LCQ19: Development and manufacture of medicines by local biotechnology industry

Following is a question by the Hon Elizabeth Quat and a written reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (September 29):

Question:

The University of Hong Kong (HKU) is currently researching and developing the world's first nasal vaccine against the Coronavirus Disease 2019 with fewer side effects, and has completed phase one clinical trial of the vaccine. It has been reported that the industrialisation of the vaccine is faced with those problems that local biotechnology research and development (R&D) personnel commonly encounter. The Research Report on Hong Kong-Shenzhen Biotechnology Collaboration (the Report) recently released by Our Hong Kong Foundation has pointed out that the problems concerned are largely related to the clinical trials and manufacture of medicines. In this connection, will the Government inform this Council:

(1) as some members of the biotechnology industry have pointed out that although Hong Kong has a worldwide reputation for its strengths in the clinical trials and research of medicines, and the data obtained from relevant clinical trials have been recognised by quite a number of major drug regulatory authorities (including those on the Mainland and in the United States and Europe), its clinical trial industry lacks support from the Government, of the Government's measures to support local hospitals and medical schools in conducting the clinical trials of medicines, and whether it has assessed the effectiveness of such measures; if such measures are not in place, of the reasons for that;

(2) as the Report has pointed out that the time currently taken for vetting and approval of an application for conducting clinical trials of medicines in Hong Kong (particularly phase one clinical trial) is longer than that on the Mainland and in other places, whether the Government will explore shortening the time taken for vetting and approval of such applications, so as to attract medical and pharmaceutical enterprises to conduct clinical trials in Hong Kong; if so, of the details; if not, the reasons for that;

(3) as HKU's R&D team has indicated that the clinical trials concerned cannot commence as early as possible because there is not any vaccine manufacturing plant in Hong Kong, and the vaccine doses to be used in the clinical trials have to be produced by a pharmaceutical company on the Mainland, whether the re-industrialisation initiatives implemented by the Government include those measures to facilitate biotechnology enterprises to set up high-end pharmaceutical manufacturing plants in Hong Kong; if so, of the details; if

not, the reasons for that; and

(4) of the measures in place to make use of the Lok Ma Chau Loop to promote the scaled development of the biotechnology industry in Hong Kong, and whether such measures include providing subsidies to the relevant organisations to facilitate the establishment in the Loop of a base for coordinating Mainland/Hong Kong multi-centre late-stage clinical trials or high-end pharmaceutical production lines?

Reply:

President,

Having consulted the Innovation and Technology Bureau, the Department of Health (DH) and the Hospital Authority (HA), the consolidated reply to the question raised by the Hon Elizabeth Quat is as follows:

(1) The Government has been supporting the local clinical trial sector, in order to promote the development of the local pharmaceutical and biopharmaceutical industries. The Health and Medical Research Fund (HMRF) under the Food and Health Bureau supports clinical trial research on infectious diseases, non-communicable diseases and advanced medical research through annual open call for investigator-initiated projects.

Apart from investigator-initiated projects, the HMRF provided funding of $80 million in 2013 under its Government-commissioned programme to support the establishment of two Phase I Clinical Trials Centres (CTCs) by the medical faculties of the Chinese University of Hong Kong and the University of Hong Kong (HKU) to enhance the capabilities of Hong Kong in clinical trial and new drug development. The two CTCs have obtained the accreditation of the National Medical Products Administration (NMPA) for conducting clinical drug trials. Additional funding of a total of $100 million has been provided to the two CTCs starting from 2019, under which over 100 clinical trials on novel therapeutic drugs have been initiated. The findings from these studies will help advance clinical practice and the standard and quality of medical care.

In addition, a total of 32 specialties from Queen Mary Hospital, Prince of Wales Hospital, Hong Kong Eye Hospital and Hong Kong Sanatorium & Hospital have gained accreditation of the clinical trial sites from the NMPA and are eligible to carry out clinical drug trial approved by the NMPA. The clinical trial data generated from these sites could be submitted to the NMPA for the purpose of drug registration in the Mainland, which facilitates Hong Kong to become an important platform for local and multinational pharmaceutical companies to venture into the vast Chinese market.

The Government has been supporting local research and development (R&D) of vaccines to enhance our knowledge base and research capabilities in vaccinology and immunology. Since April 2020, the HMRF has supported two local universities to conduct four vaccine-related R&D projects with a total commitment of $29.5 million. Among them, the HMRF has funded around $20

million to the Department of Microbiology, Faculty of Medicine of the HKU, to conduct the Phase I clinical trial on the safety of a nasal spray COVID-19 vaccine "VectorFluTM ONE" co-developed with partners in the Mainland (i.e. Xiamen University and Beijing Wantai Biological). This vaccine candidate is the first nasal spray vaccine among the COVID-19 vaccine candidates approved for Phase I clinical trials. Currently, the Phase I clinical trial of the "VectorFluTM ONE" has been completed in 30 volunteers. The Project Team is now reviewing the next phase of clinical trials to assess a wider range of immune response parameters.

(2) According to the Pharmacy and Poisons Ordinance (Cap. 138), anyone who wishes to conduct a clinical trial on pharmaceutical products in Hong Kong is required to apply to the Pharmacy and Poisons Board of Hong Kong (Board) for a Certificate for Clinical Trial (certificate). The Drug Office of the DH is responsible for providing technical and executive supports to the Board and its committees.

The DH has pledged that applications for the certificates would be processed within three months upon the submission of all required documents by the applicants. In 2020-21, the Board issued a total of 343 certificates with all applications being evaluated and approved within three months.

