DH’s first briefing seminar on “1+” mechanism for new drugs well received

The Department of Health (DH) yesterday (March 31) held the first briefing seminar on the "1+" mechanism for new drugs with an introduction of the requirements for registration of pharmaceutical products under this mechanism, as well as the upcoming workshops on good regulatory practices and pre-new drug application (NDA) meetings. The DH aims to work with the pharmaceutical industry to achieve the goals of early consultation to enhance quality and efficiency throughout the process so that registration approval can be expedited, thereby bringing more good drugs for use in Hong Kong.

"The Chief Executive's 2024 Policy Address" announced that a consultation service for NDAs under the "1+" mechanism will be introduced to enhance the efficiency of processing relevant applications. The consultation service comprises briefing seminars, workshops and pre-NDA meetings. Yesterday's seminar was well received and was attended by 76 representatives from pharmaceutical and consultation companies inside or outside Hong Kong, as well as scientific research institutions. This marks the beginning of the consultation service. The DH will organise two more seminars on April 21 and May 16 this year. For further details and to register for future seminars, please visit the Drug Office's thematic webpage on the "1+" mechanism.

The DH will also organise workshops starting from June this year to provide guidance and sharing of good practices and real-life experiences on submitting applications through the "1+" mechanism. The DH will also offer to hold pre-NDA meetings with potential "1+" registration applicants starting from the second half of this year, providing specific guidance to assist in their planning of the NDA approval process and improve the quality of application documents to enhance the efficiency of the whole process. Details of the arrangements of the workshops and meetings will be announced in due course.

The Hong Kong Special Administrative Region (HKSAR) Government has implemented the "1+" mechanism since November 1, 2023, to facilitate the registration of new drugs for treating life-threatening or severely debilitating diseases in Hong Kong. The HKSAR Government has extended the "1+" mechanism to all new drugs from November 1, 2024, including all new chemical or biological entities and new indications, and vaccines and advanced therapy products. Under the "1+" mechanism, new drugs which are supported by local clinical data and recognised by local relevant experts can be applied for registration in Hong Kong by submitting approval from the drug regulatory authority of one of the reference places (instead of two in the past).

The "1+" mechanism serves to attract more new drugs from different parts of the world seeking approval for registration in Hong Kong, giving patients more choices and further strengthening the local capacity for drug evaluation while enhancing the development of relevant software, hardware and expertise

with a view to progressing towards "primary evaluation". Since the implementation of the "1+" mechanism, a total of 11 new drugs have been approved under this mechanism. The DH has been promoting the "1+" mechanism through different channels, and so far, has received 460 enquiries from 120 pharmaceutical companies, including those from overseas and the Mainland.

Meanwhile, the Government will continue its efforts to reform the approval mechanism for drugs and medical devices. These include putting forward a timetable for establishing the Hong Kong Centre for Medical Products Regulation and charting a roadmap towards "primary evaluation" in the first half of this year, aiming to spur the growth of new industries in pharmaceutical and medical device research, and development and testing.