

Extending the "1+" mechanism to all new drugs on November 1

The Department of Health (DH) today (October 25) said that according to measures announced in "The Chief Executive's 2024 Policy Address", the "1+" mechanism will extend to all new drugs, including vaccines and advanced therapy products, on November 1, 2024, facilitating good drugs for use in Hong Kong. Extending the "1+" mechanism will 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". The Government will complement technological innovation with institutional innovation, developing Hong Kong into an international health and medical innovation hub.

Under the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical products must satisfy the criteria of safety, efficacy and quality and be registered with the Pharmacy and Poisons Board of Hong Kong before they can be sold or supplied in Hong Kong. According to the "1+" mechanism that came into effect on November 1 last year, new drugs used for the treatment of life-threatening or severely debilitating diseases that are supported by local clinical data and whose scope of application is recognised by local relevant experts are required to submit approval from one reference drug regulatory authority (instead of two in the past) for application for registration in Hong Kong. The "1+" mechanism will be extended on November 1, applicable to applications for registration of all new drugs.

The DH has announced on its relevant website the arrangement for extending the "1+" mechanism to all new drugs and issued letters to notify relevant stakeholders (including relevant pharmaceutical associations and holders of certificates of drug registration) about the extension measure and relevant details of the "1+" mechanism. For further details, please refer to the Drug Office's website. The DH will also introduce consultation service for new drug applications under the "1+" mechanism in the first quarter of 2025 to enhance efficiency in processing relevant applications.

Since the implementation of the "1+" mechanism, the DH has received more than 260 enquiries from over 80 pharmaceutical companies, including those from overseas and the Mainland. A total of five new drugs have been approved under this mechanism. These included two new drugs for treating metastatic colorectal cancer, one for treating paroxysmal nocturnal haemoglobinuria, and two new drugs for treating hypercalcaemia in patients with parathyroid carcinoma and in certain patients with primary hyperparathyroidism, bringing new hope for treatment to patients.

The first two new drugs approved under the "1+" mechanism for treating metastatic colorectal cancer have been listed under the category of "Special Drug" on the Hospital Authority (HA) Drug Formulary. Patients prescribed

these two drugs under specified clinical applications are only required to pay standard fees and charges, which are substantially subsidised, greatly alleviating their financial burden. 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 regarding the "1+" mechanism.

The Policy Address also announced other measures to expedite the reform of the approval mechanism of drugs. 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 medical products.