

Building Hong Kong SAR into an International Health and Medical Innovation Hub
 打造香港特区成为国际医疗创新枢纽

HONG KONG CENTRE FOR MEDICAL PRODUCTS REGULATION

香港药物及医疗器械 监督管理中心

ESTABLISHMENT OF THE HONG KONG CENTRE FOR MEDICAL PRODUCTS REGULATION (CMPR) 「香港药物及医疗器械监督管理中心」(「药械监管中心」)的成立



Timetable for Establishing CMPR and Roadmap for Implementing "Primary Evaluation"
 「药械监管中心」的成立时间表及推行新药「第一层审批」路线图

- ✔ **Set up in 2026**
 于2026年成立
- ✔ **Holistically upgrades the regulatory regime for Western and Chinese medicines, and medical devices**
 全面提升中西药及医疗器械的监管体系
- ✔ **Integrates regulatory expertise and resources to boost efficiency, drive medical innovation, and connect Hong Kong's medical ecosystem to the world**
 整合监管专业技能及资源，提升效能、推动药械创新，及连接全球医疗生态
- ✔ **Creating unparalleled opportunities for medical products enterprises**
 为药械企业打造无与伦比的发展机遇

SERVE AS A POWERFUL SPRINGBOARD FOR MEDICAL PRODUCTS ENTERPRISES TO EXPAND INTO GLOBAL MARKET 成为药械企业开拓全球市场的有力跳板

- ✔ **Fast-tracked approval of innovative pharmaceutical products via Primary Evaluation**
 通过「第一层审批」实现创新药剂制品快速审评审批
- ✔ **Expedited access to the Guangdong-Hong Kong-Macao Greater Bay Area (GBA) and Chinese Mainland market under national policies**
 依托国家政策，加快粤港澳大湾区及中国内地市场准入
- ✔ **Global market expansion with Hong Kong's international regulatory network**
 借香港的国际监管联系网络，助力布局全球市场
- ✔ **Comprehensive support for research & development (R&D): top clinical resources + robust intellectual property (IP) protection**
 顶尖临床研发资源+完善的知识产权保护，为研发全程保驾护航
- ✔ **Bilingual common law environment: allow smooth cross-border regulatory and commercial connectivity**
 中英双语普通法环境，便利跨境监管与商业运营接轨

"The Hong Kong Special Administrative Region ("HKSAR") Government has been actively complementing the directions set out in the National 14th and 15th Five-Year Plans, proposing the targets of supporting the accelerated development of biomedicine and improving the evaluation and approval mechanism of innovative drugs and medical devices. The HKSAR Government will reform Hong Kong's evaluation, approval and regulatory regime of medical products, as well as actively promote the translation of research and development (R&D) outcomes of innovative medical products, thereby developing Hong Kong into an international health and medical innovation hub.

特区政府积极配合国家《十四五规划》及《十五五规划》的方向，提出支持加快生物医药发展、完善创新药和医疗器械审评审批机制的工作目标，改革香港对药械的审评审批和监管制度，积极推动创新药械研发成果转化，发展香港成为国际医疗创新枢纽。”



Vision
 愿景

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

创新进取 追求卓越
 专业权威 誉满全球



ESTABLISHING AN INTERNATIONALLY RENOWNED REGULATORY AUTHORITY OF MEDICAL PRODUCTS

建立权威的国际药械监管机构

HONG KONG'S UNIQUE COMPETITIVE ADVANTAGES 香港独有的核心竞争优势

- ✔ **Staunch Policy Support**
 坚实政策支持
 - **Efficient, clean governance**
 高效廉洁的政府治理体系
 - **Unwavering policy commitment of Hong Kong SAR Government**
 香港特区政府坚定的政策承诺
 - **Strong support from the Motherland under "One Country, Two Systems"**
 “一国两制”下背靠祖国的强力政策支持
- ✔ **Common Law Jurisdiction**
 普通法司法权
 - **The only jurisdiction in China practising common law, operating bilingually in Chinese and English**
 中国唯一实行普通法的司法管辖区，并以中英双语并行
 - **Provide familiar and reliable legal environment for international businesses**
 提供自由的市场环境和国际化的运作模式
- ✔ **Top-tier Clinical Research Resources**
 卓越临床研究资源
 - **World-leading universities / medical schools + 4 hospitals with 31 specialties accredited by the National Medical Products Administration (NMPA) for clinical trials studies**
 汇聚世界顶尖大学 / 医学院，4所医院31个专科获国家药品监督管理局临床试验机构资格认定
 - **Comprehensive clinical trial and health data infrastructures**
 配套完善的临床试验与数据基建
- ✔ **PIC/S¹ GMP² Inspection Competency**
 具备PIC/S¹ GMP²检查能力
- ✔ **Robust IP Protection**
 完善的知识产权保障制度

“SUPER CONNECTOR” 「超级联系人」



PIC/S¹: The Pharmaceutical Inspection Co-operation Scheme 药品检查合作计划
 GMP²: Good Manufacturing Practice 生产质量管理规范

