LCQ8: The “1+” mechanism for approval of new drugs

Following is a question by Professor the Hon Chan Wing-kwong and a written reply by the Secretary for Health, Professor Lo Chung-mau, in the Legislative Council today (June 12):

Question:

The new "1+" mechanism for approval of new drugs ("1+" mechanism) announced in the 2023 Policy Address formally came into effect on November 1 2023. In this connection, will the Government inform this Council:

(1) of the respective numbers of applications for registration of new drugs under the "1+" mechanism that have been received, approved and rejected since the mechanism came into effect, and the main reasons for the applications being rejected;

(2) whether it has compiled statistics on the total number of patients who have benefited from the new drugs approved for registration and use in Hong Kong under the "1+" mechanism; and

(3) how the authorities will further promote the "1+" mechanism in the future?

Reply:

President,

"The Chief Executive's 2023 Policy Address" (Policy Address) announced that the Government will leverage the medical strengths of the Hong Kong Special Administrative Region (HKSAR) with the long-term objective of establishing an authority that registers drugs and medical devices (medical products) under the "primary evaluation" approach, i.e. to directly approve applications for registration of drugs in Hong Kong based on clinical trial data without relying on registration approval from other drug regulatory authorities, and start approving applications for registration of medical devices. All these aim at accelerating the clinical use of new medical products so as to enhance healthcare standards, and foster the development of industries relating to the research and development (R&D) and clinical trials of medical products, developing Hong Kong into an international health and medical innovation hub.

In the past six months or so following the announcement of the Policy Address, the HKSAR Government has implemented measures in all respects and achieved results.

Firstly, with the support and guidance of the National Medical Products Administration (NMPA), Hong Kong, China has become an observer of the International Council for Harmonisation of Technical Requirements for

Pharmaceuticals for Human Use (ICH) on October 31, 2023. This allows Hong Kong to familiarise itself with the latest developments in the drug regulation and take forward the development of the drug regulatory regime in Hong Kong, to further align Hong Kong with the World Health Organization (WHO)-Listed Authority.

Secondly, the HKSAR Government implemented a new mechanism for the approval of new drugs (the "1+" mechanism) on November 1, 2023. Under the "1+" mechanism, holders of registration from one of the reference drug regulatory authorities (instead of two) for new drugs could apply for registration in Hong Kong, on the condition that they could provide local clinical data that complies with the requirements and information recognised by local experts.

Thirdly, the HKSAR Government has established the Preparatory Office for the Hong Kong Centre for Medical Products Regulation (CMPR) under the Department of Health (DH) on June 5 this year. The Preparatory Office for the CMPR will comprehensively study and plan a regulatory and approval regime for medical products suitable for Hong Kong; and put forward proposals and steps for the establishment of the CMPR.

The HKSAR Government will continue to actively follow up on the relevant work, to attract more medical products enterprises, both locally and from around the world, to conduct R&D and clinical trials in Hong Kong, and build the capacity, recognition and status for ensuring that the eventual approval mechanism of medical products in Hong Kong would be widely recognised internationally and by the Mainland, and develop Hong Kong into an international health and medical innovation hub.

In consultation with the DH and the Hospital Authority (HA), the reply to the question raised by Professor the Hon Chan Wing-kwong in relation to the "1+" mechanism is as follows:

(1) Under the "1+" mechanism, applications for registration of new drugs in the HKSAR that are beneficial for treatment of life-threatening or severely debilitating diseases, and are supported with local clinical data and scope of application recognised by local experts, are only required to submit approval from one reference drug regulatory authority (instead of the two).

The requirements for local clinical data and recognition by experts for application for registration (i.e. the "+" under the "1+" mechanism) will continue to ensure all drugs approved for registration fulfil the stringent requirements of safety, efficacy and quality. It will also strengthen the local capacity of drug evaluation and enhance the development of relevant software, hardware and expertise.

Since the commencement of the "1+" mechanism from November 1, 2023, till May 31, 2024, two new drugs for treating cancer have been approved under that mechanism. They are oral targeted drugs in different dosages for treating metastatic colorectal cancer, for treatment of patients for whom conventional chemotherapy has been ineffective or inapplicable. Besides, the DH has received over 210 enquiries involving around 70 pharmaceutical companies.

Several of these companies have expressed interest in applying for registration under the "1+" mechanism. Applications would be submitted once the necessary information is ready. At present, no new drug applications under the "1+" mechanism have been rejected.

(2) As at May 31, 2024, 19 patients in the HA are already using abovementioned new drugs for treating metastatic colorectal cancer registered under the "1+" mechanism. The HA will encourage drug manufacturers or suppliers to apply for local registration of unregistered drugs with ongoing needs and continue to liaise closely with the DH in the light of the "1+" mechanism. Through the "1+" mechanism, the number of drugs successfully registered would increase, thus enabling clinicians to enjoy a wider choice of drugs to support their service needs. Clinicians may initiate application for new drug listing on the HA Drug Formulary to the HA Drug Advisory Committee according to the clinical service needs. In addition, when a new drug can be registered in HKSAR under the "1+" mechanism and listed on the HA Drug Formulary and is proven to have significant clinical benefits, it may be considered to be covered by the Samaritan Fund or the Community Care Fund.

(3) After the announcement of the Policy Address, the HKSAR Government has been actively seizing various opportunities to publicise the initiatives related to the development of Hong Kong as an international health and medical innovation hub (including the "1+" mechanism) to counterparts locally and in other places.

Last year, the HKSAR Government attended the Guangdong-Hong Kong-Macao Greater Bay Area (GBA) Medical Products Administration Conference held in Zhuhai and the GBA Health Cooperation Conference held in Nansha, Guangzhou, respectively, and organised the 18th Joint Meeting of the Senior Health Officials of the Mainland, Hong Kong and Macao in Hong Kong, as well as led a delegation to visit various ministries and commissions in the Mainland, including the National Health Commission and the NMPA.

On international exchanges, the Secretary for Health led a Hong Kong team as members of the Chinese delegation to attend the 77th World Health Assembly held by the WHO in Geneva, Switzerland, at the end of May this year. During the visit, the Secretary for Health visited two multinational pharmaceutical and healthcare enterprises, as well as met with the Director for Regulation and Prequalification of the WHO and representatives from the Clinical Trials Centre of the University Hospital Zurich, to promote Hong Kong's unique advantages and the latest development of health and medical innovation. The multinational pharmaceutical and healthcare enterprises welcomed the HKSAR Government's initiatives to develop into an international health and medical innovation hub.

At the same time, the DH has been actively promoting the "1+" mechanism through various channels and handling enquiries and expression of interest by the trade. In the past few months, the DH has issued letters to notify stakeholders (including relevant pharmaceutical associations and holders of registration of pharmaceutical products) and organised briefings (seven online sessions and one session in on-site and online mixed mode have been conducted so far, with more than 500 participants from relevant

pharmaceutical associations and stakeholders) for introducing the requirements and details of the new "1+" mechanism. The DH will proactively follow up on each and every enquiry and facilitate the trade in submitting applicants under the new mechanism.