

RE: LegCo - Online Registration (Reference No.: 1C45183B) Comments on "Proposed regulatory framework for medical devices"

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Medical device regulation in Asia Markets is growing important. Governments and regulatory bodies of countries across the region have placed new regulatory systems or refine the existing ones. Medical Device is one of the fastest growing industries. As an open economy, HK is expected to soon experience the same. This can be attributed to the ageing population globally and the increase in health consciousness among the public.

In local universities, Biomedical Engineering graduates are already working in medical device regulatory affairs in Asia market, CE in Europe and FDA in US. Their companies also listed the medical devices in MDCO and sell their medical devices in Hong Kong hospitals. Medical Device regulation is mature and well structure in US, Europe and worldwide, and Hong Kong as an international city, we should have the medical device regulation and lots of examples already well established for us to follow, such as ISO standards (ISO13485 and ISO14971 for medical devices quality system and risk management).

Safety and effectiveness of medical devices are important to the public in US, Europe, China, and worldwide. Hong Kong people concern about Food safety and Drug safety. We are concerning our health, and medical device safety will be important, and regulatory should help to provide a safer environment for people in Hong Kong.

Lots of advance technologies for medical applications have been developed to provide better treatment and diagnosis for diseases. Effectiveness is important for the consumer, and we should clearly know the intended use of the medical devices and their effectiveness. Hong Kong Hospitals and universities have Human Ethics subcommittee to monitor the safety and risk for the clinical trials. Those clinical trials can also provide more evidences for the effectiveness of the medical devices.

Hong Kong people are very concern their health, medical device regulation should be able to provide better environment for all of us in Hong Kong. For Hong Kong industries and service providers, we could be more in line with medical device regulation worldwide.

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