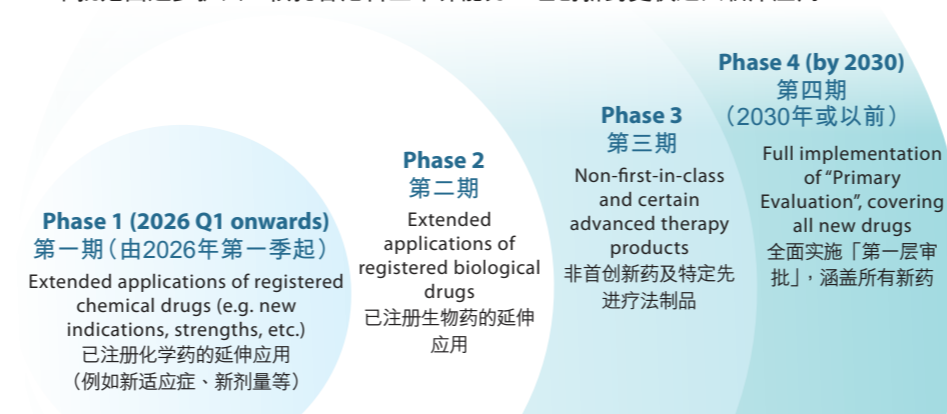
FOCUS ON 3 MAIN AREAS TO ACHIEVE THE VISION OF THE CMPR

实现「药械监管中心」愿景的三大重点范畴

I. Promoting Medical Product Innovation 促进药械创新

Expediting market access for innovative medical products, and rolling out “Primary Evaluation” in phases for new drugs (pharmaceutical products) starting from 2026: 加速创新药械的市场准入，并由2026年起分阶段推行新药（药剂制品）的「第一层审批」：

- ▶ **Phased implementation of Primary Evaluation between 2026 and 2030**
 2026至2030年分阶段推行「第一层审批」
- Leveraging Hong Kong's independent evaluation capacity to fast-track clinical application of innovative drugs
 审批范围逐步扩大，依托香港自主审评能力，让创新药更快进入临床应用



Pharmaceutical companies can flexibly select the registration pathways that suit the characteristics of their products and their global development strategies.

制药企业可灵活选择最适合其药品及全球发展战略的注册途径。

“Primary Evaluation” 「第一层审批」

Without requiring any prior registration approval from drug regulatory authority outside HK
 无需先获任何香港以外药物监管机构的注册许可



Primary Evaluation



「第一层审批」

“Secondary Evaluation” 「第二层审批」

Including “1+” mechanism
 包括「1+」机制

Bringing the benefits of good drugs,
 and research & development to Hong Kong SAR

好药港用 研发惠民

II. Driving Regulatory Excellence 推动优质监管

Building a globally credible evaluation and approval system to boost international recognition of Hong Kong's regulatory outcomes:
 构建全球公认的审评审批体系，提升香港审批成果的国际认可度：

- ▶ Enact new legislation and amend existing ordinances, safeguarding the public by ensuring the safety, quality, efficacy/performance of registered products throughout product life-cycle
 制定新法例并修订现行法规，透过确保已注册产品在全生命周期的安全、素质及效能/性能，以保障公众
- ▶ Strengthen professional evaluation capacity and fully align with international best practices
 强化审评专业能力，全面接轨国际监管最佳作业方式

III. Deepening National and International Collaboration 深化地域合作

Leverage Hong Kong's "Support from the Motherland and Close Connection with the World" to create a bridge for medical products enterprises to expand markets:
 依托香港「背靠祖国、联通世界」的区位优势，为药械企业打造市场拓展的黄金桥梁：

- ▶ Strengthen ties with national/GBA regulatory authorities; leverage the “Measure of using HK registered drugs and medical devices used in HK public hospitals in Guangdong-Hong Kong-Macao GBA” for expedited market access in the GBA
 深化与国家及粤港澳大湾区监管机构合作，借力「港澳药械通」政策，加快粤港澳大湾区市场准入
- ▶ Active participation in international regulatory organisations (PIC/S¹, ICH³, GHWP⁴); strive for ICH regulatory membership to align with global drug registration standards
 积极参与PIC/S¹, ICH³, GHWP⁴等国际监管组织事务，致力成为ICH³监管机构成员，全面接轨全球药品注册技术标准
- ▶ Attract multinational corporations to file first-in-Hong Kong applications for further expansion into the Chinese Mainland market; help local/Chinese Mainland innovative medical products go global
 吸引跨国药企在港首报，助力开拓中国内地市场；协助本地及中国内地创新药械走向国际

Hong Kong SAR is the premier city for medical products companies to set up operations, and an ideal hub for research and development.

香港特区，是药械企业落户的首选，亦是理想的研发基地。

ICH³: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
 国际人用药品注册技术协调会

GHWP⁴: Global Harmonization Working Party
 全球医疗器械法规协调会