

**Business Facilitation Advisory Committee
Wholesale and Retail Task Force**

***Establishment of the Hong Kong Centre for Medical Products
Regulation and the Roadmap for Implementation of “Primary Evaluation”***

Purpose

This paper aims to brief Members on the latest development for establishing the Hong Kong Centre for Medical Products Regulation (CMPR) and the roadmap for implementing “primary evaluation”.

Background

2. The Chief Executive announced in the 2023 Policy Address that the Government is determined to leverage Hong Kong’s medical strengths and establish the CMPR, with the long-term objective of establishing an internationally recognised authority that registers drugs and medical devices (MD) under the “primary evaluation”¹ approach. This will help accelerate the clinical use of new drugs and MD, and to drive the development of industries relating to the research and development (R&D) and testing of medical products.

3. Currently, the regulation of western medicines (or pharmaceutical products), Chinese medicines and MD (collectively known as “medical products”) are carried out by different services under the Department of Health (DH), i.e. the Drug Office, the Chinese Medicine Regulatory Office and the Medical Device Division of the Health Sciences and Technology Office respectively. The CMPR, headed by the Controller, combines the regulatory

¹ “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). Precedent registration approvals from other drug regulatory authorities are not required.

functions of medical products under a single entity and will significantly strengthen the overall regulation of medical products in Hong Kong and achieve greater benefits and synergies.

Establishment of the Preparatory Office for CMPR

4. To pave the way for the establishment of the CMPR, the Preparatory Office for CMPR (the “Preparatory Office”) was set up under the DH on 5 June 2024. Some specific tasks of the Preparatory Office include i) comprehensively studying and planning a regulatory and approval regime for drugs and MD suitable for Hong Kong; ii) putting forward proposals and steps for the establishment of the CMPR; and iii) conducting a review on the need for amending existing legislation to promote the development of medical products regulation.

5. The Preparatory Office also maintains active communication with relevant professional bodies, academia and industry partners as well as regulatory authorities in the Chinese Mainland and overseas to foster stakeholder engagement and collaboration.

Timetable for establishing CMPR

6. On 26 June 2025, the DH announced timetable for establishing CMPR². The CMPR, with the vision of “To be a leading internationally renowned medical products regulatory authority, driving excellence and innovation”, is targeted to be established by the end of 2026.

7. The preparatory work for the establishment of CMPR mainly focus on three strategic areas, namely driving regulatory excellence, promoting medical product innovation, and deepening national and international collaboration.

8. 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. A bill for medical products regulation (MPR Bill) is being

² "The Hong Kong Centre for Medical Products Regulation - Towards Primary Evaluation"
https://www.dh.gov.hk/tc_chi/main/main_pocmpr/files/cmpr_infobro202506_e_tc.pdf

prepared and aims to be introduced into the Legislative Council in 2026 after consultations with relevant industries and stakeholders. After the establishment of CMPR, the existing Ordinance that regulate pharmaceutical products, i.e. the Pharmacy and Poisons Ordinance (Cap. 138) will also be amended to align with the mandates of the CMPR and to provide necessary legal basis for regulatory enhancements. In addition, the DH is building up expertise and capacity to meet needs of the strengthened regulatory regime, and making efforts for comprehensive alignment with international best practices (e.g. Good Distribution Practice of pharmaceutical products, and Good Clinical Practice relating to conducting clinical trials).

9. To promote R&D and innovation of medical products in Hong Kong, one of the important initiatives is considered to be the implementation of “primary evaluation”. The roadmap for “primary evaluation” has been introduced in June 2025 and “primary evaluation” will be implemented in phases starting from 2026 (see Paragraph 20 below). We understand that close collaboration and partnership with stakeholders is instrumental to the successful implementation of the “primary evaluation” and promotion of medical product innovation, and the DH has initiated a series of activities including briefing seminars and meetings with different stakeholders with a view to enhance industry’s practising standards.

10. Further collaborations with various Chinese Mainland national authorities, e.g. the National Medical Products Administration (NMPA) and National Administration of Traditional Chinese Medicine (NATCM) and regulatory authorities in the Guangdong-Hong Kong-Macao Greater Bay Area (GBA) are being made to deepen collaborative relationship. With support of the Chinese Mainland authorities, the CMPR will be more proactively involved in various international platforms. To gain international recognition for the drugs approved by the CMPR, application for accession to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)³ as a regulatory member will be made by Q2 of 2027.

