"Primary evaluation" begins phased implementation and applications of new drugs for registration accepted under initial phase [1]

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Preamble

1.The Hong Kong Special Administrative Region (HKSAR) is on a mission to become a leading hub for innovation and technology, with health and medical innovation playing one of the key roles. Promoting research and development (R&D) and innovations in medicine may bring cutting-edge and affordable medical products to the market while fostering growth in the local healthcare and biotechnology industries. A robust regulatory system, on the other hand, is extremely important to ensure medical products used for the treatment of our citizens are safe, effective, and of good quality.

2.The Chief Executive announced in the 2023 Policy Address that the HKSAR would enhance the evaluation and approval mechanism for medical products, and establish the "Hong Kong Centre for Medical Products Regulation" (CMPR) with the objective of positioning the CMPR as an internationally renowned regulatory authority that registers medical products under the primary evaluation approach, i.e. Hong Kong will assess and approve new drugs and medical devices independently through its own robust system without relying solely on overseas approvals. This will help speed up patients' access to breakthrough treatments and boost medical R&D and testing industries in Hong Kong. To this end, the Department of Health (DH) set up the Preparatory Office in June 2024 to lay the groundwork for establishing the CMPR and reforming the regulatory regime for medical products, including the adoption of primary evaluation.

3.This document presents the roadmap towards the establishment of the CMPR and the adoption of primary evaluation in Hong Kong.

[1] Official Text

Part I: Timetable for the Establishment of the Hong Kong Centre for Medical Products Regulation

Background

4.The establishment of the CMPR can make fuller use of the existing highly efficient regulatory regime to achieve greater benefits and synergies. The CMPR will 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 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. At the initial stage, the CMPR will be established under the DH, the Government will explore to transform the CMPR into a standalone regulatory authority in the long run.

5.While the CMPR will consolidate the regulation of Western medicines, Chinese medicines, and medical devices, the Chinese Medicine Development Blueprint will be published in Q4 2025 and the Government is targeting to introduce a bill for the statutory regulation of medical devices into the Legislative Council (LegCo) in 2026. This timetable, therefore, mainly focuses on the timeline for the establishment of the CMPR and key milestones pertaining to Western medicines, i.e. pharmaceutical products.

The CMPR

6. The vision of the CMPR is to be a leading internationally renowned medical products regulatory authority, driving excellence and innovation. It is of paramount importance that the establishment of the CMPR is laid on a solid foundation to achieve this vision and a series of preparatory works is being conducted to build such a foundation. The preparatory works mainly focus on three strategic areas, namely driving regulatory excellence, promoting medical product innovation, and deepening national and international collaboration.

Driving Regulatory Excellence

7. While the current regulatory regimes for Western and Chinese medicines in Hong Kong are in line with international practice, there are areas that could be further improved and strengthened in order to elevate our regimes as a robust, science-driven and mature regulatory authority recognised by international counterparts. Driving regulatory excellence not only enhances the competency and efficiency of medical product evaluation and regulation, it also helps maintain high level of regulatory transparency and accountability, and build public confidence.

8.Introduction of new legislations and amendment of existing law that regulates pharmaceutical products (2025 onwards) - A bill for medical products regulation (MPR Bill) is being prepared to provide statutory authority for the CMPR to regulate medical products. The MPR Bill will also include necessary consequential amendments to the existing Ordinances that regulate pharmaceutical products and Chinese medicines. Consultations with relevant industries and stakeholders will be carried out to explain the legislative proposal and address their concerns before introducing the MPR Bill into the LegCo in 2026.

9.In addition, the existing Ordinance that regulates pharmaceutical products, i.e. the Pharmacy and Poisons Ordinance (Cap. 138), will require major revamp in order to align with the mandates of the CMPR and to provide necessary legal basis for regulatory enhancements Since the amendments to the Ordinance will have major impacts on the trade, amendment proposal and related public consultation will be prepared separately after the establishment of the CMPR. Upon the release of the Chinese Medicine Development Blueprint, the Government will also conduct a holistic review of the Chinese Medicine Ordinance (Cap. 549) for updating relevant regulations and requirements, as well as fostering scientific research and innovation in Chinese medicine and industry upgrading.

10.Buildup expertise and capacity (2025 onwards) - The implementation of primary evaluation requires strengthened analytical (especially for biological products, vaccines and advanced therapy products) and evaluation capacity, which demands new experts in various areas as well as specialised training of existing professional staff. Moreover, strengthening of inspection capacity, particularly in the areas of Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GVP), is crucial in order to support the life cycle management of new medical products under the primary evaluation approach. On the other hand, capacity building for the enforcement of new statutory regulation of medical devices is also necessary in order to properly regulate medical devices upon the enactment of the new Ordinance. The DH is actively training existing professional staff to develop the expertise and competency in conducting primary evaluation of new drugs and related activities. In parallel, plans are being formulated to engage relevant experts with extensive experience in primary evaluation, laboratory analysis, and medical devices regulation to build up CMPR's capacity.

