# The Hong Kong Centre for Medical Products Regulation

## Towards Primary Evaluation

# 香港藥物及醫療器械監督管理中心

## 邁向第一層審批

創新進取 | 追求卓越 | 專業權威 | 譽滿全球

To be a leading internationally renowned medical products regulatory authority, driving excellence and innovation.

**Department of Health**
The Government of the Hong Kong Special Administrative Region
香港特別行政區政府衞生署

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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.

# PART 1
# 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 Co-operation 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[1] (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); and
vi. Adopt ICH Tier 2 guidelines within 5 years of accession (by 2032).

[1] There are three Tier 1 guidelines, namely ICH Q1 (Stability), Q7 (Good Manufacturing Practice) and E6 (Good Clinical Practice). Tier 2 guidelines include ICH E2A (Clinical Safety Data Management: Definitions and Standards for Expedited Reporting), E2B (Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports), E2D (Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting), M1 (MedDRA Terminology) and M4 (Common Technical Document).

## 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 2
# 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[2] 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).

[2] There is a total of 36 recognised places listed in the Guidance Notes on Registration of Pharmaceutical Products Containing a New Chemical or Biological Entity issued by the PPB, including Australia, Brazil, Canada, Mainland China, 26 European Union countries, Japan, Republic of Korea, Singapore, Switzerland, the United Kingdom and the United States.

**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[3] . 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.

[3] Depending on the characteristics and features of the products concerned, they may be regulated by Pharmacy and Poisons Ordinance (Cap. 138), Radiation Ordinance (Cap. 303), Trade Descriptions Ordinance (Cap. 362), Consumer Goods Safety Ordinance (Cap. 456), Electrical Products (Safety) Regulation (Cap . 406G), etc.

## 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 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)

**33.** 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.

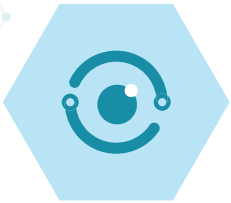
**34.** The implementation will also require significant resources and manpower. New evaluation and/or application fees will be introduced to ensure sustainability. Data collected during the early phases of the Implementation Stage will support the assessment of the resources required and formulation 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;
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.

**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.

***Department of Health***
***The Government of the Hong Kong Special Administrative Region***
***June 2025***

# VISION, MISSION AND VALUES OF THE CMPR



## VISION

To be a leading internationally renowned medical products regulatory authority, driving excellence and innovation.