Primary Evaluation

³ The ICH is an internationally renowned 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 recognised as the highest global standards for the protection of public health.

11. According to the Pharmacy and Poisons Ordinance, pharmaceutical products must meet safety, efficacy, and quality standards and obtain registration approval from the Pharmacy and Poisons Board of Hong Kong (PPB) before they can be sold or distributed in Hong Kong. The DH provides professional support to the PPB.

12. Currently, Hong Kong adopts a “secondary evaluation” approach for the registration of pharmaceutical products containing new chemical or biological entities (i.e. new drugs containing active ingredients which have not been registered in Hong Kong). Since these new drugs are generally not yet widely used, applicants are required to submit evidence of registration issued by drug regulatory authorities of at least two out of the 36 reference places (including the Chinese Mainland, the US, Canada, and Singapore) listed in the “Guidance Notes on Registration of New Chemical or Biological Entity Pharmaceutical Products”. This serves as evidence that the products have been rigorously evaluated before placing on the market. For proprietary Chinese medicines and MD, “primary evaluation” mechanism has already been put in place.

13. 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.

14. Implementing a “primary evaluation” system for medical products in Hong Kong requires a major revamp of existing regulations, including ordinances regulating pharmaceutical products and Chinese medicines; and establishing a dedicated legal framework for MD. These reforms are critical to enable life-cycle management, ensuring compliance at every stage while proactively identifying and mitigating risks. By aligning with international standards and adoption of the “primary evaluation” for regulatory approval of new medical products, Hong Kong can build a robust framework that promotes public health, supports innovation. It will attract more pharmaceutical and MD 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.

15. 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. Under the “1+” mechanism, holders of registration from one (instead of two or more) of the drug regulatory authorities of recognised reference places for new drugs could apply for registration in the Hong Kong, providing that they could provide local clinical data which complies with the requirements and information recognised by local experts, subject to the specific conditions: (i) the product is approved with orphan drug designation, breakthrough therapy designation, priority review designation, or equivalent, and marketed in any of the reference places; and (ii) there are local clinical data (e.g. clinical studies, case reports, case series, real-world data, etc.) OR clinical data generated from Chinese and/or Asian populations related to the proposed indication(s) and posology of the product.

16. The DH has been actively optimising the “1+” mechanism process. When implementing the “1+” mechanism, the PPB has made reference to the relevant procedures of other drug regulatory authorities and hence the DH introduced a target processing timeline set at 150 days, namely the “stop-clock mechanism” with effect from 1 May 2024. To enhance the efficiency of processing applications under "1+" mechanism, the DH has progressively launched pre-submission consultation services since March 2025, including briefing seminars, workshops and pre-submission consultation meetings. Furthermore, the DH has introduced one-on-one pre-new drug application (pre-NDA) consultation meetings with potential applications under the “1+” mechanism in December 2025.

Roadmap for adopting “primary evaluation” for pharmaceutical products

17. The DH announced the roadmap for adopting “primary evaluation” (the “roadmap”) on 26 June 2025¹, detailing the two stages towards adoption of “primary evaluation” (i.e. preparatory and implementation stages) for pharmaceutical products. In gist, the DH will implement "primary evaluation" for new drug registration in phases beginning in 2026, with full implementation by 2030.

Preparatory stage (from 2024 onwards)

18. The Government is working on various measures before implementation of “primary evaluation”, which include:

- (i) enhancement of 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 (2026 to 2030)

19. To strengthen evaluation capacity and improve the evaluation and approval process, the “primary evaluation” will be prudently implemented in a phased 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.

20. 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;
- (iii) **Phase 3** extends the scope to include new drugs containing certain non-first-in-class entities, and certain advanced therapy products; and
- (iv) **Phase 4** (by 2030) full implementation of the “primary evaluation” covering all kinds of pharmaceutical products.

Way forward

21. The Preparatory Office will continue its planning and communication work for the purpose of establishing the CMPR and assist in preparing the MPR Bill which will be introduced to the Legislative Council by 2026. Collaboration and partnership with stakeholders will continue to ensure the successful implementation of “primary evaluation” and the promotion of medical product innovation.

22. Members are invited to note the content of this paper.

Department of Health
January 2026