

Another two new drugs approved under "1+" mechanism

A Government spokesman announced today (December 16) that two more new drugs submitted under the "1+" mechanism have been approved for registration in Hong Kong. These new drugs in two different dosages are used to treat patients with extensive-stage small cell lung cancer, creating more treatment options for patients in Hong Kong and facilitating more good drugs for use in Hong Kong.

The Hong Kong Special Administrative Region (HKSAR) has implemented the "1+" mechanism since November 1, 2023, for facilitating the registration of new drugs used for the treatment of life-threatening or severely debilitating diseases in Hong Kong. With effect from November 1, 2024, the "1+" mechanism has been extended to all new drugs, including all new chemical or biological entities and new indications, and vaccines and advanced therapy products. New drugs that are supported by local clinical data and recognised by local experts can be applied for registration in Hong Kong by submitting approval from one reference drug regulatory authority (instead of two in the past).

The above products for extensive-stage small cell lung cancer have been approved by the drug regulatory authority in the United States and submitted for registration application in Hong Kong under the "1+" mechanism. Having evaluated the clinical data and relevant information submitted by the applicant and advice given by local expert, the Registration Committee under the Pharmacy and Poisons Board of Hong Kong considered that the new drugs satisfied the criteria of safety, efficacy and quality, and approved the registration of the new drugs. The Department of Health (DH) has already notified the applicant of the result of the applications.

The "1+" mechanism serves to attract more new drugs from different parts of the world seeking approval for registration in Hong Kong, giving patients more choices and further strengthening the local capacity for drug evaluation while enhancing the development of relevant software, hardware and expertise with a view to progressing towards "primary evaluation".

Since the implementation of the "1+" mechanism, a total of nine new drugs have been approved under this mechanism. The DH has been promoting the "1+" mechanism through different channels and so far has received more than 350 enquiries from over 90 pharmaceutical companies, including those from overseas and the Mainland. Many companies have expressed interests in submitting applications for registration of their products, including advanced therapy products, under the extended "1+" mechanism.

Meanwhile, the DH will continue its efforts to bring along the reform of the approval mechanism of drugs and medical devices as announced in "The Chief Executive's 2024 Policy Address". These include putting forward a timetable for establishing the Hong Kong Centre for Medical Products Regulation and charting a roadmap towards "primary evaluation" in the first

half of 2025, as well as formulating strategies and measures to facilitate research and development of drugs and medical devices.