LCQ19: Evaluation, registration and introduction of new pharmaceutical products

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 (October 27):

Question:

Under the Pharmacy and Poisons Ordinance (Cap. 138) and the relevant regulations, pharmaceutical products must meet the standards of safety, efficacy and quality, as well as have been approved for registration with the Pharmacy and Poisons Board of Hong Kong (the Board) before such products may be sold or distributed in Hong Kong. The Board currently adopts a "secondary evaluation" approach for vetting and approval of applications for registration of pharmaceutical products containing new chemical or biological entities (collectively referred to as "NCEs"), i.e. relying mainly on the registration approvals from competent drug regulatory authorities of designated reference countries (of a total of 32 countries, including Australia, Canada and the United States but excluding China) which have conducted the primary evaluation. Regarding the evaluation, registration and introduction of NCEs, will the Government inform this Council:

(1) given that the Nation started to reform its drug review and approval system in 2015, that the National Medical Products Administration has joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2017 and was/has been elected a member of the ICH Management Committee in 2018 and in 2021, and that the alignment of China's drug registration regulatory regime and standards with the international regulatory regime has accelerated, whether it knows if the Board will, in vetting and approving NCEs, consider afresh accepting the documentary proof of evaluation and registration issued by Mainland drug regulatory authorities; if the Board will, of the details; if not, the reasons for that;

(2) whether it will take measures to support the development of the departments of pharmacology/pharmacy of the faculties of medicine of two local universities into internationally recognised institutions for evaluation of NCEs, and to promote Hong Kong as Asia's hub for NCE evaluations; if so, of the details; if not, the reasons for that;

(3) as it has been reported that some anti-cancer drugs independently developed by Mainland enterprises have been included on the national drug catalogue for basic medical insurance, whether it knows if the Hospital Authority (HA) will consider introducing such drugs; if the HA will, of the details; if not, the reasons for that;

(4) given that the Chief Executive has, in the Policy Address just delivered, put forward vigorous development of life and health technology, and has asked the relevant departments to conduct a review on the complementing areas such as clinical data, clinical trials and drug registration as well as to tie in with the needs, of the details and timetable for the relevant work; and

(5) as it has been reported that the HA intends to procure Molnupiravir, a new drug developed by a pharmaceutical company in the United States for treating coronavirus disease 2019, whether it knows the progress of the relevant work?

Reply:

President,

My reply to the various parts of the question raised by the Hon Elizabeth Quat is as follows:

(1) and (2) According to the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance) and the Pharmacy and Poisons Regulations (Cap. 138A) (the Regulations), pharmaceutical products must satisfy the criteria of safety, efficacy and quality for registration with the Pharmacy and Poisons Board of Hong Kong (the Board) before they can be sold or supplied in Hong Kong. Applicant of registration of pharmaceutical products is required to submit sufficient information to the Board to substantiate the safety, efficacy and quality of the pharmaceutical product. Applicant of registration of pharmaceutical products containing new chemical or biological entities (NCEs, i.e. contain active ingredients which have not been registered in Hong Kong) is required to provide documents as stated in the "Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity" (Note 1) promulgated by the Board, which include the expert evaluation report on the safety, efficacy and quality of the NCEs, and documentary proof of registration of the pharmaceutical products issued by at least two drug regulatory agencies or authorities of recognised countries (Note 2) (e.g. free sale certificate), in order to provide supporting evidence that the product has been rigorously evaluated before placing in market.

The aforementioned approval system is also referred to as "secondary evaluation". That is, the Board relies on the registration approvals from drug regulatory agencies or authorities of recognised countries which have conducted "primary evaluation" (Note 3) in order to process applications for registration of pharmaceutical products containing NCEs. Currently, the drug regulatory agencies or authorities of the "primary evaluation" countries that the Board makes reference to are members of the Stringent Regulatory Authority (SRA) as designated by the World Health Organization (WHO) as well as members of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). These countries have fully complied with the technical standards and requirements promulgated by the ICH (Note 4). The National Medical Products Administration (NMPA) has been a member of the ICH and is implementing relevant guidelines. It is

understood that currently the NMPA has yet to fully comply with the technical standards and requirements promulgated by the ICH. The Hong Kong Special Administrative Region Government is keeping in view of the NMPA's implementation of the relevant guidelines of the ICH. In the meantime, the Board reviews the relevant registration requirements of drug registration from time to time while upholding the principle of ensuring the relevant standards of safety, efficacy and quality of pharmaceutical products. This includes making reference to registration approvals from drug regulatory agencies or authorities of the Mainland and other countries.

The Government currently has no plan on developing departments of pharmacology/pharmacy of the faculties of medicine of the two local universities into internationally recognised institutions for evaluation of NCEs.

