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**THE AMERICAN
CHAMBER OF COMMERCE
IN HONG KONG**

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會

June 16, 2004

The Hon Mr. Michael Mak Kwok-fung
Chairman, Health Care Panel, Legislative Council
Flat 27, 8/F, Hing Wan Commercial Building
25-27 Parkes Street
Jordan, Kowloon

Dear Mr. Mak,

The American Chamber of Commerce in Hong Kong represents the interests of all AmCham companies including a large group of member companies which deal with the supply and service of medical devices and equipment in Hong Kong. These companies are world-renowned top class medical manufacturers, many of which are amongst the Financial Times Global Top 500 companies and the Business Week Global Top 1000 companies. We would like to bring to your attention our position on the regulation and registration of medical devices in Hong Kong.

Based on your review in February of 2004, we understand that the Legislative Council has postponed its deliberation relative to the promulgation of these regulations, we would like to take this opportunity to make you aware of the position paper, which The American Chamber of Commerce submitted in response to the consultation document drafted by the Hong Kong Department of Health. Please find attached herewith a copy of that position paper.

We would also like to propose a meeting with your committee together with representatives from the industry to apprise you of our position on this matter and to address any questions you may have. We would appreciate holding such a meeting prior to the end of this legislative session.

We look forward to hearing from you to arrange a mutually agreeable meeting date.

Sincerely yours,



The American Chamber of Commerce in Hong Kong

Cc: The Hon Mrs. Rita Fan Hsu Lai-tai, GBS, JP

THE AMERICAN CHAMBER OF COMMERCE IN HONG KONG

Position Paper

Department Of Health's Regulation of Medical Devices in Hong Kong

The American Chamber of Commerce supports the regulation of Medical Devices in Hong Kong as contemplated in the Hong Kong Department of Health's Consultation Document issued 4th of July 2003. With regard to the Consultation Document, Amcham recommends that the Hong Kong Government adopt an efficient registration process, which will ensure the standard of the products but require minimum resource expenditure to the government.

Amcham supports such legislation, provided regulations recognize the principles of the General Harmonization Task Force (GHTF). We believe that regulations should be minimal in order to accomplish the task and that such regulations should not require the re-filing of documents which have already been made available in other filings made to GHTF member countries and used for the issuance of registration certificates by such countries.

In this regard we would like to raise the following for consideration:

- The submission of approval evidence from any GHTF country should be sufficient to establish and approve product registration and change of particulars. The submission of a full dossier should not be necessary provided evidence of approval or evidence of permission to sell the device in other GHTF member countries is presented.
- Unless substantial technical changes affecting safety are made to the product, no further approval or re-registration should be required. A self-declaration regarding the changes can be required for submission. If changes need to be reported to any GHTF member country, then such changes should also be reported to Hong Kong authorities. This proposal is in line with international practice and should adequately protect the interests of the public.
- Different devices that are used as part of a system should be allowed to be registered together as one system submission. In this regard, parts, components, peripherals and any items that are used solely with a particular medical device, should be allowed to be registered as part of the initial system registration. New applications, parts, components, peripherals and other items to be used solely with the originally approved system can be required to be recorded through a future self-declaration, forming part of the original system.
- Further consideration needs to be given to the grandfathering of certain classes of medical devices if the devices were legally in commercial distribution before the enactment of the new regulation and no adverse incidents in relation to their use in Hong Kong have been reported.

Labeling of Medical Devices

- Compliance to labeling requirements in GHTF countries should be sufficient for Hong Kong. The name of the manufacturer or importer should be clearly labeled on the product. Such information should provide sufficient detail for consumers or other members of the public to address any issues that might arise from the use of the device.

Post market Control

- If mandatory reporting of serious device problems is to be instituted, then a single government department should have the responsibility of managing that function.
- Once the DOH has issued a license for the registration of a device, such registration and certificate evidencing such registration should be sufficient for use by all Hong Kong bodies requiring submission of documents related to the procurement of the same. In this regard various organizations including the Private Hospital's Association, The Hospital Authority and other professional societies and associations have established device standards. Such standards should be replaced by any new regulatory requirements and such requirements should be deemed sufficient for compliance with documentation needs in all areas. Consolidation of procedural requirements will minimize duplication of tasks and facilitate reduced expenditure at all levels.
- Key stakeholders (e.g. Hospital Authority, Private Hospitals Association, Industry Association, Professional Organizations etc) should be invited to join the Review Committee meeting. This will avoid duplication of product registration or listing and ensure reciprocal recognition.

Implementation

- During the voluntary compliance period the DOH should mandate that no organization may require prior registration as a condition of procurement.
- A differentiation should be made between originally registered devices and those that have been re-sterilized, refurbished or otherwise reprocessed for resale or reuse.
- Official, authorized importers should only be required to be responsible for post market control of products which they import/distribute.
- A grace period and provisional licence should be used during the transition period.