Response on donation of medical devices to local healthcare institutions

In view of media enquiries on the donation of histotripsy medical devices to local healthcare institutions, the Health Bureau, the Department of Health (DH) and the Hospital Authority (HA) provide a consolidated response today (March 12) as follows:

The Government of the Hong Kong Special Administrative Region is committed to complementing technological innovation with institutional innovation. Through a series of measures such as the establishment of the Greater Bay Area Clinical Trial Collaboration Platform and the setting up of the Hong Kong Centre for Medical Products Regulation for the purpose of establishing the "primary evaluation", the Government has been enhancing Hong Kong's drug and medical device approval and clinical trial capabilities on all fronts, so as to facilitate the translation of innovative biomedical research results into clinical applications, expedite patients' access to advanced diagnostic and treatment services, and foster new quality productive forces in biomedical technology.

Innovative research and development of the most advanced, effective and up-to-date medical products can benefit the public. However, innovative medical products must be scientifically proven, including proven by clinical trials that they are safe and effective before they can be translated to clinical applications and at the same time form the basis for industrial development.

Regulation of medical devices

At present, the DH provides support to the Pharmacy and Poisons Board of Hong Kong in assessing applications for registration of pharmaceutical products (including advanced therapy products) and approving applications for registration of pharmaceutical products after proving the relevant safety, efficacy and quality requirements have been met. In addition, the Board also approves applications for clinical trials / medicinal tests in relation to pharmaceutical products.

Unlike pharmaceutical products of which registration and clinical trials are governed by legislation, there is no specific legislation to regulate medical devices in Hong Kong, including the clinical trials and use. Making reference to the recommendation of the Global Harmonization Task Force (now known as the International Medical Device Regulators Forum), the DH has introduced a voluntary Medical Device Administrative Control System (MDACS), under which a listing system for medical devices and traders as well as a post-market monitoring system are in place to ensure that medical devices supplied in Hong Kong meet the requirements on safety, quality and

performance. Information of listed medical devices is uploaded to the website of the DH's Medical Device Division (www.mdd.gov.hk/en/mdacs/search-database/list-md/index.html). The HA has also implemented the priority procurement strategy since 2024, giving preference in considering the procurement of medical devices listed under the MDACS.

The medical devices donated to the local healthcare institutions have not been listed under the MDACS. The DH has recently received an application for listing a histotripsy medical device, and the application is being processed.

Trial of medical devices

Clinical trials carry a certain degree of risk to the participants and should be conducted by registered healthcare professionals after informing the participants of the associated risks and obtaining their explicit informed consent. At present, even though there is no statutory provision prohibiting healthcare professionals from using new medical devices on patients, healthcare professionals have the professional responsibility to act in the best interests of patients and ensure that all trials are conducted with the explicit informed consent of patients.

It is understood that the LKS Faculty of Medicine of the University of Hong Kong, the Faculty of Medicine of the Chinese University of Hong Kong and the Hong Kong Sanatorium & Hospital are using the donated histotripsy medical devices for clinical trials on liver cancer treatment. These clinical trials can effectively assess the safety and efficacy of the devices for the Asian population, in particular patients in Hong Kong. The Government and the HA are paying attention to the results of these clinical studies, and expect that the data will provide a scientific basis for wider application in the future.

Application of medical devices

Regarding the application of new drugs and medical devices in the public healthcare system, the HA has established robust mechanisms for evaluating and deciding on the introduction of new drugs, devices and other innovative treatments for public healthcare services. The safety of the treatment methods, whether there is sufficient evidence supporting their therapeutic effectiveness, the cost-effectiveness of such introduction, as well as comprehensive comparisons with existing treatment services have to be considered. When making consideration according to these mechanisms, the HA must ensure fairness and objectivity as well as prudent use of public resources. Also, the consideration process will not and should not be influenced by whether the treatment method is provided or sponsored by individual pharmaceutical or device manufacturers.

The application in the public healthcare system of new drugs and medical devices, and methods for treatment that are still in the clinical trial phase without sufficient clinical data should be handled in a very careful and

prudent manner. The HA will closely monitor medical technology developments, with experts regularly studying and reviewing treatment options for patients and the latest developments in clinical and scientific evidence of related technologies, while considering healthcare professionals' opinions and overseas developments to plan for the introduction of medical technologies. Meanwhile, the availability of relevant expertise, manpower and facilities, as well as complementarity with government policy directions, will also be taken into account.

Concerning the research and development (R&D) of medical devices and drugs, clinical trials should be distinguished from clinical services. No clinical service may be provided when clinical trial is still unfinished. Citizens who need to seek medical services due to illnesses should consult professionals including medical practitioners, and should not be influenced by other online advertisements or publicity through endorsements.

As announced in the Chief Executive's 2024 Policy Address, the Government is expediting the reform of the approval mechanism for drugs and medical devices, including devising the timetable for the establishment of the Hong Kong Centre for Medical Products Regulation and the roadmap towards adoption of "primary evaluation", formulating strategies and measures to facilitate R&D of drugs and medical devices, and taking forward the preparatory work for legislating for the statutory regulation of medical devices, so as to further enhance the overall regulatory regime of medical products in Hong Kong, thereby facilitating Hong Kong's development into an international health and medical innovation hub, and at the same time benefitting local patients.