

LCQ8: Promoting research and development of drugs and medical devices

Following is a question by Dr the Hon Dennis Lam and a written reply by the Secretary for Health, Professor Lo Chung-mau, in the Legislative Council today (June 19):

Question:

In recent years, the Government has indicated that it will develop life and health technology. Regarding the promotion of the research and development (R&D) of drugs and medical devices, will the Government inform this Council:

(1) of the number of R&D of drugs of various universities and private enterprises in Hong Kong which received approval for conducting clinical trials of new drugs from the drug regulatory authorities in places such as the United States, the United Kingdom and the European Union in the past 10 years, and the number of new drugs which were approved for registration, with a breakdown by country/region;

(2) of the number of medical devices from various universities and private enterprises in Hong Kong which received approval for registration and marketing from the regulatory authorities in places such as the United States, the United Kingdom and the European Union in the past 10 years, with a breakdown by country/region;

(3) of the amount of funds invested by the Government in R&D of drugs and medical devices in the past five years and the specific details of the work; and

(4) of the specific measures to promote Hong Kong as an R&D centre of drugs and medical devices in the Guangdong-Hong Kong-Macao Greater Bay Area and even internationally?

Reply:

President,

"The Chief Executive's 2023 Policy Address" (Policy Address) announced that the Government will leverage the medical strengths of the Hong Kong Special Administrative Region (HKSAR) with the long-term objective of establishing an authority that registers drugs and medical devices (medical products) under the "primary evaluation" approach, i.e. to directly approve applications for registration of drugs in Hong Kong based on clinical trial data without relying on registration approval from other drug regulatory

authorities, and also start approving applications for registration of medical devices. All these aim at accelerating the clinical use of new medical products so as to enhance healthcare standards, and foster the development of industries relating to the research and development (R&D) and clinical trials of medical products, developing Hong Kong into an international health and medical innovation hub.

In consultation with the Innovation, Technology and Industry Bureau, Education Bureau, Invest Hong Kong (InvestHK), the Office for Attracting Strategic Enterprises (OASES) and the Department of Health (DH), the reply to the question raised by Dr the Hon Dennis Lam is as follows:

(1) to (3) The HKSAR has excellent research capabilities, with a clinical research framework highly compatible with international standards and clinical research data widely recognised by drug regulatory authorities including those from Europe and the United States for drug registration purposes. Meanwhile, a total of 31 clinical specialties or areas (located in four hospitals) have been accredited by the National Medical Products Administration (NMPA) to conduct clinical trials for applying drug registration with the NMPA.

Relevant bureaux/departments of the HKSAR Government provide support in various aspects on the R&D of medical products. Specific examples are set out below:

Innovation, Technology and Industry Bureau

- The InnoHK Research Clusters, a HK\$10 billion initiative of the HKSAR Government, have set up 29 laboratories formed by local universities in collaboration with over 30 top-notch universities/research institutions around the world, among which 16 are related to life and health. The Innovation and Technology Fund (ITF) has set up funding schemes to finance R&D projects on I&T. As at the end of April 2024, the ITF has already funded almost 830 projects on biotechnology and Chinese medicine, including multiple advanced technologies, such as artificial "mini-hearts", internally motorised minimally invasive robot surgeon, non-invasive prenatal diagnostic technique, etc.
- The HKSAR Government has earlier earmarked HK\$10 billion for promoting the development of life and health technology in the HKSAR. Of this, HK\$6 billion will be used for the Subsidy Programme for the Setup of Life and Health Technology Research Institute(s) to promote cross-institutional and multi-disciplinary research co-operation, under which the R&D of drugs and vaccine as well as biomedical engineering are eligible research themes.
- The Corporate Venture Fund (CVF) of the Hong Kong Science and Technology

Parks Corporation (HKSTPC) has also invested in biotechnological start-ups engaging in drug delivery, stem cell technology and cancer treatment research, etc. As at the end of May 2024, the CVF has invested in 10 biotechnology-related start-ups with a total investment amount of about HK\$100 million. The Incu-Bio Programme of the HKSTPC provides funding of up to HK\$6 million to start-ups engaging in biotechnology for rental subsidy, financial subsidy and certification or investigational new drug applications, etc. As at May 2024, the Programme has supported 87 start-ups, with a total funding amount of about HK\$180 million.

Health Bureau

- The Health and Medical Research Fund (the HMRF) under the Health Bureau (HHB) supports clinical research and research on infectious diseases with public health implications from bench to bedside and at community level through its annual open call for investigator-initiated projects as well as commissioned programmes. In the past five years, the HMRF has funded around HK\$80 million for about 70 investigator-initiated projects on clinical trials related to drugs and medical devices. These research projects include disease prevention, diagnosis, management and treatment, surgical techniques and rehabilitation covering a wide range of health issues, such as cancer, diabetes, mental health, cognitive impairment, sarcopenia, pain and muscle weaknesses, eye diseases, pregnancy-related complication, infertility, influenza and COVID-19.
- Since April 2020, the HHB and HMRF have approved a total of about HK\$550 million to support 70 COVID-19-related medical research studies (covering 105 individual projects). Among them, about HK\$130 million have been allocated to support Phase I and Phase II clinical trials on COVID-19 vaccine development and projects on COVID-19 treatment which cover a full spectrum from R&D of drugs, pre-clinical animal testing and clinical testing.
- The HMRF subsidised the establishment and development of the Phase I Clinical Trial Centres (CTCs) of the medical faculties of the Chinese University of Hong Kong and the University of Hong Kong to enhance the capabilities of the HKSAR in clinical trial and R&D of new drugs. Since 2013, a total of HK\$180 million has been provided to initiate clinical trials on over 200 items of novel therapeutic drugs.
- As regards Chinese medicine (CM), since the official launch of the Chinese Medicine Development Fund (CMDf) established by the HHB in June 2019, various funding schemes have been rolled out to support the development of CM sector on all fronts, including supporting the

