For discussion
on 20 February 2024

Legislative Council Panel on Health Services

Developing into a Health and Medical Innovation Hub

Purpose

This paper briefs Members on the Health Bureau (HHB)'s efforts in developing Hong Kong Special Administrative Region (HKSAR) into a health and medical innovation hub.

Background

2. The HKSAR has an efficient healthcare system and high-quality medical care services. It is one of the places with the highest life expectancy worldwide. The National 14th Five-Year Plan proposes to develop HKSAR into an international innovation and technology hub. Health and medical innovation can bring the benefits of good drugs and research and development (R&D) to Hong Kong. Through innovative R&D, our citizens may benefit from some of the most advanced, effective and up-to-date drugs with reduced price through more drug registrations. The translation of innovative technologies into clinical applications can benefit the public and further contribute to the development of the industry.

3. It was announced in the Chief Executive's 2023 Policy Address that the HKSAR will enhance the evaluation and approval mechanism for drugs, and to establish an internationally renowned regulatory authority of drugs and medical devices. The HKSAR Government is determined to leverage Hong Kong's medical strengths and establish the "Hong Kong Centre for Medical Products Regulation" (CMPR), with the long-term objective of establishing an internationally recognised authority that registers drugs and medical devices under the "primary evaluation" approach[1], i.e. to directly approve applications for registration of drugs and medical devices based on clinical trial data. This will help accelerate the clinical use of new drugs and medical devices, and to

[1] The "secondary evaluation" approach adopted in the HKSAR is the process to approve applications for registration of drugs containing new chemical or biological entities (NCEs). It relies on the approvals from recognised competent drug regulatory authorities which have conducted primary evaluation. Primary evaluation 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.

drive the development of industries relating to the R&D and testing of medical products.

4. To become an internationally renowned regulatory authority and to drive local development of biomedicine, the HKSAR Government must establish a comprehensive regulatory regime for drugs and medical devices that is recognised by the Mainland and other places. In this connection, the HKSAR is proactively carrying out the following six steps –

(a) Firstly, to establish a new mechanism for the approval of new drugs (the "1+" mechanism) under the "secondary evaluation" approach. Under the "1+" mechanism, holders of registration from one of the recognised drug regulatory authorities for drugs containing NCEs could apply for registration in the HKSAR, on the condition that they could provide local clinical data which complies with the requirements and information recognised by local experts;

(b) Secondly, to access to International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[2] under the name of Hong Kong, China (ICH observership already obtained in end-2023). This allows the HKSAR to familiarise with the latest development of drug regulation and to enhance the local drug regulatory regime, so as to further align HKSAR with the World Health Organization-Listed Authority (WLA);

(c) Thirdly, the Department of Health (DH) to set up the Preparatory Office for the CMPR. The Office will put forward proposals and steps for the establishment of the CMPR and to study potential restructuring and strengthening of the current regulatory and approval regimes for drugs and medical devices;

(d) Fourthly, to formally establish the CMPR, which consolidates and enhances to regulation and evaluation of drugs (including both Chinese medicines and Western medicines) and medical devices. The CMPR can make fuller use of the existing highly efficient regulatory regime to achieve greater benefits and synergies. The CMPR could also centralise relevant expertise and optimise resource allocation, with the aim of supporting the approval of innovative medical products, promoting the scientific advancement of drugs, medical devices and

[2] The ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) is an internationally recognised association. The mission of the ICH is to harmonise the technical requirements for drug registration among its members and to promulgate various guidelines on safety, efficacy and quality that are being recognised as the highest global standards for the protection of public health.

medical technology, and expediting their clinical application, thereby driving the development of industries relating to the R&D as well as testing of medical products;

(e) Fifthly, to implement primary evaluation of drugs and medical devices, i.e. to approve applications for registration of medical products in the HKSAR independently based on clinical data, without relying on other drug regulatory authorities; and

(f) Finally, to become an ICH regulatory member and gain international recognition for drugs approved in the HKSAR.

Based on international experience, it usually takes about eight to ten years from initial engagement with the ICH to becoming an ICH regulatory member. In the approximately four months since the announcement of the Chief Executive's 2023 Policy Address, the HKSAR Government has advanced several of the above steps. Details are set out in paragraphs 7 to 16 below.

