DH organises workshop for new drug applications under “1+” mechanism (with photos)

â€‹The Department of Health (DH) today (June 16) organised the first workshop to provide guidance and share good practices and real-life experiences on submitting applications under the "1+" mechanism with the pharmaceutical industry and relevant stakeholders. 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 new drug applications (NDAs) under the "1+" mechanism would be introduced to enhance the efficiency in processing relevant applications. The consultation service comprises three components, including briefing seminars, workshops and pre-NDA meetings. The first workshop held today attracted over 90 participants from local pharmaceutical and consultancy companies.

Additionally, since March of this year, the DH has organised four briefing seminars to brief the trade and stakeholders on the basic requirements and procedures for Hong Kong drug registration under the "1+" mechanism. These seminars have attracted approximately 200 representatives from pharmaceutical companies, consultancy firms and research institutes, etc, in and outside of Hong Kong. The response from the trade was very positive and the DH will continue to organise workshops and briefing seminars from time to time. The next briefing seminar is scheduled for August 12 and online registration is open. The materials of the briefing seminar have been uploaded to the thematic webpage on the "1+" mechanism for the trade's reference.

As for one-on-one pre-NDA meetings with potential applicants under the "1+" mechanism, the DH will launch them in the fourth quarter of this year as planned. As the trade gains a better understanding of the application process through the briefing seminars and workshops, the pre-NDA meetings will greatly improve the quality of the application documents and hence the processing efficiency. Details of the arrangements of the pre-NDA meetings will be announced in due course.

The Hong Kong Special Administrative Region Government implemented the "1+" mechanism on November 1, 2023, and has extended it 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 its implementation, registration of a total of 11 new drugs has been approved under this mechanism. These included five new drugs (including two drugs for treating colorectal cancer, one for treating paroxysmal nocturnal hemoglobinuria, and two for treating secondary hyperparathyroidism and certain hypercalcaemia) that have already been approved for listing on the Hospital Authority Drug Formulary, facilitating more good drugs for use in Hong Kong.

Meanwhile, the Government will expedite the reform of the approval mechanism for drugs and medical devices, including announcing the timetable for establishing the Hong Kong Centre for Medical Products Regulation and a roadmap towards "primary evaluation" very soon, aiming to spur the growth of new industries in pharmaceutical and medical device research and development and testing.