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To: sc_hsci_dbi@legco.gov.hk
Cc:

Date: Monday, February 25, 2019 07:28PM
Subject: HKDU's Submission Re: Joint Subcommittee Meeting on on 26 February 2019 On Issues Relating to the Regulation of Devices and Development of Beauty Industry

Our Ref.: HKDU/034/2019
25th February 2019

By Hand & Email

Hon. Tommy Cheung Yu-Yan, GBS, JP
Chairman,
Joint Subcommittee on
Issues Relating to the Regulation of Devices and
Development of Beauty Industry,
Legislative Council,
The Government of the Hong Kong Special Administrative Region
Email: sc_hsci_dbi@legco.gov.hk

Dear Mr. Cheung,

**Re: Joint Subcommittee Meeting on on 26 February 2019 On
Issues Relating to the Regulation of Devices and Development of Beauty Industry**

Hong Kong Doctors Union (HKDU) is the unique trade union with doctor members in both public and private services, registered with the Trade Union Registry to look after the interests and rights of doctors in their employer employee relationship. While we are committed to upgrade the standard of medical doctors to cater for the health of the Hong Kong community, we also relate to the Government the urgent needs of the patients and reflect the true situation in the context of medical care so that the Government will appropriately and efficiently set up policies with long term benefits for the health of Hong Kong citizens.

HKDU is strongly supportive of the long awaited action by the Government to put in place statutory regulation to ensure the safety, performance and quality of medical devices supplied in Hong Kong. While learning the Government's plan to introduce the Medical Devices Bill to the Legislative Council for scrutiny in this current legislative session, we would like to take this opportune occasion of the Joint Subcommittee meeting to reiterate and express further our views:

1. While the issue of "use control" is far from reaching consensus, HKDU fully appreciates and supports the Government's hard efforts in speeding up legislative exercise focusing on "pre-market control" and "post-market control".
2. The next step to implement "use control" regulatory legislation should follow closely. We

expect the government to give us a tentative timetable of the progress. In order to expedite the process, we suggest to shorten the duration for the application of listing of medical devices as proposed by the Government from 5 years back to 3 years, which was originally proposed. After the deadline for making listing application, new models of medical devices must fulfil the requirements for registration of medical devices for their legal supply in Hong Kong. During the interim period, the listed devices must be registered with local agents and comply with the requirements stipulated by the Department of Health.

3. For registration of medical devices, the definition must be clear-cut with practical examples to clarify any doubts and misconception among the lay public. Apart from classifying them based on their risks, the HS Panel should also take into account the indications for treatment.

4. To assure any device of fulfilling its requirements during the listing period, the government should have a system of monitoring and taking legal actions on the owner and/or operator and also the agent concerned.

5. We welcome the establishment of the Joint Subcommittee on Issue Relating to the Regulation of Devices and Development of Beauty Industry under Legco Panel on Health Services and look forward to its early successes in formulating and implementing legislation of regulatory measures for medical devices.

Thank you for your attention.

Yours sincerely,

Dr. Chan Pui Kwong
Hon. Secretary
Hong Kong Doctors Union

CC: Prof. Sophia Chan, Secretary for Food and Health
Dr. Chan Hon Yee, Constance, Director of Health
Media