5. At the same time, clinical trial is an important process in translating clinical research into marketing authorisation and clinical application. Given the high level of medical expertise in the HKSAR, the high quality of data generated from clinical trials conducted in the HKSAR has been recognised by drug regulatory authorities both in the Mainland and abroad. The HKSAR Government also plans to set up the "Greater Bay Area International Clinical Trial Institute" (GBAICTI) to provide a one-stop clinical trial support platform for biomedical and research institutions, to co-ordinate clinical trial resources in the public and private healthcare sectors in the HKSAR, and to further enhance the development of clinical trials, which will complement the development of the primary evaluation mechanism. Details are set out in paragraphs 17 to 19 below.

Latest Developments

6. To further promote and implement the work to develop the HKSAR into a health and medical innovation hub, the HKSAR Government has established the "Steering Committee on Health and Medical Innovation and Development" (SCHMID), chaired by the Secretary for Health and comprising members from relevant bureaux, departments, institutions, and local medical schools. The SCHMID is tasked with co-ordinating and advancing the work related to health and medical innovation. The SCHMID has held its first meeting on 30 January 2024 and advised the HKSAR Government on the direction and policy initiatives for driving medical innovation, including measures to enhance the regulation on drugs and medical devices, and clinical

trial development. The HHB will continue to play the leading role in ensuring that the HKSAR builds up its capacity, recognition and status at different stages to ensure that the eventual approval mechanism of drugs and medical devices would be widely recognised internationally and by the Mainland. Specifically, the HKSAR Government has introduced / will introduce measures as set out below.

(1) Accession to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

7. With the support of the National Medical Products Administration (NMPA), the ICH formally accepted Hong Kong, China as its observer at the assembly meeting held in the Czech Republic on 31 October 2023. This enables the HKSAR to familiarise itself with the latest development in drug regulation and to enhance the local drug regulatory regime, paving the way for the long-term objective of establishing a medical products registration system with the "primary evaluation" approach.

8. The accession to ICH as an observer provides the basis for the HKSAR Government to gradually implement the ICH guidelines in Hong Kong. This will strengthen the local capacity of drug approval as well as facilitate software, hardware and manpower development, with the ultimate aim to become an ICH regulatory member. Becoming an ICH regulatory member can demonstrate the drug regulatory authority's commitment to ensuring the compliance of the highest global standards of safety, efficacy and quality by local drug enterprises, for the protection of public health.

9. After becoming an ICH observer, the HKSAR Government will gradually implement the ICH guidelines in the local pharmaceutical industry and to consider the adoption of relevant guidelines in the local drug registration requirements. The DH will proactively liaise with stakeholders and formulate the direction and roadmap for becoming an ICH regulatory member, and will also work out relevant plans and collaborative measures.

(2) The "1+" Mechanism

10. According to the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical products must satisfy the criteria of safety, efficacy and quality, and registered with the Pharmacy and Poisons Board of Hong Kong (the Board) before they can be sold or supplied in Hong Kong. Applicants for registration of pharmaceutical products are required to submit the necessary documents in accordance with the Guidance Notes on Registration of Pharmaceutical Products/Substances as promulgated by the Board. In general, applicants for

registration of pharmaceutical product containing NCEs are required to provide necessary information including documentary proof for registration issued by at least two drug regulatory authorities of reference places in accordance with the Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity as promulgated by the Board, in order to provide supporting evidence that the product has been rigorously evaluated before placing in the market (i.e. the "secondary evaluation" approach). The Board reviews the registration requirements of drug regulation from time to time, including the update of the list of reference places. Since 1 November 2022, the regulatory authorities of Mainland China, Brazil, Korea and Singapore were included in the list of reference places for registration of drugs containing NCEs. The current list comprises 36 reference places.[3]

11. To enhance the existing drug regulatory regime, the Chief Executive's 2023 Policy Address announced the new "1+" mechanism for registration of new drugs, which came into effect on 1 November 2023. Under the newly established "1+" mechanism, applicants could apply for registration of new drugs that are beneficial for the treatment of life-threatening or severely debilitating diseases that are supported with local clinical data and scope of application recognised by local expert, if they submit approval from one reference drug regulatory authority (instead of two).

