HKAPI
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HKAPI views on the latest proposed Medical Devices Bill

The Hong Kong Association of the Pharmaceutical Industry (HKAPI), representing 38 multinational member companies, who engage in the research and development of novel pharmaceuticals, including the world's top 20, some of which also involved in the import and regional distribution of medical devices, is pleased to submit its views on the Government's latest Proposed Regulatory Framework for Medical Devices.

We would like to reiterate our full support for the legislation of a regulatory framework for medical devices, and believe that such framework should be based upon the principles of safeguarding public health, as well as allowing flexibility for continued access to new medical technologies for the benefits of patients. We welcome the introduction of pre-market and post-market control for medical devices, since such measures are essential for ensuring these objectives.

In keeping with the current international practice, we agree that "cosmetic devices" should not be differentiated from medical devices, but instead be regulated under the same framework as proposed for medical device. While we understand and accept that the proposed transitional listing system is designed for those devices that fall short of the registration requirements, as well as agree that clear listing criteria (such as complying with basic safety requirements stipulated by the Director of Health and committing to carry out post-market obligations by traders) must be in place, we are of the opinion that this transition period should last no longer than 5 years; which means all types of medical devices shall finish migrating to full registration, by phase in sequence of their risk level, by the end of this 5-year period.

Last but not least, besides the pre-market and post-market control of medical devices, which we look forward to, we recommend, as a next step to perfecting the regulatory regime, that users operating medical devices should be appropriately trained according to the risk level of the devices in order to further ensure public safety.