Another new drug approved under “1+” Mechanism

Government spokesman announced today (July 5) that another new drug submitted for registration under the new drug approval mechanism ("1+" mechanism) announced in the "Chief Executive's 2023 Policy Address" has been approved for registration in Hong Kong. This new oral drug is used to treat paroxysmal nocturnal hemoglobinuria, bringing more treatment options for patients.

The Hong Kong Special Administrative Region (HKSAR) Government implemented "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 drug regulatory authority in one of the reference places (instead of two originally) and recognised by local experts can be registered in Hong Kong.

The above product for paroxysmal nocturnal hemoglobinuria has been approved by the drug regulatory authority in the United States 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 drug satisfied with the criteria of safety, efficacy and quality, and approved the registration of the new drug at a meeting held yesterday (July 4). The Department of Health (DH) has already notified the applicant the result of the application. The HKSAR Government will also complete the relevant registration processes in accordance with established procedures.

At present, under the "Subsidy for Eligible Patients to Purchase Ultra-expensive Drugs (Including Those for Treating Uncommon Disorders)" (CCF Ultra-expensive Drugs Programme) launched by the HKSAR Government and the Hospital Authority (HA), there is already a drug that can treat the same clinical indication. The above new drug approved for registration under the "1+" mechanism will provide patients and healthcare professionals with more choices, increase market competition and may reduce procurement costs.

"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.

On December 7, 2023, two new drug applications for treating cancer were approved under the "1+" mechanism for the first time. The two new cancer drugs are oral targeted drugs in different dosages for treating metastatic colorectal cancer in patients for whom conventional chemotherapeutic drugs are ineffective or unsuitable. As at July 3 this year, about 30 patients in the HA have already used the two new cancer drugs concerned. 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. Under the "1+" mechanism, the number of drugs successfully registered would increase, thus enabling clinicians to enjoy a wider choice of drugs to support service needs. In addition, when a new drug could be registered in Hong Kong under the "1+" mechanism, listed on the HA Drug Formulary and is proven to have significant clinical benefits, it may be considered to be covered by the Samaritan Fund or the Community Care Fund. At the same time, the DH has been promoting the "1+" mechanism by seizing various opportunities and through different channels, and has received over 210 enquiries involving around 70 pharmaceutical companies. At present, several companies have expressed interest in applying for registration under the "1+" mechanism.

Whilst 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.

Besides, the HKSAR Government has set up the Preparatory Office for the Hong Kong Centre for the Medical Products Regulation (CMPR) under the DH on June 5 this year to comprehensively study and plan a regulatory and approval regime for drugs and medical devices suitable for Hong Kong, and to put forward proposals and steps for the establishment of the CMPR.

â€‹The HKSAR Government will continue to attract more pharmaceutical and medical device enterprises, both locally and from around the world, to conduct research and development and clinical trials in Hong Kong as well as build up the capacity, recognition and status to ensure that the eventual approval mechanism of medical products in Hong Kong would be widely recognised internationally and by the Mainland, and develop Hong Kong into an international health and medical innovation hub.