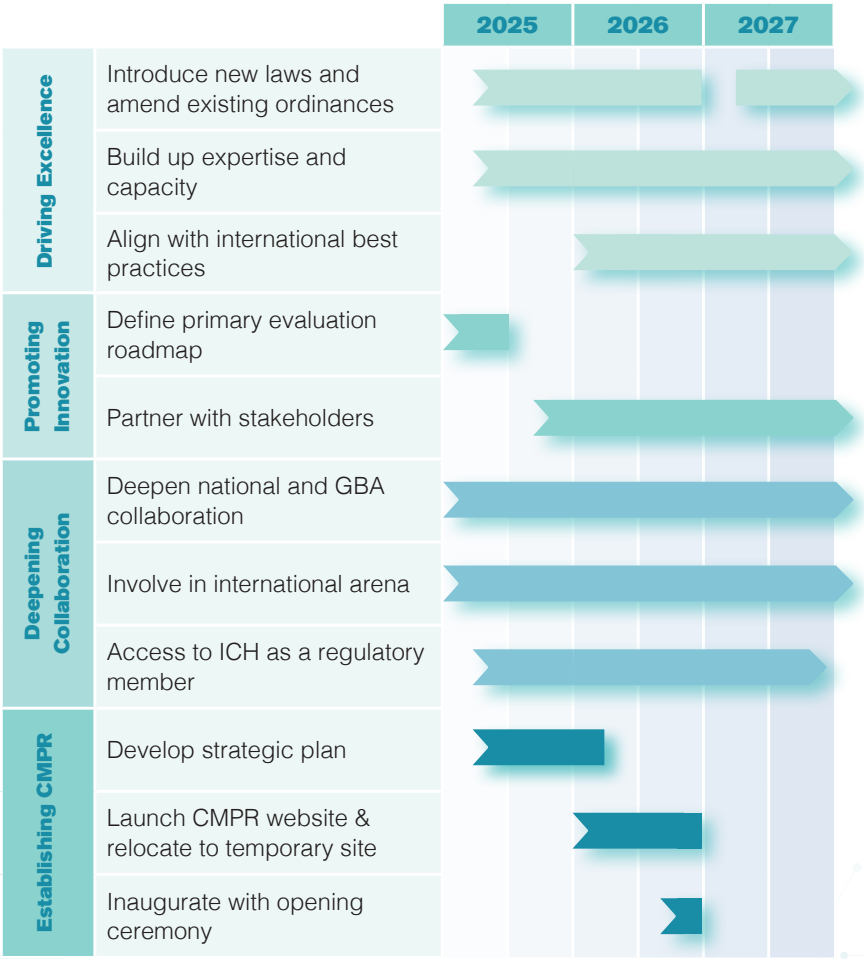
## MISSION

We build a reputable regulatory hub that promotes public health and fosters international collaboration.

## VALUES

- Professionalism
- Integrity
- People-oriented
- Transparency
- Partnership
- Continuous Improvement
- Accountability
- Innovation

# TIMETABLE FOR THE ESTABLISHMENT OF THE CMPR



# 序

**1.** 香港特別行政區（香港特區）銳意成為創新科技樞紐，領先全球，醫療創新更是其中關鍵。促進藥物的研發與創新工作，不僅為市場帶來尖端且價格合理的藥械產品，更可推動本地醫療及生物科技產業的發展。要確保為市民進行治療所用的藥械產品安全、有效和品質優良，健全的監管制度至關重要，不可或缺。

**2.** 行政長官於2023年《施政報告》中公布，香港特區政府會優化現行的藥械審批和註冊制度，並成立「香港藥物及醫療器械監督管理中心」（「藥械監管中心」），冀將「藥械監管中心」定位為國際權威監管機構，以「第一層審批」的方式處理藥械註冊。換句話說，香港會透過健全的系統獨立審批新藥物和醫療器械的註冊申請，而不完全依賴海外的註冊許可。此舉令病人可更快獲得突破性的治療，同時帶動本地的醫學研發和測試等產業的發展。為此，衞生署於2024年6月成立「藥械監管中心籌備辦公室」，為成立「藥械監管中心」及實施「第一層審批」等藥械監管制度改革奠定基礎。

**3.** 本文件闡述香港成立「藥械監管中心」及邁向「第一層審批」的路線圖。

# 第一部分
# 「香港藥物及醫療器械監督管理中心」成立時間表

## 背景

**4.** 成立「藥械監管中心」可充分地利用現時高效的監管制度，藉此取得更大效益，發揮更大的協同效應。「藥械監管中心」將融合相關專業知識，優化資源分配，以支援創新藥械的審批工作，推動藥械和醫療科技進步，加快藥械和醫療科技的臨床應用，從而帶動藥械研發和測試的相關產業發展。在初始階段，「藥械監管中心」將隸屬衞生署，長遠而言，政府會探討將「藥械監管中心」升格為獨立的監管機構。

**5.** 西藥、中藥及醫療器械的監管工作均由「藥械監管中心」負責。然而，由於《中醫藥發展藍圖》將於2025年第四季公布，而政府料於2026年向立法會提交條例草案，就醫療器械進行法定規管，因此本文件將聚焦於「藥械監管中心」成立的時間表，以及有關西藥（即藥劑製品）監管工作的重要里程碑。

## 「香港藥物及醫療器械監督管理中心」

**6.** 「藥械監管中心」的願景是「創新進取，追求卓越，專業權威，譽滿全球」。為實現這一願景，我們必須為「藥械監管中心」奠定穩健的基礎。就此，衞生署正循三大策略範疇開展一系列籌備工作：推動優質監管、促進藥械創新、深化與國家及國際機構的合作。

## 推動優質監管

**7.** 本港現時的中西藥監管制度與國際做法一致，但仍有改善和優化的空間，使我們的制度更健全成熟、以科學為主導，成為國際認可的監管權威。推動優質監管不但可以提高藥械審評與監管的能力和效率，更有助維持高水平的監管透明度及問責性，建立公眾信心。

