

Two more new drugs approved under "1+" mechanism

A Government spokesman announced today (November 12) that two more new drugs submitted under the "1+" mechanism have been approved for registration in Hong Kong. These new oral drugs in two different dosages are used to treat patients with anaemia caused by chronic kidney disease, bringing more treatment options for patients and facilitating good drugs for use in Hong Kong.

The Hong Kong Special Administrative Region (HKSAR) Government has implemented the "1+" mechanism since November 1, 2023. New drugs used for the treatment of life-threatening or severely debilitating diseases that are supported by local clinical data and recognised by local 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. According to "The Chief Executive's 2024 Policy Address", 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 with effect from November 1, 2024.

The above products for anaemia caused by chronic kidney disease have been approved by the drug regulatory authority on the Mainland 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 a local expert, the Registration Committee under the Pharmacy and Poisons Board of Hong Kong considered that the new drugs satisfy the criteria of safety, efficacy and quality, and approved the registration of the new drugs on November 8, 2024.

The HKSAR Government anticipates that 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".

Since the implementation of the "1+" mechanism, a total of seven new drugs have been approved under this mechanism. In addition to the above two new drugs, five new drugs have been approved under this mechanism so far. These included two new drugs for treating metastatic colorectal cancer, one for treating paroxysmal nocturnal haemoglobinuria, and two for treating hypercalcaemia in patients with parathyroid carcinoma and in certain patients with primary hyperparathyroidism. The two new drugs for treating metastatic colorectal cancer have been listed in the "Special Drug" category of the Hospital Authority Drug Formulary. Not only has the procurement cost of the drugs been reduced by nearly 30 per cent after price negotiation, but patients are only required to pay standard fees of \$15 if prescribed under

specified clinical applications, greatly alleviating their financial burden. It is expected that nearly 300 cancer patients will benefit each year.

The DH is actively implementing measures pertinent to 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 taking forward preparatory work for legislating the statutory regulation of medical devices.