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THE HONG KONG PAEDIATRIC SOCIETY

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(By fax and by post)
15th March 2004

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

Responses of The Hong Kong Paediatric Society to Consultative Paper on Regulation of Medical Devices

The Hong Kong Paediatric Society (HKPS) is a professional body of paediatricians and health care workers who are dedicated to the advancement of child health and care. I am writing on behalf of HKPS to reflect the views and concern of our colleagues, as regards to the captioned subject on regulation of Medical Devices. We would like to emphasize on the following points:

1. The document lost focus on the original issue of regulating the use of high risk equipment by untrained personnel. The definition of high risk should come from consensus of experts in the field. The training should include not just the use of the equipment but the training on understanding of the function of the body and medical knowledge as a whole.

2. We propose the development of a database capturing the complaints related to the use of medical devices so that the Regulatory Board can focus on the appropriate problems.

3. We propose the monitoring of the efficiency of the Regulatory Board making sure that no delay is made in the introduction of new devices to benefit our patients including both the aged and the young.

4. We also propose sufficient investment be made by the Government in developing expertise in the related professions in this area to make the right judgment.

5. For accountability purposes, we propose that the applicants / suppliers of medical devices should be required to make declaration during the registration process to the effect that products under application are identical with those which were approved for marketing in GHTF founding members countries (say at least 2). Hence the onus of proof lies with the applicant / supplier.

6. For regulation and monitoring purposes, once received, a copy of all adverse events, complaints or incident reports must be sent to the regulatory authority. Again, like declaration during registration, the incident reporting process lies with the applicant / supplier and these two processes would ease the burden of the regulatory authority in proving the authenticity and quality assurance of the submitted evidence.

Thank you for your attention.

Yours sincerely,

Dr. William Wong
President
The Hong Kong Paediatric Society