12. The DH has promulgated the "1+" arrangement to the trade and issued letter to notify the relevant stakeholders (including relevant pharmaceutical associations and holders of certificate of drug registration) on the implementation details of the "1+" mechanism, and to handle relevant enquiries and potential applications. Since the commencement of the "1+" mechanism, the DH has received and followed up 126 enquiries involving 55 companies (as of 13 February 2024). The DH has also proactively approached the pharmaceutical trade and invited the submission of applications for registration under the "1+" mechanism for suitable products, and organised four online seminars (with attendance of 175 participants) to explain the arrangements for the "1+" mechanism. Under the "1+" mechanism, two new drugs for cancer treatment have already been approved for registration in Hong Kong, which are oral target therapy products with different strengths indicated for metastatic

[3] The Board reviews the registration requirements of drug regulation from time to time. The Board noted that the Mainland China, Brazil, Korea and Singapore have joined the ICH and demonstrated good progress of promoting and implementing relevant ICH Guidelines and considered that the relevant regulatory systems have generally met the stringent requirements for becoming WLA. As such, the four relevant drug regulatory authorities have been included in the reference list for the purpose of registration of drugs containing NCEs since 1 November 1 2022. Starting from 23 February 2023, applications for registration of NCEs are only required to submit documentary evidence of registration issued by any two or more of the 36 reference drug regulatory authorities. Upon updating the list, the Board has received 12 applications involving drug regulatory authorities of the four newly added reference countries (as of 13 February 2024). Eight of those applications have been approved, while the remaining four are being processed.

colorectal cancer. The first batch of products has arrived in Hong Kong in early February, bringing new hope of treatment to patients. In addition, several pharmaceutical companies have expressed interest in applying for registration under the "1+" mechanism. Applications would be submitted to the Board once the necessary information is available.

13. Since the implementation of the Hospital Authority (HA) Drug Formulary, the HA has continued to refine its review mechanism of the Drug Formulary to expedite the introduction of new drugs. The HA Drug Formulary is an important cornerstone in the application of drugs in public healthcare and its coverage should also be driven by clinical service needs. The HA will liaise closely with the DH in the light of the "1+" mechanism to cater for the clinical needs of local patients. Through the "1+" mechanism, the number of drugs successfully registered in Hong Kong will be increased, thus enabling clinicians to have a wider choice of drugs to support their service needs. Clinicians may initiate application for new drug listing on the HA Drug Formulary to the HA Drug Advisory Committee according to the clinical service needs. In addition, when a new drug can be registered in a more expeditious manner and listed on the HA Drug Formulary in Hong Kong under the "1+" mechanism and is proven to have significant clinical benefits, it may be covered by the Samaritan Fund or the Community Care Fund.

14. The "1+" mechanism will facilitate the registration of new drugs that meet local unmet medical needs in Hong Kong from different parts of the world and allow patients' early access to new drugs. The new mechanism could attract more drug development and clinical trials to be conducted in Hong Kong. The requirements for local clinical data and recognition by relevant experts for application for registration (the "+" under the "1+" mechanism) will ensure that all the drugs approved for registration fulfil the stringent requirements of safety, efficacy and quality. It will also strengthen the local capacity of drug evaluation and strengthen the development of relevant software, hardware and expertise.

(3) Establishing the Preparatory Office for the CMPR

15. It was announced in the Chief Executive's 2023 Policy Address that a preparatory office for CMPR will be set up in the first half of 2024. The preparatory office will review the regulatory functions of the DH, including the regulation of Chinese and Western medicines and medical devices, study the potential restructuring and strengthening of the current regulatory and approval regime for drugs and medical devices, with a view to implementing "primary evaluation" approach for medical product registration. This will help

accelerating the clinical application of new drugs and medical devices, and to foster the development of medical product industries.

16. The HKSAR Government will explore the establishment of the CMPR as a standalone statutory authority in a long run. This will help accelerate the launching of new drugs and medical devices to the market, and foster the development of R&D and testing of medical products and related industries. The specific work of the preparatory office will include comprehensive study and planning of a regulatory and approval regime for drugs and medical devices suitable for Hong Kong, as well as the need for amending existing legislations. In addition, the preparatory office will make recommendations to the Steering Committee, and liaise and communicate closely with various stakeholders. The preparatory office will report the progress to the Steering Committee in due course, with the aim of formally establishing the CMPR within two to three years. The establishment of the CMPR will require additional professional human resources. The HKSAR Government will review the staffing requirements and seek necessary resources through the established mechanism.

(4) Promote Clinical Trials Development

17. Since the announcement of the 2023 Policy Address in October 2023, the HKSAR Government has been actively reaching out to various stakeholders and has carefully studied the recommendations in the policy research report entitled "Develop Hong Kong into Asia's Leading Clinical Innovation Hub" published by Our Hong Kong Foundation in November 2023, in order to gather views on how to promote clinical trial development with a comprehensive approach. The HKSAR Government plans to establish the GBAICTI in the Hetao area, and the preparatory work has already been kick-started. The GBAICIT will provide a one-stop clinical trial support service, with a view to further enhance the capacity and efficiency of clinical trials in Hong Kong and to transform Hong Kong into a leading clinical trial hub in Asia. Key functions to be performed by the GBAICIT include –

(a) To coordinate clinical trial resources in the public and private healthcare sectors in Hong Kong;

(b) To establish clinical trial collaboration network and training programmes;

(c) To work continuously with stakeholders to review and improve different clinical trial processes; and

(d) To advise on the long-term planning for clinical trial infrastructure and resources required to support clinical trial development.