11.Alignment with international best practices (2026 onwards) - Hong Kong's accession to the Pharmaceutical Inspection Cooperation Scheme (PIC/S) in 2016 has greatly enhanced the quality of pharmaceutical products produced and registered in Hong Kong. To pave the way for the CMPR to implement primary evaluation and to become an internationally renowned regulatory authority, the overall regulatory regime for medical products must be further strengthened to align with international best practices (i.e. GxPs). Therefore, essential GxPs such as the International Council for Harmonisation of Technical Requirements for

Pharmaceuticals for Human Use (ICH) GCP Guidelines and PIC/S Good Distribution Practice (GDP) Guide will be promulgated starting from 2026. The CMPR will also develop and implement the GVP Guidelines based on international practice after its establishment. Meanwhile, plans would be formulated to further strengthen the regulation of Chinese medicines in line with the Chinese Medicine Development Blueprint to be released in Q4 2025.

Promoting Medical Product Innovation

12. One of the key objectives of the CMPR is to promote R&D and innovation of medical products. This aligns with the National 14th Five-Year Plan to drive health and medical innovation, and attracts companies with cutting-edge technologies to invest in Hong Kong, thus benefitting our citizens with the most advanced, safe, effective and affordable medical products. Under this strategy, the most important initiative is the implementation of primary evaluation.

13. Definement of the roadmap for primary evaluation (Q2 2025) - Since the introduction of the "1+" mechanism at the end of 2023 and extension of the mechanism to cover all new drugs at the end of 2024, the Government has been implementing various measures, e.g. stop-clock system for registration evaluation and consultation service for applications under the "1+" mechanism, to work towards the adoption of primary evaluation of new medical products. A detailed roadmap has been worked out in Part 2 of this document to set out the steps towards the adoption of primary evaluation.

14. Partnership with stakeholders (Q3 2025 onwards) - Close collaboration and partnership with stakeholders is instrumental to the successful implementation of the primary evaluation and promotion of medical product innovation. Following the publication of this timetable, a series of briefing seminars and meetings with various stakeholders, including academia, industry, institutes, legislators, licencees, researchers, relevant professional and trade organisations, as well as potential applicants and interested parties outside Hong Kong, will be carried out to elucidate the plan for the CMPR.

15. In addition, to ensure that the trade and all licencees could comply with international best practices, task forces would be set up with affected stakeholders on the implementation of GxPs and organisation of related capacity building initiatives. The CMPR will also proactively

consult relevant stakeholders on potential measures to improve the regulatory system and streamline various application processes, so as to facilitate R&D and promote innovation.

Deepening National and International Collaboration

16. Deepening of collaboration with national and GBA counterparts (continuous efforts) - The DH has been closely collaborating with various Mainland national authorities (e.g. National Health Commission of the People"s Republic of China, National Medical Products Administration (NMPA) and National Administration of Traditional Chinese Medicine) and regional regulatory authorities in the Guangdong-Hong Kong-Macao Greater Bay Area (GBA). The CMPR will further deepen the collaboration with Guangdong Medical Products Administration and relevant GBA authorities to facilitate approval of Hong Kong registered medical products under the GBA measures. Close partnership with GBA authorities could also leverage the resources and capacity in the region to enhance R&D, clinical trial, and production of medical products. On the other hand, the CMPR will also build up working relationship with GBA Center for Drug Evaluation and Inspection of NMPA and GBA Center for Medical Device Evaluation and Inspection of NMPA to enhance medical product evaluation in the region.

17.Involvement in international regulatory arena (continuous efforts) - In the international arena, the DH has also been working closely with various authorities and regulatory organisations (e.g. World Health Organization, PIC/S, Forum for the Harmonization of Herbal Medicines and Global Harmonization Working Party Towards Medical Device Harmonization (GHWP)), and actively participating in their activities (Hong Kong has been hosting various international events with these organisations and Hong Kong is also the Secretariat of GHWP). In November 2025, the DH will also organise the PIC/S annual seminar to enhance international collaboration and exchanges. The theme of this seminar is “Advanced technologies in pharmaceutical manufacturing”, which will further promote innovation and Hong Kong’s reputation in the area of Good Manufacturing Practice. Such collaborations are important for Hong Kong to maintain a high-standard regulatory regime. With the support of the Mainland authorities, the CMPR will be more proactively involved in various international platforms to become an internationally renowned regulatory authority.