(3) As the major provider of publicly-funded public healthcare services, the Hospital Authority (HA) attaches great importance to providing optimal care for all patients while ensuring patients an equitable access to cost-effective drugs of proven safety and efficacy under the highly subsidised public healthcare system.

On drug management, the HA has an established mechanism for regular evaluation of new drugs and review of its Drug Formulary (HADF) and coverage of the safety net. The process follows the principles of evidence-based practice, rational use of public resources, targeted subsidy, opportunity cost consideration and facilitation of patients' choice, taking into account the safety, efficacy and cost-effectiveness of drugs and other relevant considerations, including international recommendations and practices as well as views of professionals and patient groups.

The HA has also put in place a mechanism to allow doctors to use non-HADF drugs (whether it is registered or not) under special circumstances in the light of the clinical needs of individual patients so as to meet individual needs and ensure that patients are provided with appropriate clinical care. When the use of drug(s) which has/have not been registered in Hong Kong is considered necessary for an individual patient, the HA hospital concerned should submit applications to the DH and ensure compliance with all statutory requirements.

Evaluation of drugs is an on-going process driven by evolving medical evidence, the latest clinical developments and market dynamics. The HA will continue to keep abreast of the latest development of clinical and scientific evidence of different cancer drugs from Mainland and overseas, listen to the views and suggestions of patient groups, and review the HADF and coverage of the safety net under the principle of rational use of limited public resources while providing adequate medical care to the largest number of patients in need.

(4) The Government and the HA have been facilitating the development of the sector in areas such as clinical data, clinical trials and drug registration.

The HA provided data to over 200 researchers in 28 collaboration

projects through the HA Data Collaboration Lab since 2019, and launched the Self Services Platform to facilitate local researchers using healthcare data for further exploration and innovation. On the other hand, from April 2020 to September 2021, the FHB and its Health and Medical Research Fund have approved a total of $513 million to support 67 COVID-19 research studies by local universities from bench to bedside and at the community level through application of new technologies.

The Chief Executive has recently announced in the Policy Address that the Government will further promote life and health technology. To this end, the FHB, the HA and the DH will conduct a comprehensive review of the current practices and provide facilitation. This includes:

(i) To encourage the use of big data and further promote research and development (R&D), the HA will assist more institutions to explore the potential use of healthcare data for R&D collaboration with the HA with a view to elevating the standard of Hong Kong's medical services and maintaining their competitiveness. Besides, the collaboration between the HA and Hong Kong Science and Technology Parks Corporation on the use of HA's clinical data for R&D will be explored by the FHB.

(ii) The HA will continue to provide support through various aspects including research ethics review governance, stakeholder engagement, as well as provision of study sites in public hospitals with patient involvement. In order to improve the efficiency of application for ethics review, the HA has formed the Central Institutional Review Board in April 2021 and opinions will be given within 60 days upon receiving a valid application to support researchers in conducting clinical trials. The HA will continue to monitor the effectiveness of the procedures in order to support researchers in conducting clinical research.

(iii) The Government will also expedite the legislative process for registration of drugs containing NCEs under the Regulations, with a view to making relevant pharmaceutical products available in the market as early as possible, supporting the development of life and health technology and benefitting more patients in need.

(5) Regarding the testing and treatment of COVID-19, the HA, the FHB, and the DH have been maintaining close liaison to keep in view the epidemic situation, the latest development of clinical treatment and scientific evidence, and updated data from global drug regulatory authorities as well as pharmaceutical companies. The HA is closely communicating with the drug manufacturers concerned with a view to procure and stockpile suitable COVID-19 drugs timely. In addition, the HA experts will continue to ensure access by COVID-19 patients to new drugs of proven safety and efficacy through evaluation under the established mechanism.

Note 1: Please see the full text of the Guidance Notes at: www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Guidance_on_Reg_of_Pharm_Prod_Containing_New_Chem_or_Bio_Entity_en.pdf

Note 2: There are 32 recognised countries. The drug regulatory authorities of

the countries concerned are members of the SRA as designated by the WHO, and are also members of the ICH that have implemented all relevant ICH guidance.

Note 3: "Primary evaluation" is generally conducted by highly developed and large scale drug regulatory authorities (e.g. SRAs as designated by the WHO). It involves the assessment of primary data and information of all pre-clinical studies (i.e. animal testing), clinical studies, manufacturing and quality control in order to fully evaluate the safety, efficacy and quality of a medicine. By making reference to the "primary evaluation" conducted in other countries, it requires multidisciplinary assessment including the professional assessment and evaluation from chemistry, microbiology, toxicology, pathology, statistics and different clinical specialities, which involves a vast amount of human and hardware resources (e.g. independent and accredited laboratories).

Note 4: The ICH plays a unique role in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. ICH regulators are required to implement the final Guidelines to ensure that the medicines that were developed and registered are safe, effective and of high quality.