18. On the other hand, the HKSAR Government is actively promoting collaboration with the Guangdong-Hong Kong-Macao Greater Bay Area (GBA) to dovetail with the "Development Plan for Shenzhen Park of Hetao Shenzhen-Hong Kong Science and Technology Innovation Co-operation Zone" promulgated by the State Council in August 2023. The HKSAR Government is working with the Shenzhen Municipal Government on the establishment of a clinical trial co-operation platform in the Shenzhen Park and the Hong Kong Park of the Hetao Shenzhen-Hong Kong Science and Technology Innovation Co-operation Zone, with a view to promote the coordinated development of clinical trials, cooperation with the clinical trial network in the Mainland (especially the GBA) through the GBAICTI, and coordination of clinical trial work in the two places with the aim of meeting national and international standards. The HKSAR Government will capitalise on the excellent quality, international standard of local healthcare and clinical trials and experience of international cooperation, together with the number of cases in the GBA, so as to leverage on the strengths of the two places in clinical trials. The initiative will attract more local and overseas pharmaceutical and medical device enterprises to conduct R&D and clinical trials in the HKSAR and other network organisations in the GBA. The HKSAR Government, through the GBAICTI to be established in the near future, will coordinate with the relevant organisations in the Mainland, to jointly build the clinical trial collaboration platform, so as to fully play the HKSAR's important role in "attracting foreign investment and assisting Mainland enterprises to go global" in the field of innovative medical technology.

19. At the same time, the HA has an extensive public healthcare system and the clinical data in the system is an important resource to support clinical trials. In line with the HKSAR Government's policy, the HA will implement various measures to facilitate researchers and medical professionals in the public health care sector to conduct more clinical researches and trials –

(a) Setting up the "Central Clinical Research and Innovation Office" and the "Cluster Clinical Research Support Office": To set up the "Central Clinical Research and Innovation Office" in the HA Head Office in the first quarter of 2024 to collaborate with the GBAICTI, universities and relevant institutions of Medicine and Life Sciences, etc.; and to set up the "Cluster Clinical Research Support Office" in each cluster in 2024-2025 to provide advisory and support services on clinical research, such as research study design, data collection and analysis, assistance in processing research ethics applications and provision of training, etc.,

to encourage medical teams to participate in clinical researches and trials;

(b) Central coordination of ethics review for cross-cluster clinical research: The existing cluster Clinical Research Ethics Committees will be consolidated into the Central Institutional Review Board in the first quarter of 2024, and the application and review process for research ethics will be further streamlined in the second quarter of 2024, so as to facilitate cross-cluster clinical researches and trials;

(c) Streamlining the process and expediting ethics review of clinical research: Upon receipt of a valid application for expedited ethics review for clinical research, the Central Institutional Review Board will give its advice within 30 days to support and facilitate investigators to conduct clinical trials. Relevant work is in progress (first quarter of 2024);

(d) Encouraging and acknowledging frontline staff participation in clinical research: Clinical research (as well as teaching and training) has been included in the assessment criteria for promotion of doctors in July 2023 and will soon be extended to other clinical grades. The HA will also consider other measures to encourage and acknowledge the participation of frontline staff in clinical researches;

(e) Data sharing: The "Hong Kong Science and Technology Parks Corporation (HKSTP) HA Data Collaboration Lab", a collaboration between the HA and the HKSTP, has been commissioned in the Hong Kong Science Park in October 2023, and upon completion of the pilot project, it will be further opened up for eligible scientific research companies in the Park to access the anonymised healthcare data for scientific research and development purposes; and

(f) IT system infrastructure: The HA is in the process of designing the relevant IT system infrastructure and platform to facilitate the workflow of clinical trials.

The HA will continue to support clinical research through strengthening research ethics governance and providing clinical trial sites as well as patient participation in public hospitals, and work with different research teams to promote the development of scientific research for the benefit of the local healthcare system and patients.

Advice Sought

20. Members are invited to note the content of this paper and comment on HHB's work in developing the HKSAR into a health and medical innovation hub.

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