

# The Hong Kong Centre for Medical Products Regulation Towards Primary Evaluation

## 香港药物及医疗器械监督管理中心 迈向第一层审批

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



**Department of Health**  
The Government of the Hong Kong  
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香港特别行政区政府卫生署

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English



简体中文

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# 序

1. 香港特别行政区（香港特区）锐意成为创新科技枢纽，领先全球，医疗创新更是其中关键。促进药物的研发与创新工作，不仅为市场带来尖端且价格合理的药械产品，更可推动本地医疗及生物科技产业的发展。要确保为市民进行治疗所用的药械产品安全、有效和品质优良，健全的监管制度至关重要，不可或缺。
2. 行政长官于2023年《施政报告》中公布，香港特区政府会优化现行的药械审批和注册制度，并成立「香港药物及医疗器械监督管理中心」（「药械监管中心」），冀将「药械监管中心」定位为国际权威监管机构，以「第一层审批」的方式处理药械注册。换句话说，香港会透过健全的系统独立审批新药物和医疗器械的注册申请，而不完全依赖海外的注册许可。此举令病人可更快获得突破性的治疗，同时带动本地的医学研发和测试等产业的发展。为此，卫生署于2024年6月成立「药械监管中心筹备办公室」，为成立「药械监管中心」及实施「第一层审批」等药械监管制度改革奠定基础。
3. 本文件阐述香港成立「药械监管中心」及迈向「第一层审批」的路线图。

# 第一部分

## 「香港药物及医疗器械 监督管理中心」成立时间表

### 背景

4. 成立「药械监管中心」可充分地利用现时高效的监管制度，藉此取得更大效益，发挥更大的协同效应。「药械监管中心」将融合相关专业知识，优化资源分配，以支援创新药械的审批工作，推动药械和医疗科技进步，加快药械和医疗科技的临床应用，从而带动药械研发和测试的相关产业发展。在初始阶段，「药械监管中心」将隶属卫生署，长远而言，政府会探讨将「药械监管中心」升格为独立的监管机构。
5. 西药、中药及医疗器械的监管工作均由「药械监管中心」负责。然而，由于《中医药发展蓝图》将于2025年第四季公布，而政府料于2026年向立法会提交条例草案，就医疗器械进行法定规管，因此本文件将聚焦于「药械监管中心」成立的时间表，以及有关西药（即药剂制品）监管工作的重要里程碑。

## 「香港药物及医疗器械监督管理中心」

6. 「药械监管中心」的愿景是「创新进取，追求卓越，专业权威，誉满全球」。为实现这一愿景，我们必须为「药械监管中心」奠定稳健的基础。就此，卫生署正循三大策略范畴开展一系列筹备工作：推动优质监管、促进药械创新、深化与国家及国际机构的合作。

### 推动优质监管

7. 本港现时的中西药监管制度与国际做法一致，但仍有改善和优化的空间，使我们的制度更健全成熟、以科学为主导，成为国际认可的监管权威。推动优质监管不但可以提高药械审评与监管的能力和效率，更有助维持高水平的监管透明度及问责性，建立公众信心。
8. **制定新法例及修订现行监管药剂制品的法例（由2025年起）**：政府现正就药械监管拟备条例草案，让「药械监管中心」具备法定权力，可监管药械产品。该条例草案亦会包括对现行监管药剂制品及中药的条例作出相应修订。政府于2026年向立法会提交该条例草案前，亦会先咨询相关业界及持份者，详述立法建议内容并释除各界疑虑。
9. 此外，现行监管药剂制品的条例，即《药剂业及毒药条例》（第138章），亦须作出重大修订，以配合「药械监管中心」的使命，并为加强监管提供所需的法律依据。由于修例将对业界带来重大影响，政府将待「药械监管中心」成立后另行拟备修订建议及筹备相关公众咨询工作。政府亦会在《中医药发展蓝图》公布后，通盘检视《中医药条例》（第549章）以修订相关法规和要求，并推动中医药的科研创新工作及产业升级。

**10. 加强专业与能力（由2025年起）：**要实施「第一层审批」，便须加强检测分析能力（尤其是对生物制剂、疫苗及先进疗法制品的检测分析能力）和审评能力，当中须要各个领域新加入的专家参与，以及对现有专业人员进行专门培训。此外，要在「第一层审批」机制下协助管理新药械产品的生命周期，关键在于加强检查能力（尤其是在《临床试验质量管理规范》及《药物警戒管理规范》两方面的检查能力）。另一方面，为确保在新条例实施后能妥善监管医疗器械，卫生署须要加强执法能力，以配合医疗器械的最新法定监管要求。卫生署正积极培训现有的专业人员，提升他们为新药进行「第一层审批」及相关工作的专业技术及能力。与此同时，卫生署正制定计划聘任在「第一层审批」、检测分析及医疗器械监管等相关领域具丰富经验的专家，以全面提高「药械监管中心」的监管能力。