**8.** **制定新法例及修訂現行監管藥劑製品的法例（由2025年起）：** 政府現正就藥械監管擬備條例草案，讓「藥械監管中心」具備法定權力，可監管藥械產品。該條例草案亦會包括對現行監管藥劑製品及中藥的條例作出相應修訂。政府於2026年向立法會提交該條例草案前，亦會先諮詢相關業界及持份者，詳述立法建議內容並釋除各界疑慮。

**9.** 此外，現行監管藥劑製品的條例，即《藥劑業及毒藥條例》（第138章），亦須作出重大修訂，以配合「藥械監管中心」的使命，並為加強監管提供所需的法律依據。由於修例將對業界帶來重大影響，政府將待「藥械監管中心」成立後另行擬備修訂建議及籌備相關公眾諮詢工作。政府亦會在《中醫藥發展藍圖》公布後，通盤檢視《中醫藥條例》（第549章）以修訂相關法規和要求，並推動中醫藥的科研創新工作及產業升級。

**10. 加強專業與能力（由2025年起）：**要實施「第一層審批」，便須加強檢測分析能力（尤其是對生物製劑、疫苗及先進療法製品的檢測分析能力）和審評能力，當中須要各個領域新加入的專家參與，以及對現有專業人員進行專門培訓。此外，要在「第一層審批」機制下協助管理新藥械產品的生命周期，關鍵在於加強檢查能力（尤其是在《臨床試驗質量管理規範》及《藥物警戒管理規範》兩方面的檢查能力）。另一方面，為確保在新條例實施後能妥善監管醫療器械，衞生署須要加強執法能力，以配合醫療器械的最新法定監管要求。衞生署正積極培訓現有的專業人員，提升他們為新藥進行「第一層審批」及相關工作的專業技術及能力。與此同時，衞生署正制定計劃聘任在「第一層審批」、檢測分析及醫療器械監管等相關領域具豐富經驗的專家，以全面提高「藥械監管中心」的監管能力。

**11. 與國際最佳作業方式一致（由2026年起）：**香港於2016年加入「藥品檢查合作計劃」（PIC/S），大大提升了本地製造及註冊藥劑製品的素質。為使「藥械監管中心」落實「第一層審批」，並成為國際權威監管機構，政府須要進一步強化整體藥械監管制度，以符合國際最佳作業方式（即各種良好規範）。為此，政府將於2026年頒布「國際醫藥法規協調會議」（ICH）的《臨床試驗質量管理規範》及PIC/S的《藥物分銷質量管理規範》等主要良好規範。「藥械監管中心」成立之後，亦會根據國際慣例制定及實施《藥物警戒管理規範》。為進一步加強中藥規管制度，政府會配合2025年第四季公布的《中醫藥發展藍圖》，制訂相關方案。

# 促進藥械創新

**12.** 促進藥械研發及創新是「藥械監管中心」的主要目標之一，不僅配合國家《十四五規劃綱要》推動醫療創新，亦能引進創科企業來港投資，為市民提供最尖端、安全、高效且價格合理的藥械產品。因應這策略，實施「第一層審批」機制可說是至為重要的舉措。

**13.** **制定「第一層審批」路線圖（2025年第二季）：**政府於2023年年底推出「1+」新藥審批機制，並於2024年年底將「1+」機制擴展至涵蓋所有新藥，至今已實施多項措施逐步邁向「第一層審批」，例如為「1+」機制下的註冊審批程序設立「計時」制度及提供申請前會面諮詢服務。邁向「第一層審批」之步驟詳載於本文件第二部分的路線圖。

**14.** **建立與持份者的夥伴關係（由2025年第三季起）：**與持份者保持緊密合作及夥伴關係將有助順利落實「第一層審批」及促進藥械創新。在公布「藥械監管中心」的成立時間表後，衞生署將舉行一系列簡介會及會議，向學術界、業界、研究機構、立法會議員、持牌人、研究人員、相關專及行業組織、有意申請藥械註冊及有興趣的海外人士等相關持份者闡述「藥械監管中心」的計劃。

**15.** 此外，為確保業界及所有持牌人能遵守國際最佳作業方式，衞生署會與受影響的持份者成立專責小組，商議如何實施各種良好規範並籌劃相關措施提升能力。「藥械監管中心」亦會主動諮詢相關持份者，探討改善監管制度及精簡各項申請程序的可行措施，以促進研發及推動創新。