18. The CMPR will also explore building up collaborative relationship with regulatory authorities in other jurisdictions to promote mutual recognition or reliance on regulatory efforts. Such collaborations under joint regulatory initiatives and/or agreements will heighten the reputation of the CMPR and enhance the accessibility of innovative products in these jurisdictions. The

CMPR will also participate actively in regulatory events held in the Mainland and other places for proactive global engagement.

19. Accession to ICH as a regulatory member (Q2 2025 to 2027) - It is crucial for HKSAR to access to ICH as a regulatory member in order to gain international recognition for the drugs approved by the CMPR. Since the accession to ICH as an observer at the end of 2023, Hong Kong has been actively participating in ICH meetings. With a view to becoming a regulatory member of ICH, the accession process would involve the following steps:

i. Establish ICH Taskforce with industry to plan for stepwise implementation of ICH guidelines (by Q2 2025);

ii. Derive timetable for adoption of ICH Tiers 1 & 2 guidelines' (by Q3 2025);

iii. Participate in ICH working groups (by Q2 2026);

iv. Adopt ICH Tier 1 guidelines (by Q2 2027);

v. Apply for accession to ICH regulatory membership (by Q2 2027);

vi. Adopt ICH Tier 2 guidelines within 5 years of accession (by 2032).

The Establishment of the CMPR

20. The CMPR is targeted to be established at the end of 2026. Apart from the above preparatory work, several tasks will be completed before the establishment of the CMPR. In 2025, the DH has conducted a workshop and formulated the vision and mission statements for the CMPR (Annex 1). The DH will also develop a strategic plan for the CMPR (by Q1 2026), launch the CMPR website (by Q4 2026), and relocate existing medical products regulatory services under the DH to the CMPR temporary office (by Q4 2026). Finally, the establishment of the CMPR will be inaugurated with an official opening ceremony (in Q4 2026). The Government plans to build a permanent headquarter for the CMPR in the long run. A chart presenting the timetable is appended at Annex 2.

Looking Forward

21. Establishment of the CMPR marks the beginning of regulatory reform and the efforts to become an internationally renowned regulatory authority for medical products. Regulatory strengthening and modernisation is a continuous process. The CMPR will continue to evolve in order to support the objective of developing Hong Kong into a health and medical innovation hub, and making significant contributions to our country at the same time.

22. After establishment, the CMPR will continue to modernise the regulatory regime and take forward the implementation of primary evaluation of medical products. The CMPR will strive to actively collaborate with national and international regulatory counterparts to further strengthen protection of public health. It will work closely with the NMPA to facilitate R&D in the region. The CMPR will also nurture medical products regulatory capacity and promote health and medical innovation.

23. In the long run, the Government will explore to transform the CMPR into a standalone regulatory authority to drive sustainable development and fortify international collaboration.

Part II: Roadmap Towards Adoption of Primary Evaluation

Background

24. Primary evaluation is the regulatory process to approve applications for registration of new drugs which involves the independent assessment of primary data and information of all pre-clinical studies (i.e. animal testing), clinical studies, pharmacovigilance studies, manufacturing and quality control in order to fully evaluate their safety, efficacy and quality before and also after the drugs are placed on the market (i.e. throughout the product life-cycle). To carry out primary evaluation, a multidisciplinary team with a variety of experts and professionals is a prerequisite. In addition, various regulatory measures such as clinical trial oversight and robust vigilance system as well as analytical support must be in place for proper life-cycle management of new medical products.

25. Implementing a primary evaluation system for medical products in Hong Kong requires a major revamp of existing regulations, including updating Ordinances for pharmaceutical products and Chinese medicines; and establishing a dedicated legal framework for medical devices. These reforms are critical to enable life-cycle management, ensuring compliance at every stage while proactively identifying and mitigating risks. By aligning with global standards

and adoption of the primary evaluation for regulatory approval of medical products, Hong Kong can build a robust framework that promotes public health, supports innovation, and positions the city as a trusted hub for safe, cutting-edge medical advancements. It will attract more pharmaceutical and medical device enterprises, both locally and from around the world, to conduct R&D and clinical trials in Hong Kong. This will in turn accelerate the clinical use of new medical products.

Current Approval System for Medical Products

26. According to the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical products must satisfy the criteria of safety, efficacy and quality, and be registered with the Pharmacy and Poisons Board (PPB) before they can be sold or supplied in Hong Kong. Applications for pharmaceutical products registration in Hong Kong are classified into two main categories, namely pharmaceutical products with active ingredients of new chemical or biological entities which have not been registered in Hong Kong (i.e. new drugs) and those without new chemical or biological entities (i.e. generic drugs).

