DH establishes Preparatory Office for Hong Kong Centre for Medical Products Regulation

â€‹The Department of Health (DH) announced today (June 5) the establishment of the Preparatory Office for the Hong Kong Centre for Medical Products Regulation (CMPR) to put forward proposals and steps for the formal establishment of the CMPR, and to study the potential restructuring and strengthening of the regulatory and approval regimes for drugs and medical devices.

The Chief Executive's 2023 Policy Address (Policy Address) announced that the Government will leverage the medical strengths of the Hong Kong Special Administrative Region (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 (R&D) and clinical trials of medical products, developing Hong Kong into an international health and medical innovation hub.

Hong Kong would become an internationally renowned regulatory authority and implement the "primary evaluation" approach for medical products in six major steps (see Annex). In more than six months following the announcement of the Policy Address, the HKSAR Government has implemented measures in all respects and achieved results.

Firstly, with the support and guidance of the National Medical Products Administration (NMPA), Hong Kong, China has officially become an observer of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (Note 1) on October 31, 2023. This allows Hong Kong to familiarise itself with the latest developments in the drug regulation regime, to further align Hong Kong with the World Health Organization (WHO)-Listed Authority.

Secondly, the HKSAR Government implemented a new mechanism for the approval of new drugs (the "1+" mechanism) on November 1, 2023. Under the "1+" mechanism, holders of registration from one of the recognised drug regulatory authorities (instead of two) for drugs containing new chemical or biological entities could apply for registration in Hong Kong, on the condition that they could provide local clinical data that complies with the requirements and information recognised by local experts. Since the implementation of the "1+" mechanism, the DH has received more than 210 inquiries from about 70 pharmaceutical companies, including many pharmaceutical companies from overseas and the Mainland. Under the "1+"

mechanism, two new drugs for cancer treatment have already been approved for registration, bringing new hopes of treatment to patients.

Considering the establishment of the Preparatory Office for the CMPR under the DH today, the HKSAR Government has completed the first three of six major steps. The specific work of the Preparatory Office includes:

(i) comprehensively studying and planning a regulatory and approval regime for drugs and medical devices suitable for Hong Kong;

(ii) putting forward proposals and steps for the establishment of the CMPR;

(iii) conducting a review on the need for amending existing legislation to promote the development of medical products regulation; and

(iv) making recommendations to the Steering Committee on Health and Medical Innovation and Development (Note 2) as well as maintaining close communication with various stakeholders.

The HKSAR Government will continue to actively follow up on the remaining major steps, including the establishment of the CMPR and the implementation of the "primary evaluation" approach for medical products. Based on international experience, it usually takes about eight to 10 years from initial engagement with the ICH to becoming an ICH regulatory member.

In May this year, the Commissioner of the NMPA led a delegation to visit Hong Kong and signed the Co-operation Agreement on Regulation of Drugs with the Health Bureau of the HKSAR Government. The Agreement underpinned the liaison and co-ordination arrangements among the NMPA, the DH, and the CMPR to be set up. In the same month, the Secretary for Health, Professor Lo Chung-mau, along with the Director of Health, Dr Ronald Lam Man-kin, led a Hong Kong, China delegation to attend the 77th World Health Assembly held in Geneva, Switzerland, as members of the Chinese delegation. They had then visited multinational pharmaceutical and healthcare enterprises, and a clinical trial centre. During the visit, they highlighted Hong Kong's unique advantages and the latest developments in health and medical innovation to various WHO and other government officials and organisations responsible for healthcare, as well as international scientific research and medical experts (including the Director for Regulation and Prequalification of the WHO and personnel from the Clinical Trials Center of the University Hospital Zurich). Multinational pharmaceutical and healthcare enterprises which were visited welcomed the HKSAR Government's plan to establish the CMPR and the initiatives to develop a health and medical innovation hub.

The HKSAR Government will continue to attract more pharmaceutical and medical device enterprises, both locally and from around the world, to conduct R&D and clinical trials in Hong Kong, and build 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.

Note 1: The ICH is an international recognised association. The mission of the ICH is to harmonise the technical requirements for drug registration among its members and to promulgate various guidelines on safety, efficacy and quality that are recognised as the highest global standards for the protection of public health.

Note 2: The Steering Committee on Health and Medical Innovation and Development (SCHMID) is chaired by the Secretary for Health and comprises members from the Innovation, Technology and Industry Bureau, relevant bureaux, departments, institutions, and local medical schools. SCHMID is tasked with co-ordinating and advancing the work related to health and medical innovation, and advising the Government on the direction and policy initiatives for driving medical innovation, including measures to enhance the regulation of drugs and medical devices, and clinical trial development.