DH and Center for Drug Reevaluation of National Medical Products Administration sign Agreement on Authorizing the Department of Health of the Hong Kong Special Administrative Region to Use VigiLyze – the Uppsala Monitoring Centre Adverse Drug Event Information System

The Department of Health (DH) and the Center for Drug Reevaluation (CDR) of the National Medical Products Administration (NMPA) today (September 13) signed the Agreement on Authorizing the Department of Health of the Hong Kong Special Administrative Region to Use VigiLyze – the Uppsala Monitoring Centre Adverse Drug Event Information System (Agreement). The Agreement authorises the DH to continue making use of the Uppsala Monitoring Centre (UMC) adverse drug event information system, VigiLyze. The Hong Kong Special Administrative Region (HKSAR) Government expresses gratitude to the NMPA for their trust and support to the HKSAR Government in the area of pharmacovigilance activities, which have played a positive role in developing Hong Kong into an international health and medical innovation hub.

Developed and maintained by the UMC for the World Health Organization (WHO) Programme for International Drug Monitoring (PIDM), VigiLyze is a global signal detection and signal management tool for adverse events of medicinal products. It is a web-based platform accessible to national pharmacovigilance centres of member countries of the WHO PIDM. Through its close integration with the WHO global database of adverse event reports for medicines and vaccines, VigiLyze provides member countries with global data on adverse events on medicines and vaccines, and access to related investigations. Being a member country of the WHO PIDM enables China to utilise this platform and enhance the national pharmacovigilance system. As a part of China, Hong Kong needs to obtain authorisation from relevant national units in order to use the platform.

The DH signed the Agreement with the NMPA for the first time in 2020. This Agreement played a significant role in the safety monitoring of COVID-19 vaccines during the COVID-19 pandemic. In response to the COVID-19 outbreak, two COVID-19 vaccines were authorised for emergency use in Hong Kong in 2021. The DH has put in place a pharmacovigilance system for COVID-19 vaccination, to detect potential signals of possible side effects of the vaccines. The DH has also established the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation (Expert Committee) to provide independent

assessment on potential causal link between adverse events following immunisation (AEFIs) and COVID-19 vaccines used in Hong Kong and to provide expert advice to the Government on safety-related matters. The signing of the Agreement has allowed the DH to use VigiLyze's global adverse drug event data of COVID-19 vaccines to provide the Expert Committee with a reference to assist their causality assessment of AEFIs for COVID-19 vaccines, and also assisted the Expert Committee in identifying potential signs of possible side effects of the vaccines.

The signing of a new Agreement between the NMPA and the DH allows the DH to continue using VigiLyze, which fully demonstrates the country’s recognition of the HKSAR. The DH expresses gratitude to the NMPA for the continuous trust and support to the HKSAR Government in the area of pharmacovigilance activities. The DH hopes to continue collaborating closely with the NMPA and the CDR to ensure all pharmaceutical products used in Hong Kong meet the criteria of safety, quality and efficacy, to effectively safeguard public health.

At the same time, since putting forward in the Chief Executive's 2023 Policy Address the vision of developing Hong Kong into an international health and medical innovation hub, the HKSAR Government has been pushing ahead with multiple initiatives on all fronts to strengthen the HKSAR's capacity of drug evaluation for progressing towards a primary evaluation approach, and has achieved results, including the establishment of the Preparatory Office for the Hong Kong Centre for Medical Products Regulation (CMPR) under the DH on June 5, 2024, 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 HKSAR Government will continue to strengthen policies and measures for the regulation of drugs and medical devices, and to build the capacity, recognition and status at different stages 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, striving towards high-quality development.