# 深化與國家及國際機構的合作

**16. 深化與國家及大灣區監管機構的合作（持續推進的工作）：**衞生署一直與國家不同的監管機構保持緊密合作，例如中華人民共和國國家衞生健康委員會、國家藥品監督管理局（國家藥監局）、國家中醫藥管理局，以及粵港澳大灣區的地區監管機構。「藥械監管中心」將進一步與廣東省藥品監督管理局及相關大灣區監管機構深化合作，在大灣區政策措施下便利其審批已在本港註冊的藥械產品，而透過與大灣區監管機構建立緊密的聯繫，亦可善用區內的資源與能力，促進藥械產品的研發、臨床試驗及生產。另一方面，「藥械監管中心」會與國家藥監局藥品審評檢查大灣區分中心及國家藥監局醫療器械技術審評檢查大灣區分中心建立合作關係，強化區內藥械產品的審評工作。

**17. 投入國際監管領域（持續推進的工作）：**國際方面，衞生署一直與世界衞生組織、PIC/S、草藥協調論壇、全球醫療器械法規協調會等監管機構及組織緊密合作，積極參與相關活動（香港曾與相關組織舉辦各項國際會議，亦為全球醫療器械法規協調會提供秘書處服務）。衞生署將於2025年11月舉辦PIC/S周年研討會，以期促進國際合作與交流。研討會的主題是「先進製藥技術」，可進一步推動創新及提升香港於實施《生產質量管理規範》方面的聲譽。此等合作對香港維持高水平的監管制度十分重要。在內地監管機構的支持下，「藥械監管中心」將更積極投入國際舞台，發展成為國際權威監管機構。

**18.** 「藥械監管中心」亦會探討與其他司法管轄區的監管機構建立合作關係一事，務求推動雙方監管工作互認互信。這些根據聯合監管計劃及/或協議進行的合作，將提升「藥械監管中心」的聲譽，並加快在相關地區引入創新產品。此外，「藥械監管中心」將積極參與在國內外舉辦的規管會議及活動，加強國際聯繫。

**19.** **加入成為ICH監管機構成員（2025年第二季至2027年）：**香港特區以監管機構成員身分加入ICH將發揮重要作用，有助「藥械監管中心」審批的藥物獲得國際認可。香港於2023年年底以觀察員身分加入ICH後，一直積極參與ICH的會議。加入ICH成為監管機構成員的程序涉及以下步驟：

i. 與業界成立ICH專責小組，制定逐步實施ICH指導原則的計劃（2025年第二季前）；
ii. 制定實施ICH一級及二級指導原則的時間表[1]（2025年第三季前）；
iii. 參與ICH工作小組（2026年第二季前）；
iv. 實施ICH一級指導原則（2027年第二季前）；
v. 申請加入成為ICH監管機構成員（2027年第二季前）；以及
vi. 加入成為ICH監管機構成員後的五年內實施ICH二級指導原則（2032年前）。

[1] ICH一級指導原則有三項，即ICH Q1（穩定性）、Q7（生產質量管理規範）及E6（臨床試驗質量管理規範）。二級指導原則包括ICH E2A（臨床安全性數據的管理：快速報告的定義和標準）、E2B（臨床安全性數據的管理：個例安全報告傳輸的數據元素）、E2D（上市後安全性數據的管理：快速報告的定義和標準）、M1（MedDRA — 監管活動醫學詞典）及M4（通用技術文件）。

## 成立「香港藥物及醫療器械監督管理中心」

**20.** 政府的目標是於2026年年底前成立「藥械監管中心」，除上述籌備工作外，部分工作須於「藥械監管中心」成立前完成。衞生署已於2025年舉辦工作坊及訂定「藥械監管中心」的願景與使命宣言**（附件一）**。另外，衞生署將會制定「藥械監管中心」的策略計劃（2026年第一季前）、推出「藥械監管中心」官方網站（2026年第四季前）及將目前衞生署統轄的相關藥械監管服務單位遷往「藥械監管中心」臨時辦公室（2026年第四季前）。最後，「藥械監管中心」啓用時，將舉行開幕儀式，以標誌其正式成立（2026年第四季）。長遠而言，政府計劃籌建「藥械監管中心」永久總部。「藥械監管中心」成立時間表的示意圖列載於**附件二**。