In addition, the DH has implemented a number of enhancement measures with an aim to shorten the time for evaluating and approving the applications for clinical trials. These measures include extending the validity period of certificates, simplifying the application procedures for low-risk clinical trials and developing an online submission system, etc. As the approval of the certificate is subject to the approval of the ethic committee of the respective research or healthcare institution, in order to further shorten the processing time of clinical trial applications, the applicants could submit applications for certificates to the DH in parallel while their clinical trials are being approved by the ethic committee of their institutions.

Moreover, the HA has also been supporting the development of clinical research in Hong Kong through various aspects including research ethics review governance, stakeholder engagement, as well as provision of study sites in public hospitals with patient involvement. To further optimise the research ethics review application for multi-cluster clinical research, the HA has established the HA Central Institutional Review Board (not for phase 1 clinical trial) in April 2021 to provide a one-stop service to handle and coordinate the ethics review of multi-cluster clinical research.

(3) Hong Kong has a competitive edge in the R&D of biotechnology. The Government has been adopting a multi-pronged approach in promoting the development of biotechnology enterprises through infrastructure, funding schemes and various support measures. The Government has implemented a new listing regime since end April 2018 to facilitate the listing of pre-revenue/pre-profit biotechnology companies in Hong Kong. At present, Hong Kong is Asia's largest and the world's second largest fundraising hub for biotechnology.

In terms of infrastructure, the InnoHK research clusters have successfully attracted a number of world-renowned universities and research institutes to the Hong Kong Science Park (HKSP). Health@InnoHK focuses on healthcare technologies, including drug discovery, personalised medicine and vaccine development, etc. This initiative will further consolidate Hong Kong's status as the hub for global biotechnological research collaboration. The Hong Kong Science and Technology Parks Corporation (HKSTPC) has also been striving to develop various infrastructure facilities in the Industrial Estates, including the Medical Accessory Resilience Supplies Manufacturing Centre, the Precision Manufacturing Centre and the Advanced Manufacturing Centre, in order to encourage manufacturers (including biotechnology enterprises) to set up high-end production bases in Hong Kong. In addition, wet laboratories (wet-labs) are indispensable to biomedical research. Currently, the leasable area of wet-labs in the HKSP amounts to 59 000 square metres (sq. m.), and will increase to about 68 000 sq. m. after the completion of the conversion works of Building 6W to wet-labs by the end of this year.

In addition, various funding schemes currently support enterprises engaging in the R&D of biotechnology. The Enterprise Support Scheme (ESS) under the Innovation and Technology Fund provides dollar-for-dollar matching funding of up to $10 million for private companies to carry out in-house downstream R&D projects, including pre-clinical research and preliminary clinical trials. In 2020-21, the ESS supported 14 biotechnology-related projects with around $30.4 million in funding. The Re-industrialisation Funding Scheme subsidises manufacturers, on a 1 (Government) : 2 (Company) matching basis, to set up new smart production lines in Hong Kong. The funding for each project is capped at $15 million. As at end August 2021, the Government has received 27 applications in total, and three of the supported applications come from biotechnology enterprises, which involve the manufacturing of biologics, as well as in vitro diagnostic reagents and testing systems. The Incu-Bio Incubation Programme of the HKSTPC provides funding of up to $4 million to incubatees engaging in biotechnology, as well as targeted additional funding of up to $2 million for certification or investigational new drug applications, etc. As at end August 2021, the Incu-Bio has supported 47 start-ups, with around $63.5 million approved by the HKSTPC.

In terms of capital, the Innovation and Technology Venture Fund (ITVF) encourages venture capital funds to invest in local innovation and technology (I&T) start-ups, and co-invests at a matching investment ratio of approximately 1 (Government) : 2 (co-investment partners). The ITVF has invested in start-ups with businesses covering different areas. For instance, the major business of a start-up involves the R&D of DNA sequencing technology and manufacturing of relevant portable sequencers. The Corporate Venture Fund (CVF) of the HKSTPC has invested in biotechnological start-ups engaging in drug delivery, stem cell technology and cancer treatment research, etc. As at end August 2021, the CVF has invested in six biotechnology-related start-ups with a total investment amount of $66.4 million.

(4) The Government is pressing ahead with the development of the Hong Kong-Shenzhen Innovation and Technology Park (HSITP) in the Lok Ma Chau Loop. The vision of the HSITP is to become the world's knowledge hub and I&T centre, and converge technology enterprises, R&D institutions and higher education institutions from Hong Kong, the Mainland and overseas, thereby connecting upstream and midstream research to downstream market, and further enhancing the collaboration among the industry, academic and research sectors. One of its priority development areas is healthcare technologies. High value-added processes including R&D, prototyping, product design, testing, etc., can be performed at the HSITP. With the geographical advantage of the HSITP, enterprises therein can leverage the strong production facilities of Shenzhen and the Guangdong-Hong Kong-Macao Greater Bay Area for mass production.

Relevant works projects of the HSITP, including infrastructure works, are being carried out at full steam, and the eight buildings in Batch 1 will be completed in phases starting from end-2024. The Hong Kong-Shenzhen Innovation and Technology Park Limited (HSITPL) will draw up plans as appropriate to attract tenants in accordance with the vision of the HSITP and its priority technology areas, as well as the experience of I&T platforms around the world in developing appropriate admission criteria and rental policies. As for start-ups, the HSITPL will take into account the relevant plans and experience of the HKSP and Cyberport to attract more start-ups to the HSITP and put in place appropriate incubation programmes and support schemes.