“1+” mechanism for approval of new drugs to commence on November 1

The Department of Health (DH) today (October 26) said that the new mechanism for registration of New Drugs ("1+" mechanism) announced in "The Chief Executive's 2023 Policy Address" was endorsed by the Pharmacy and Poisons Board of Hong Kong (the Board) and will come into effect on November 1.

The implementation of the "1+" mechanism will allow Hong Kong to be more proactive to expedite the approval of applications for registration of new drugs (i.e., pharmaceutical products containing new chemical or biological entities) for life-threatening or severely debilitating diseases and will also strengthen Hong Kong's capacity in drug evaluation in the long run, which is an important step in progressing toward a primary evaluation approach.

Under the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical products must satisfy the criteria of safety, efficacy and quality for registration before they can be sold or supplied in Hong Kong. According to existing requirements, generally, applicants for registration of new drugs are required to provide, among others, documentary proof for registration of pharmaceutical products issued by drug regulatory authorities from at least two reference places for rigorous evaluation before placing in the market.

The DH spokesman said that under the newly established "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 and scope of application recognised by local relevant expert are required to submit approval from one reference drug regulatory authority (instead of the two) and could submit application for registration in Hong Kong.

The DH has announced the arrangement in the relevant website, issued letter to notify the relevant stakeholders (including relevant pharmaceutical associations and holders of certificate of drug registration) to introduce the relevant details of the "1+" mechanism. For further details, please refer to the Drug Office's website.

The "1+" mechanism will facilitate the registration of new drugs from different parts of the world that meet local unmet medical needs in Hong Kong and allow patients' early access to new drugs. The new mechanism would attract more drug development and clinical trials to be conducted in Hong Kong, and the requirements of local clinical data and recognition by relevant expert for application for registration (the "+" under the "1+" mechanism) will ensure that all the pharmaceutical products approved for registration fulfil 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.

To progress towards the primary evaluation of drugs and medical devices, "The Chief Executive's 2023 Policy Address" also announced the set-up of a preparatory office for the establishment of the Hong Kong Centre for Medical Products Regulation (CMPR) to study the potential restructuring and strengthening of the current regulatory and approval regimes for medicines, medical devices and medical technology, and put forward proposals and steps for the establishment of the CMPR. The Government will also explore upgrading the CMPR to be a standalone statutory body in the long run. This will help accelerate the launching of new drugs and medical devices to the market, and foster the development of research and development, and testing of medical products and related industries.

The DH spokesman said that maintaining a drug regulatory system that is on par with the international standard would facilitate the future development of Hong Kong's local healthcare system and services as well as maintaining international recognition of healthcare technology and clinical research. The DH would adopt a more proactive strategy to review and enhance the arrangement.