## 展望

**21.** 成立「藥械監管中心」，標誌着監管制度改革的第一步，亦體現了我們致力建設國際藥械權威監管機構所作的努力。監管制度強化、現代化是一個持之以恆的過程。「藥械監管中心」將與時並進，支持香港發展成為醫療創新樞紐的願景，為國家的發展作出重大貢獻。

**22.** 「藥械監管中心」成立後，將會持續推進監管制度現代化並落實藥械「第一層審批」，更會積極與國家及國際監管機構合作，進一步保障公眾健康。此外，「藥械監管中心」亦會與國家藥監局緊密合作，促進區內研發、培育藥械監管能力，多管齊下推動醫療創新。

**23.** 長遠而言，政府會探討將「藥械監管中心」升格為獨立的監管機構，推動機構可持續發展並深化國際合作。

# 第二部分
# 邁向「第一層審批」路線圖

## 背景

**24.** 「第一層審批」指審批新藥註冊申請的監管程序，透過自主審核所有臨床前研究（即動物實驗）、臨床研究、藥物警戒研究，以及有關生產和品質控制的原始數據及資料，全面審評藥物上市前和上市後的安全、效能和素質（涵蓋整個產品生命周期）。要實施「第一層審批」，本港必須有一個由不同專家和專業人士組成的跨專業團隊。不僅如此，臨床試驗監督、健全的警戒系統、檢測服務支援等監管措施必須齊備，方能妥善管理新藥械產品的生命周期。

**25.** 要在本港實施藥械「第一層審批」，現行法例須要作出重大修訂，包括更新藥劑製品及中藥的法例，以及建立專責監管醫療器械的法律框架。這些改革有助管理藥械產品的生命周期，確保每個階段均符合要求，同時亦可主動識別並降低風險。我們致力與全球標準一致，並採取「第一層審批」的方式審批藥械產品，務求建立完善、健全的架構，提升公眾健康並促進創新，將本港定位為一個安全可靠、醫療發展不斷創新的樞紐。這樣定能吸引更多本地和世界各地的藥械企業在港進行研發及臨床試驗，有利於加快新藥械的臨床應用。

## 現行的藥械審批機制

**26.** 根據《藥劑業及毒藥條例》（第138章），藥劑製品必須符合安全、效能及素質方面的標準，並獲藥劑業及毒藥管理局註冊，方可在本港銷售或供應。在香港，藥劑製品的註冊申請主要分為兩類：（一）含有未在香港註冊的新化學或生物元素的有效成分的藥劑製品（即新藥）；以及（二）不含新化學或生物元素的藥劑製品（即仿製藥）。

**27.** 一般而言，新藥註冊申請人須根據藥劑業及毒藥管理局發布的《新藥劑或生物元素藥劑製品註冊申請指南》，提供最少兩個指明參考地區[2]的藥物監管機構發出的註冊證明文件，以證明有關產品在上市前已獲嚴謹審評（即「第二層審批」制度）。

**28.** 為優化藥物監管制度並長遠落實「第一層審批」，藥劑業及毒藥管理局已於2023年11月1日推行「1+」新藥審批機制，並於2024年11月1日將其適用範圍擴展至所有新藥。含有新化學或生物元素的藥劑製品，只要有本地臨床數據支持，而新藥的適用範圍經本地相關專家認可後，申請人只須提交一個（而非兩個或以上）參考藥物監管機構的註冊許可，即可在香港申請註冊。「1+」新藥審批機制，是我們邁向「第一層審批」的重要里程碑。

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[2] 藥劑業及毒藥管理局發出的《新藥劑或生物元素藥劑製品註冊申請指南》共列出36個認可地區，包括澳洲、巴西、加拿大、中國內地、歐盟26個國家、日本、韓國、新加坡、瑞士、英國及美國。

**29.** 此外，本港已建立中藥規管制度。根據《中醫藥條例》（第549章），所有中成藥必須符合香港中醫藥管理委員會轄下中藥組就中成藥的安全、品質及成效所訂明的註冊要求，方可進口香港，並在香港銷售或製造。現時，即使有關中成藥並未在其他地方註冊或銷售，其註冊申請同樣會以「第一層審批」機制作出審評。

