

13 July 2018

The Chairman & Clerk to Panel on Health Services
Panel on Health Services
Legislative Council
Legislative Council Complex
1 Legislative Council Road, Central
Hong Kong

By email

Dear Sirs,

Proposed Regulatory Framework for Medical Devices

The HKAPI represents 39 multi-national companies engaged in the research and development of pharmaceuticals including the world's top 20. As some of our member companies are also involved in the import and regional distribution of medical devices, we would like to take this opportunity to express our views on the Government's latest Proposed Regulatory Framework for Medical Devices.

We would like to reiterate our full support to putting in place a regulatory framework for medical devices that not only protects public health, but would also ensure continued access to the new medical technologies for the benefits of patients. However, it is important to allow sufficient time for the industries to transition from the current voluntary listing to full registration of medical devices.

We agree that medical devices for cosmetic purposes ("cosmetic devices") should be regulated under the same framework as per current international practices. The proposed transitional listing system for "cosmetic devices" which could not fulfil medical device registration requirements should be considered as a temporary measure only.

All in all, we find that the proposal is reasonable and feasible, and we are in particular delighted to see that the registration validity period of medical devices has been proposed to remain as 5 years.



Yours faithfully,

Sabrina Chan

A handwritten signature in blue ink, appearing to read 'Sabrina Chan', is written over a horizontal line. The signature is fluid and cursive.

Senior Executive Director

The Hong Kong Association of the Pharmaceutical Industry

c.c.:

Dr. Terence CHEUNG, Principal Medical and Health Officer, Department of Health,
HKSARG

Ms. Jennifer MAK Kit-shu, Senior Electronics Engineer, Medical Device Control Office,
Department of Health, HKSARG