commencement of more than 60 research and applied studies projects on CM, which are instrumental in promoting the academic and clinical research, professional as well as industry development of CM in Hong Kong. In order to encourage the clinical research and innovative development in CM in a focused manner, areas such as clinical and methodological research on the application of CM theory, research on the relationship between the quality of Chinese medicines and the theory and clinical efficacy of CM, research related to the application of innovative technology in CM, as well as prevention and treatment of the diseases (such as cancer, influenza and mental health promotion) in CM have been listed as priority themes. In addition, Hong Kong's first CM hospital, which is expected to commence service in phases from the end of 2025, will set up a Clinical Trial and Research Centre which will be capable of conducting Phase I and Phase II clinical trials to facilitate R&D of proprietary Chinese medicines (pCms) including the development of new pCms and expand clinical indications from existing pCms, providing an important platform for the collaboration of R&D as well as innovation of CM among local and Mainland/international organisations.

Education Bureau

- Through the Research Grants Council under the University Grants Committee (UGC), the HKSAR Government has all along been supporting the eight UGC-funded universities to carry out academic research in various disciplines, including drugs and CM. The UGC also launched the Research Impact Fund and Research Matching Grant Scheme in 2018 and 2019 respectively to encourage institutions to collaborate with different bodies (including pharmaceutical companies) on the development of Bacterial Pseudaminic Acid-based vaccine, research on novel antibiotics, study on the therapeutic effect of Pien Tze Huang, and research on controllable activation of anticancer prodrugs in vivo, etc.

InvestHK and OASES

- The HKSAR Government has been endeavouring to attract high potential and representative strategic enterprises from around the world, particularly of priority industries including the life and health technology sector. To date, the OASES has met with more than 300 enterprises, many of which are leaders in the life and health technology sector, as well as companies engaging in cutting-edge technologies. The OASES team have been engaging with these enterprises in detailed discussions about their five-year development plans and provides one-stop services to support their growth in Hong Kong, including introduction and promotion of the policies of the Hong Kong Government and funding schemes, as well as formulation of tailor-made plans to facilitate the setting-up or expansion of their operations in the HKSAR, such as assisting with visa applications for their staff and dependents, as well as supporting education arrangements for their children.

- The OASES have attracted close to 50 strategic enterprises which committed to investing more than HK\$40 billion in total in the HKSAR, and create over 13 000 jobs, the majority of which would be R&D and management positions. Around half of these enterprises are engaged in life and health technology and will set up their R&D centres or regional headquarters in Hong Kong. Since January 2023, the OASES and InvestHK have successfully supported the setting-up or expansion of 45 life and health technology companies in the HKSAR from nine jurisdictions. These enterprises will provide more than 3 200 job opportunities in the HKSAR and their total investment approached HK\$6.5 billion.

Relevant bureaux/departments do not keep other information as mentioned in the questions.

(4) In the past six months or so following the announcement of the Policy Address, the HKSAR Government has been making proactive moves in all respects to develop the HKSAR into an international health and medical innovation hub and achieved results.

Firstly, with the support and guidance of the NMPA, Hong Kong, China has become an observer of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use on October 31, 2023. This allows the HKSAR to familiarise itself with the latest developments in drug regulation and take forward the development of the drug regulatory regime in Hong Kong, to further align the HKSAR with the World Health Organization-Listed Authority.

Secondly, the HKSAR Government implemented a new mechanism for the approval of new drugs (the "1+" mechanism) on November 1, 2023. Under the "1+" mechanism, holders of registration from one of the reference drug regulatory authorities (instead of two) for new drugs could apply for registration in Hong Kong, on the condition that they could provide local clinical data that complies with the requirements and information recognised by local experts.

Thirdly, the HKSAR Government has established the Preparatory Office for the Hong Kong Centre for Medical Products Regulation (CMPR) under the DH on June 5 this year. The Preparatory Office for the CMPR will comprehensively study and plan a regulatory and approval regime for medical products suitable for Hong Kong; and put forward proposals and steps for the establishment of the CMPR. Looking ahead, the regulation of medical devices will fall within the scope of the CMPR's work. The HKSAR Government is conducting a comprehensive review of the proposed legislative framework for medical device regulation in tandem with the progress of establishing the CMPR for considering the legislative timetable, thereby further enhancing the regulatory regime for medical products in Hong Kong.

Besides, the HKSAR Government will establish the Greater Bay Area

International Clinical Trial Institute (GBAICTI) in the Hetao area by the end of 2024. The GBAICTI will provide one-stop clinical trial support services to further enhance the capacity and efficiency of clinical trials in Hong Kong. The HKSAR Government is proactively discussing with the Shenzhen Municipal Government to jointly establish a clinical trial collaboration platform in the Hong Kong Park and Shenzhen Park of the Hetao Shenzhen-Hong Kong Science and Technology Innovation Co-operation Zone under the "one zone, two parks" model for the co-ordinated development of clinical trials, with a view to establishing a GBA clinical trial network leveraging a population base of over 86 million for conducting cross-boundary multi-centre clinical trials.

The HKSAR Government will continue to actively follow up on the relevant work to attract more medical product enterprises, both locally and from around the world, to conduct R&D and clinical trials in the HKSAR, and build the capacity, recognition and status in different phases for ensuring that the eventual approval mechanism of medical products in the HKSAR would be widely recognised internationally and by the Mainland, and to develop the HKSAR into an international health and medical innovation hub.