**11. 与国际最佳作业方式一致（由2026年起）：**香港于2016年加入「药品检查合作计划」（PIC/S），大大提升了本地制造及注册药剂制品的素质。为使「药械监管中心」落实「第一层审批」，并成为国际权威监管机构，政府须要进一步强化整体药械监管制度，以符合国际最佳作业方式（即各种良好规范）。为此，政府将于2026年颁布「国际人用药品注册技术协调会」（ICH）的《临床试验质量管理规范》及PIC/S的《药物分销质量管理规范》等主要良好规范。「药械监管中心」成立之后，亦会根据国际惯例制定及实施《药物警戒管理规范》。为进一步加强中药规管制度，政府会配合2025年第四季公布的《中医药发展蓝图》，制订相关方案。

## 促进药械创新

12. 促进药械研发及创新是「药械监管中心」的主要目标之一，不仅配合国家《十四五规划纲要》推动医疗创新，亦能引进创科企业来港投资，为市民提供最尖端、安全、高效且价格合理的药械产品。因应这策略，实施「第一层审批」机制可说是至为重要的举措。
13. **制定「第一层审批」路线图（2025年第二季）**：政府于2023年年底推出「1+」新药审批机制，并于2024年年底将「1+」机制扩展至涵盖所有新药，至今已实施多项措施逐步迈向「第一层审批」，例如为「1+」机制下的注册审批程序设立「计时」制度及提供申请前会面咨询服务。迈向「第一层审批」之步骤详载于本文件第二部分的路线图。
14. **建立与持份者的伙伴关系（由2025年第三季起）**：与持份者保持紧密合作及伙伴关系将有助顺利落实「第一层审批」及促进药械创新。在公布「药械监管中心」的成立时间表后，卫生署将举行一系列简介会及会议，向学术界、业界、研究机构、立法会议员、持牌人、研究人员、相关专业及行业组织、有意申请药械注册及有兴趣的海外人士等相关持份者阐述「药械监管中心」的计划。
15. 此外，为确保业界及所有持牌人能遵守国际最佳作业方式，卫生署会与受影响的持份者成立专责小组，商议如何实施各种良好规范并筹划相关措施提升能力。「药械监管中心」亦会主动咨询相关持份者，探讨改善监管制度及精简各项申请程序的可行措施，以促进研发及推动创新。

## 深化与国家及国际机构的合作

- 16. 深化与国家及大湾区监管机构的合作 (持续推进的工作) :** 卫生署一直与国家不同的监管机构保持紧密合作, 例如中华人民共和国国家卫生健康委员会、国家药品监督管理局 (国家药监局)、国家中医药管理局, 以及粤港澳大湾区的地区监管机构。「药械监管中心」将进一步与广东省药品监督管理局及相关大湾区监管机构深化合作, 在大湾区政策措施下便利其审批已在本港注册的药械产品, 而透过与大湾区监管机构建立紧密的联系, 亦可善用区内的资源与能力, 促进药械产品的研发、临床试验及生产。另一方面, 「药械监管中心」会与国家药监局药品审评检查大湾区分中心及国家药监局医疗器械技术审评检查大湾区分中心建立合作关系, 强化区内药械产品的审评工作。
- 17. 投入国际监管领域 (持续推进的工作) :** 国际方面, 卫生署一直与世界卫生组织、PIC/S、草药协调论坛、全球医疗器械法规协调会等监管机构及组织紧密合作, 积极参与相关活动 (香港曾与相关组织举办各项国际会议, 亦为全球医疗器械法规协调会提供秘书处服务)。卫生署将于2025年11月举办PIC/S周年研讨会, 以期促进国际合作与交流。研讨会的主题是「先进制药技术」, 可进一步推动创新及提升香港于实施《生产质量管理规范》方面的声誉。此等合作对香港维持高水平的监管制度十分重要。在内地监管机构的支持下, 「药械监管中心」将更积极投入国际舞台, 发展成为国际权威监管机构。

**18.** 「药械监管中心」亦会探讨与其他司法管辖区的监管机构建立合作关系一事，务求推动双方监管工作互认互信。这些根据联合监管计划及/或协议进行的合作，将提升「药械监管中心」的声誉，并加快在相关地区引入创新产品。此外，「药械监管中心」将积极参与在国内外举办的规管会议及活动，加强国际联系。