**30.** 現時，部分醫療器械受現有法例監管[3]。經參考國際醫療器械監管機構論壇的建議，政府設立了一套自願醫療器械行政管理制度（器械管理制度）以保障公眾健康，並為長遠實施醫療器械的法定監管鋪路。器械管理制度涵蓋推出市面前及推出市面後的醫療器械，以雙管齊下模式管理。政府現正進行籌備工作，為醫療器械的法定監管制訂特定法例。法定監管架構落實後，只有符合安全、品質及性能要求的醫療器械方可在香港註冊。政府亦已按照國際慣例設立相關機制，透過認證評核機構對醫療器械進行「第一層審批」。

## 邁向「第一層審批」路線圖

**31.** 衞生署已就藥劑製品邁向「第一層審批」制定路線圖，詳細規劃涉及的兩個階段：準備階段和實施階段。實施階段將於2026年開展，而「第一層審批」將分期正式執行。鑑於中成藥和醫療器械目前已有既定機制進行審批，本路線圖只聚焦於藥劑製品的「第一層審批」。

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[3] 視乎其特徵、特點，相關產品可能受《藥劑業及毒藥條例》（第 138章）、《輻射條例》（第 303章）、《商品說明條例》（第 362章）、《消費品安全條例》（第 456章）或《電氣產品（安全）規例》（第 406G章）等法例所規管。

## 準備階段（由2024年起）

**32.** 除「藥械監管中心」成立時間表（即本文件第一部分）中提及的各項措施外，推行「第一層審批」前須落實的其他措施包括：(i) 優化電子註冊平台，將ICH通用技術文件格式和臨床試驗系統納入平台之中，以方便申請人提交申請，並由審評小組處理有關申請；(ii) 將註冊申請分類，為申請人提供清晰的註冊要求和途徑，同時優化審評資源的分配；以及 (iii) 就不同的註冊途徑和臨床試驗引入新收費，以配合所投放的資源。政府亦會探討應用人工智能等新工具，務求強化審評能力和效率。

## 實施階段（2026至2030年）

**33.** 為加強審評能力並改善審評和審批程序，「第一層審批」的實施工作審慎周詳，按四期分階段推行，逐步擴大適用範圍。前期的目標是找出可改善的空間，予以加強，並協助強化審評能力和改善規程、指引、電子註冊系統等。此舉有助減少申請人和「藥械監管中心」在推行初期所遇到的困難。

**34.** 推行「第一層審批」須要投放大量資源和人力。為確保計劃可持續推行，計劃將訂立新的審評及/或申請費用。計劃實施初期收集得來的數據也將有助評估所需要的資源及制定不同申請途徑的收費標準。「第一層審批」將於2026至2030年間分期推行：

i. **第一期（由2026年起）**先由含有已註冊化學元素的產品的延伸應用（例如新適應症、新劑量、新用法用量、新劑型等）開始推行；

ii. **第二期**範圍涉及已註冊生物元素產品的延伸應用；

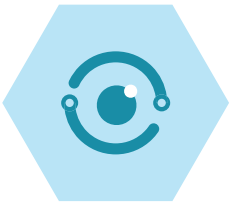
iii. **第三期**將適用範圍擴大至非首創新藥的註冊申請，及特定先進療法產品；以及

iv. **第四期（2030年或以前）**「第一層審批」將全面實施，涵蓋所有藥劑製品。

**35.** 監管醫療器械的新法例一併實施後，香港將於2030年全面推行「第一層審批」，屆時將可涵蓋所有藥械產品。

**香港特別行政區政府衞生署**
**二零二五年六月**

# 「香港藥物及醫療器械監督管理中心」的願景、使命及信念



## 願景

創新進取 追求卓越
專業權威 譽滿全球

## 使命

建構監管樞紐 樹立信譽權威
提升公眾健康 推動國際合作

## 信念

| | |
|---|---|
| 專業精神 | 齊心協力 |
| 秉持誠信 | 精益求精 |
| 以人為本 | 勇於承擔 |
| 公開透明 | 進取創新 |

# 「香港藥物及醫療器械監督管理中心」成立時間表