen for the good of my patients according to my ability and my judgment and never do harm to anyone.”

“I will not cut for stone (financial benefits), even for patients in whom the disease is manifest; I will leave this operation to be performed by practitioners (specialists in this art).”

~ *The Hippocratic Oath, Greece, 460-375 B.C.*

Based on part of the “Hippocratic Oath” as stated above, our Union has the following opinion:

1. Most (if not all) medical instruments that carry beneficial effect are also carrying side-effects.
2. No matter how small is the side-effects' magnitude, as far as it is significant, the corresponding medical instrument must be properly controlled.
3. Only a well trained and qualified medical practitioner possesses the essential physiological, psychological and pathological knowledge to *balance the risks and benefits of the medical instrument operation.*
4. Only a well trained and qualified medical practitioner possesses the essential physiological, psychological and pathological knowledge to *explain the risks and benefits of the medical instrument operation to the consumer; in order to obtain an “Informed Consent” medical-legally.*
5. Only a well trained and qualified medical practitioner possesses the essential physiological, psychological and pathological knowledge to *perform the remedial medical actions to minimize the damage from side-effect (may be urgent and life-rescuing).*
6. For the protection of the patients' best interest, *a medical practitioner in Hong Kong is governed by the Hong Kong Medical Council and his/her belonging Specialty Board.*

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7. For the protection of the patients' best interest, *most medical practitioners (> 97%) in Hong Kong are practicing with his/her professional indemnity insurance.*
8. According to the information from the Consumers' Council, the number of complaints from the operation of medical instruments by non-medical personnel is increasing rapidly and this is only the tip of an iceberg.
9. In view of all the above, our Union suggests the followings:-
 - A. A proper control on the operation of medical instrument is necessary;**
 - B. The earlier the implementation of proper control is better;**
 - C. All "High" and "Medium" risk medical instruments must operate only under the supervision of a medical practitioner;**
 - D. The low risk medical instrument can operate under well trained and qualified non-medical persons;**
 - E. The training of non-medical persons must be provided by medical practitioners specialized in the corresponding fields.**

Yours truly,

Dr. Ho Ock Ling
Hon. Secretary
Hong Kong Doctors Union

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