**19. 加入成为ICH监管机构成员（2025年第二季至2027年）：**香港特区以监管机构成员身分加入ICH将发挥重要作用，有助「药械监管中心」审批的药物获得国际认可。香港于2023年年底以观察员身分加入ICH后，一直积极参与ICH的会议。加入ICH成为监管机构成员的程序涉及以下步骤：

- i. 与业界成立ICH专责小组，制定逐步实施ICH指导原则的计划（2025年第二季前）；
- ii. 制定实施ICH一级及二级指导原则的时间表<sup>1</sup>（2025年第三季前）；
- iii. 参与ICH工作小组（2026年第二季前）；
- iv. 实施ICH一级指导原则（2027年第二季前）；
- v. 申请加入成为ICH监管机构成员（2027年第二季前）；以及
- vi. 加入成为ICH监管机构成员后的五年内实施ICH二级指导原则（2032年前）。

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<sup>1</sup> ICH一级指导原则有三项，即ICH Q1（稳定性）、Q7（生产质量管理规范）及E6（临床试验质量管理规范）。二级指导原则包括ICH E2A（临床安全性数据的管理：快速报告的定义和标准）、E2B（临床安全性数据的管理：个案安全报告传输的数据元素）、E2D（上市后安全性数据的管理：快速报告的定义和标准）、M1（MedDRA — 监管活动医学词典）及M4（通用技术文件）。

## 成立「香港药物及医疗器械监督管理中心」

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。衛生署已於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，衛生署將會制定「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）及將目前衛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」啟用時，將舉行開幕儀式，以標志其正式成立（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」，標志著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

## 迈向「第一层审批」 路线图

### 背景

- 24.** 「第一层审批」指审批新药注册申请的监管程序，透过自主审核所有临床前研究（即动物实验）、临床研究、药物警戒研究，以及有关生产和品质控制的原始数据及资料，全面审评药物上市前和上市后的安全、效能和素质（涵盖整个产品生命周期）。要实施「第一层审批」，本港必须有一个由不同专家和专业人士组成的跨专业团队。不仅如此，临床试验监督、健全的警戒系统、检测服务支持等监管措施必须齐备，方能妥善管理新药械产品的生命周期。
- 25.** 要在本港实施药械「第一层审批」，现行法例须要作出重大修订，包括更新药剂制品及中药的法例，以及建立专责监管医疗器械的法律框架。这些改革有助管理药械产品的生命周期，确保每个阶段均符合要求，同时亦可主动识别并降低风险。我们致力与全球标准一致，并采取「第一层审批」的方式审批药械产品，务求建立完善、健全的架构，提升公众健康并促进创新，将本港定位为一个安全可靠、医疗发展不断创新的枢纽。这样定能吸引更多本地和世界各地的药械企业在港进行研发及临床试验，有利于加快新药械的临床应用。

## 现行的药械审批机制

26. 根据《药剂业及毒药条例》（第138章），药剂制品必须符合安全、效能及素质方面的标准，并获药剂业及毒药管理局注册，方可在本港销售或供应。在香港，药剂制品的注册申请主要分为两类：（一）含有未在香港注册的新化学或生物元素的有效成分的药剂制品（即新药）；以及（二）不含新化学或生物元素的药剂制品（即仿制药）。
27. 一般而言，新药注册申请人须根据药剂业及毒药管理局发布的《新药剂或生物元素药剂制品注册申请指南》，提供最少两个指明参考地区<sup>2</sup>的药物监管机构发出的注册证明文件，以证明有关产品在上市前已获严谨审评（即「第二层审批」制度）。
28. 为优化药物监管制度并长远落实「第一层审批」，药剂业及毒药管理局已于2023年11月1日推行「1+」新药审批机制，并于2024年11月1日将其适用范围扩展至所有新药。含有新化学或生物元素的药剂制品，只要有本地临床数据支持，而新药的适用范围经本地相关专家认可后，申请人只须提交一个（而非两个或以上）参考药物监管机构的注册许可，即可在香港申请注册。「1+」新药审批机制，是我们迈向「第一层审批」的重要里程碑。
29. 此外，本港已建立中药规管制度。根据《中医药条例》（第549章），所有中成药必须符合香港中医药管理委员会辖下中药组就中成药的安全、品质及成效所订明的注册要求，方可进口香港，并在香港销售或制造。现时，即使有关中成药并未在其他地方注册或销售，其注册申请同样会以「第一层审批」机制作出审评。

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<sup>2</sup> 药剂业及毒药管理局发出的《新药剂或生物元素药剂制品注册申请指南》共列出36个认可地区，包括澳洲、巴西、加拿大、中国内地、欧盟26个国家、日本、韩国、新加坡、瑞士、英国及美国。

