Two more new drugs approved under “1+” mechanism

A Government spokesman announced today that two more new drugs submitted for registration under the new drug approval mechanism ("1+" mechanism) announced in the Chief Executive's 2023 Policy Address have been approved for registration in Hong Kong. These new oral drugs in two different dosages are used to treat hypercalcaemia in patients with parathyroid carcinoma and in certain patients with primary hyperparathyroidism, bringing more treatment options for patients.

The Hong Kong Special Administrative Region (HKSAR) Government has implemented the "1+" mechanism since November 1, 2023. Under the "1+" mechanism, new drugs used for treatment of life-threatening or severely debilitating diseases that are supported with local clinical data are only required to submit approval from a drug regulatory authority in one of the reference places (instead of two originally) and be recognised by local experts to be registered in Hong Kong.

The above products for hypercalcaemia have been approved by the drug regulatory authority in Japan and submitted for registration application in Hong Kong under the "1+" mechanism. Having considered the clinical data submitted by the applicant and advices 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 application. The HKSAR Government will also complete the relevant registration processes in accordance with established procedures.

The Chief Executive's 2023 Policy Address announced that the Government will leverage the medical strengths of the 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 medical products in Hong Kong based on clinical trial data, without relying on registration approval from other drug regulatory authorities. This will help accelerate the clinical use of new drugs and medical devices, and foster the development of industries relating to the research and development and clinical trials of medical products, developing Hong Kong into an international health and medical innovative hub.

Since the implementation of the "1+" mechanism, two new drug applications for treating metastatic colorectal cancer and one for treating paroxysmal nocturnal haemoglobinuria were approved under the "1+" mechanism in December 2023 and July 2024 respectively. 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. It is estimated that around 300 patients will benefit every year. 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.

At the same time, the DH has been promoting the "1+" mechanism through different channels, and has received over 250 enquiries involving more than 70 pharmaceutical companies. More companies have expressed interest in applying for registration under the "1+" mechanism. While the "1+" mechanism brings good drugs for use in Hong Kong, the requirements of local clinical data and recognition by relevant expert for application for registration (the "+" under the "1+" mechanism) will ensure all the pharmaceutical products approved for registration have fulfilled 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.