27.In general, applicants for new drug registration are required to, in accordance with the Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity as promulgated by the PPB, provide documentary proof for registration issued by at least two drug regulatory authorities of specified reference places? in order to provide supporting evidence that relevant products have been rigorously evaluated before being placed on the market (i.e. the secondary evaluation approach).

28. To enhance the drug regulatory regime with a view to implementing the primary evaluation approach in the long run, the PPB has launched the “1+" mechanism for approval of new drugs on 1 November 2023 and widened its applicability to all new drugs on 1 November 2024. For pharmaceutical products containing new chemical or biological entities that are supported with local clinical data and scope of application recognised by relevant local expert, applicants concerned are only required to submit approval from one reference drug regulatory authority (instead of two or more) to apply for registration in Hong Kong. The “1+” mechanism is a major milestone towards the adoption of the primary evaluation approach.

29.On the other hand, Hong Kong has already established a regulatory system for Chinese medicines. According to the Chinese Medicine Ordinance (Cap. 549), all proprietary Chinese

medicines (pCm) must meet the registration requirements on safety, quality and efficacy prescribed by the Chinese Medicines Board under the Chinese Medicine Council of Hong Kong before they can be imported, sold or manufactured in Hong Kong. Currently, primary evaluation is being adopted to review application for pCm registration even though the pCm concerned is not registered or marketed in other places.

30. Some medical devices are currently regulated by existing legislations® . Moreover, making reference to the recommendations of the International Medical Device Regulators Forum, the Government has established the voluntary Medical Device Administrative Control System (MDACS) as a measure to safeguard public health and to pave the way for implementing statutory control on medical devices. The MDACS operates through a two-pronged approach, encompassing pre-market and post-market controls. Furthermore, the Government is taking forward preparatory work for enacting a specific legislation for the statutory regulation of medical devices. When the statutory regulatory framework is in place, only medical devices that meet the requirements on safety, quality and performance could be registered in Hong Kong. Mechanism for primary evaluation of medical devices via Conformity Assessment Bodies has been put in place based on international practice.

Roadmap Towards Adoption of Primary Evaluation

31. A roadmap detailing the two stages towards adoption of primary evaluation (i.e. preparatory and implementation stages) for pharmaceutical products has been worked out and is set out below. It is planned that implementation stage will commence in 2026 where primary evaluation will be formally implemented in phases. Since there are mechanisms to conduct primary evaluation for pCm and medical devices, this roadmap will only focus on the primary evaluation of pharmaceutical products.

Preparatory Stage (2024 Onwards)

32. Apart from various measures to be taken as mentioned in the Timetable for the Establishment of the CMPR (i.e. Part 1 of this document), other measures that need to be carried out before implementation of primary evaluation include (i) enhancement o the electronic registration platform to incorporate ICH Common Technical Document format and clinical trial systems to facilitate applicants' submission and management of applications by the evaluation teams; (ii) categorisation of registration applications to provide clear registration requirements and pathways for applicants and optimise resources to be allocated for evaluation; and (iii) introduction of new fees for different registration pathways and clinical trials to align with the

resources involved. The Government will also explore the application of new tools such as artificial intelligence to strengthen the evaluation capacity and efficiency.

Implementation stage

33. To strengthen evaluation capacity and improve the evaluation and approval process, the primary evaluation will be prudently implemented inaphased approach by gradually expanding the scopes of application when progressing in four different phases. The early phases aim to identify and fill possible gaps as well as to help strengthen evaluation capacity and improve protocols, guidelines, electronic registration system, etc. It will help alleviate teething issues for both applicants and the CMPR.

34. The implementation will also require significant resources and manpower. New evaluation and/or application fees will be introduced to ensure sustainability. Data collected during the early phases of the Implementation Stage will support the assessment of the resources required and formulation of fees and charges for different application pathways. Primary evaluation will be implemented in phases in the period between 2026 and 2030:

i. Phase 1 (2026 onwards) begins with products containing registered chemical entities with extended applications (e.g. new indications, new strengths, new posology, new dosage forms, etc.);

ii. Phase 2 involves products containing registered biological entities with extended applications;
Phase 3 extends the scope to include new drugs containing certain non-first-in-class entities, and certain advanced therapy products;

iv. Phase 4 (by 2030) full implementation of the primary evaluation covering all kinds of pharmaceutical products.

35. Together with the implementation of a new legislation for medical devices, 2030 will mark the fulfilment of adopting primary evaluation for all medical products in Hong Kong.