30. 现时，部分医疗器械受现有法例监管<sup>3</sup>。经参考国际医疗器械监管机构论坛的建议，政府设立了一套自愿医疗器械行政管理制度（器械管理制度）以保障公众健康，并为长远实施医疗器械的法定监管铺路。器械管理制度涵盖推出市面前及推出市面后的医疗器械，以双管齐下模式管理。政府现正进行筹备工作，为医疗器械的法定监管制订特定法例。法定监管架构落实后，只有符合安全、品质及性能要求的医疗器械方可在香港注册。政府亦已按照国际惯例设立相关机制，透过认证评核机构对医疗器械进行「第一层审批」。

## 迈向「第一层审批」路线图

31. 卫生署已就药剂制品迈向「第一层审批」制定路线图，详细规划涉及的两个阶段：准备阶段和实施阶段。实施阶段将于2026年开展，而「第一层审批」将分期正式执行。鉴于中成药和医疗器械目前已有既定机制进行审批，本路线图只聚焦于药剂制品的「第一层审批」。

## 准备阶段（由2024年起）

32. 除「药械监管中心」成立时间表（即本文件第一部分）中提及的各项措施外，推行「第一层审批」前须落实的其他措施包括：(i) 优化电子注册平台，将ICH通用技术文件格式和临床试验系统纳入平台之中，以方便申请人提交申请，并由审评小组处理有关申请；(ii) 将注册申请分类，为申请人提供清晰的注册要求和途径，同时优化审评资源的分配；以及 (iii) 就不同的注册途径和临床试验引入新收费，以配合所投放的资源。政府亦会探讨应用人工智能等新工具，务求强化审评能力和效率。

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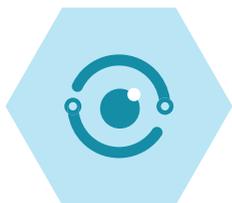
<sup>3</sup> 视乎其特徵、特点，相关产品可能受《药剂业及毒药条例》（第138章）、《辐射条例》（第303章）、《商品说明条例》（第362章）、《消费品安全条例》（第456章）或《电气产品（安全）规例》（第406G章）等法例所规管。

## 实施阶段（2026至2030年）

- 33.** 为加强审评能力并改善审评和审批程序，「第一层审批」的实施工作审慎周详，按四期分阶段推行，逐步扩大适用范围。前期的目标是找出可改善的空间，予以加强，并协助强化审评能力和改善规程、指引、电子注册系统等。此举有助减少申请人和「药械监管中心」在推行初期所遇到的困难。
- 34.** 推行「第一层审批」须要投放大量资源和人力。为确保计划可持续推行，计划将订立新的审评及/或申请费用。计划实施初期收集得来的数据也将有助评估所需要的资源及制定不同申请途径的收费标准。「第一层审批」将于2026至2030年间分期推行：
- i. **第一期（由2026年起）**先由含有已注册化学元素的产品延伸应用（例如新适应症、新剂量、新用法用量、新剂型等）开始推行；
  - ii. **第二期**范围涉及已注册生物元素产品的延伸应用；
  - iii. **第三期**将适用范围扩大至非首创新药的注册申请，及特定先进疗法产品；以及
  - iv. **第四期（2030年或以前）**「第一层审批」将全面实施，涵盖所有药剂制品。
- 35.** 监管医疗器械的新法例一并实施后，香港将于2030年全面推行「第一层审批」，届时将可涵盖所有药械产品。

香港特别行政区政府卫生署  
二零二五年六月

# 「香港药物及 医疗器械监督管理局」的 愿景、使命及信念



## 愿景

创新进取 追求卓越  
专业权威 誉满全球



## 使命

建构监管枢纽 树立信誉权威  
提升公众健康 推动国际合作



## 信念

专业精神 齐心协力  
秉持诚信 精益求精  
以人为本 勇于承担  
公开透明 进取创新



# 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. Refinement 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<sup>1</sup> (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).

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<sup>1</sup> 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<sup>2</sup> 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).

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<sup>2</sup> 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.

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- 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<sup>3</sup>. 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.

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<sup>3</sup> 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)

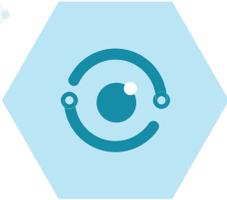
- 32.** Apart from various measures to be taken as mentioned in the Timetable for the Establishment of the CMPR (i.e. Part 1 of this document), other measures that need to be carried out before implementation of primary evaluation include (i) enhancement of the electronic registration platform to incorporate 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.

# 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



