# Secretary for Health delighted by acceptance of Hong Kong, China as observer of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

The Department of Health (DH) announced today (November 9) that the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has formally accepted Hong Kong, China as its observer at the assembly meeting held in the Czech Republic on October 31, which is an important step for Hong Kong in moving towards the establishment of a registration mechanism of drugs and medical devices based on "primary evaluation" in the long run.

The Secretary for Health, Professor Lo Chung-mau, was delighted by the good news and said that "Our objective is to take progressive steps to bloom from the current 'secondary evaluation' approach towards the establishment of a 'primary evaluation' approval mechanism recognised internationally and by the Mainland. In that event, approval of drugs, medical devices and technologies in Hong Kong will no longer rely on the approval from other reference drug regulatory authorities but directly base on supporting clinical data and expert advices. This would enable patients to get early access to new drugs, and at the same time attract more local, Mainland and overseas pharmaceutical and medical device enterprises to conduct research and development (R&D) and clinical trials in Hong Kong, thereby gradually building up the capacity, recognition and status of the approval mechanism of drugs and medical devices of Hong Kong to ensure that the eventual mechanism would be widely recognised by the Mainland and internationally.

"To this end, a series of key initiatives was announced in 'The Chief Executive's 2023 Policy Address'. Following the implementation of the '1+' mechanism for registration of new drugs on November 1, another initiative is the accession of Hong Kong, China to the ICH as an observer so that we can get familiarised with the latest development of drug regulation and take forward the development of the drug regulatory system in Hong Kong. This would also enable us becoming more on par with the World Health Organization-Listed Authority, paving the way for developing Hong Kong into an internationally recognised regulatory authority for drugs and medical devices in the long run."

He added, "I would like to express my deepest gratitude to the National Health Commission and the National Medical Products Administration for fully supporting Hong Kong, China in the application for accession to the ICH as an

observer, as well as their unfailing support, guidance and assistance in the work of drug approval in Hong Kong. I would also like to thank my colleagues in the DH for their extensive work in making this happened, including sending delegates to the Czech Republic to introduce our work and stringent standards in drug approval and regulation at the ICH Assembly."

The ICH is an internationally recognised association. At present, there are 15 regulatory members comprising drug regulatory authorities from Mainland China, Europe, Switzerland, the United Kingdom and the United States, where "primary evaluation" approach is adopted. 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 being recognised as the highest global standards. In compliance with the relevant guidelines, drug regulatory authorities in various parts of the world can mutually accept or recognise the clinical trial data generated in accordance with the ICH guidelines for drug registration. The accession to ICH as an observer will lay the foundation for the Hong Kong Special Administrative Region Government in advancing the implementation of the ICH guidelines in Hong Kong, with a view to strengthening the local capacity of drug approval, and facilitating relevant software, hardware and manpower development, with becoming an ICH regulatory member as the ultimate goal.

The DH and the Pharmacy and Poisons Board of Hong Kong (a statutory body set up under the Pharmacy and Poisons Ordinance, Cap. 138 of Hong Kong Legislation) are currently responsible for the approval of registration of pharmaceutical products in Hong Kong. The Policy Address has announced the setting up of a preparatory office next year to study the potential restructuring and strengthening of the regulatory and approval regimes for medicine, medical devices and medical technology. The preparatory office will also put forward proposals and steps for the establishment of the Hong Kong Centre for Medical Products Regulation (CMPR) which will be a step towards the transition to the "primary evaluation" approach in approval of drugs, medical devices and technologies, and explore the upgrading of the CMPR as a standalone statutory body in the long run. This will help expedite the launching of new drugs and medical devices to the market, and foster the development of R&D and testing of medical products and related industries.