New “1+” mechanism expedites approval of new drugs

The Government announced today (December 8) that for the first time, two new drugs for treating cancer were approved for registration in Hong Kong yesterday (December 7) after review under the new mechanism for registration of New Drugs ("1+" mechanism). They are oral targeted drugs in different dosages for treating metastatic colorectal cancer, bringing new hope for treatment to patients for whom conventional chemotherapy has been ineffective or inapplicable.

A Government spokesman said that the approval of new drugs for registration in just one month or so after the "1+" mechanism came into effect enabled the earlier use of effective new drugs in treating serious or rare diseases. This demonstrated the effective operation of the new "1+" mechanism and the realisation of the policy objective of "good drugs for Hong Kong". In addition to the important mission of life saving, the "1+" mechanism strengthens local capacity in drug evaluation, marking an important milestone for Hong Kong in the progressive development into an internationally recognised regulatory authority for drugs and medical devices and an international health and medical innovation hub.

The "1+" mechanism announced in "The Chief Executive's 2023 Policy Address" came into effect on November 1. Under the "1+" mechanism, applications for registration of new drugs beneficial for treatment of life-threatening or severely debilitating diseases that are supported with local clinical data are only required to submit approval from one reference drug regulatory authority (instead of two originally). The new drugs can register in Hong Kong after the applications are assessed by local experts and approved by the Pharmacy and Poisons Board of Hong Kong.

Since the commencement of the "1+" mechanism, the Department of Health (DH) has received enquiries from nearly 50 pharmaceutical companies and two new drug applications submitted under the above mechanism. Having the registration approval from the reference drug regulatory authority and the local clinical data submitted by the applicant considered and the Expert Group on Drug Registration consulted, the Board considered that the two new drugs satisfied the criteria of safety, efficacy and quality. The Board has officially approved the registration of the relevant new drugs at a meeting held yesterday afternoon. The DH will notify the applicant of the results of their applications. Details of the registered products will be uploaded to the website of the Board. The two new drugs secured approval for registration for use within a month or so after the "1+" mechanism came into effect.

The "1+" mechanism facilitates the registration of worldwide new drugs that can meet the local unmet medical needs for life-threatening or severely debilitating disease in Hong Kong. These new drugs can also benefit patients in the Mainland cities of Guangdong-Hong Kong-Macao Greater Bay Area (GBA) under the measure of using Hong Kong-registered drugs and medical devices

used in Hong Kong public hospitals in the GBA. Furthermore, the new mechanism can attract more research and development, and clinical trials in relation to drugs to be conducted in Hong Kong. The requirements of local clinical data and recognition by relevant experts for application for registration (the "+" under the "1+" mechanism) will ensure fulfilment of the stringent requirements of safety, efficacy and quality by all pharmaceutical products approved for registration. It will also strengthen the local capacity of drug evaluation and enhance the development of relevant software, hardware and expertise, thereby contributing to the establishment of a drug registration regime based on the "primary evaluation" approach in Hong Kong and recognised by the Mainland and internationally in the long run.