

**The Submission of Hong Kong Five-Year Plan on
Pharmaceutical Industry in Hong Kong (2026 – 30)**

By

The Hong Kong Association of the Pharmaceutical
Industry (HKAPI)

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Preamble

The Hong Kong Association of the Pharmaceutical Industry representing 34 multi-national R&D pharmaceutical companies in Hong Kong. The global R&D for member companies exceeds USD270 billion annually¹.

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Hong Kong possesses world-class foundational strengths to become a leading global biomedical innovation hub: a mature, high-quality healthcare system, top-tier academic and research institutions, strong intellectual property protection, international regulatory credibility, robust rule of law, global financial connectivity, and strategic proximity to the Guangdong-Hong Kong-Macao Greater Bay Area (GBA). To fully unlock this potential, a coherent, forward-looking, and actionable five-year strategy is essential.

Building on Hong Kong's strengths, this plan sets up a **five-pillar framework** to position the city as a premier regional and global Centre for pharmaceutical innovation, regulatory excellence, and clinical translation. The core objectives are:

- To establish Hong Kong and GBA as a leading biomedical innovation hub in Asia and globally.
- Strengthen the end-to-end ecosystem covering clinical research, regulation, market access, data infrastructure, and collaboration.

¹ https://www.ispor.org/docs/default-source/intl2024/j-j-access-policy-research---ispor-2024---pharma-r-d-ecosystem-investment137860-pdf.pdf?sfvrsn=d28181d4_0

- To accelerate patient access to safe, effective, and innovative therapies while ensuring the long-term sustainability of Hong Kong's healthcare system.

The five pillars are:

1. Clinical Research – Build a World-Class Clinical Trial Ecosystem
2. Intellectual Property & Market Incentives – Create a sector-specific framework to protect biomedical innovation and align incentives with clinical trial investment.
3. Robust Regulatory framework
4. Sustainable Market Access & Value-Based Healthcare
5. Cross-Sector Collaboration & GBA Strategy

Cross-Sector Collaboration & GBA strategy – Institutionalize government, academic, and industry partnership; collaborate with strength of GBA, to global and Mainland markets.

However, more importantly is the mindset of comparison that Hong Kong has done a lot to enhance its competitiveness in the region, but multi-national companies will compare and look for the best to invest. Meanwhile, the speed of policy execution in Hong Kong will be critical. It's important for the government to move quickly—not only to catch up with neighboring markets but also to stay ahead if they want to become a leader within Asia. For instance, the GBA clinical trial supported by GBAICTI is a relevant example; even now, cross-border biological samples and data remain inaccessible, despite the policy being in place. Perhaps it's worth considering if a point about execution speed should be included in the plan.

Multinational companies are the anchor companies for developing a sector. As HK works toward becoming an international biomedical hub, it is crucial for the government to actively incentivize MNCs to prioritize global first-launch innovation here, with reference to Singapore.

1. Pillar One: Clinical Research – Build a World-Class Clinical Trial Ecosystem

Strategic Goal

Ensure clinicians, patients, and innovators have timely access to advanced medical technologies. Attract global clinical trial investment by positioning Hong Kong as a priority R&D market for multinational pharmaceutical enterprises. Establish measurable outcomes to assess Hong Kong's progress as a clinical research hub.

1.1 Promote and Reward Innovation

- Provide fiscal and policy incentives linked to clinical trial activity in Hong Kong.
- Integrate clinical trial performance into formal appraisal for principal investigators, hospitals, and Hospital Authority (HA) clusters, with rewards including research grants, official recognition, and career advancement.
- Grant faster review, priority assessment, and formulary advantages for products supported by Hong Kong-generated clinical evidence.

1.2 Ensure Stable, Efficient Resources and Predictable Processes

- Allocate dedicated, long-term clinical trial resources within the HA and hospital clusters with clear KPIs; treat clinical research as core infrastructure, not ad-hoc work.
- Expand Phase I and early-phase trial capacity, including additional sites, facility upgrades, and specialized workforce support.

- Develop structured talent programs for investigators, study coordinators, trial nurses, pharmacologists, and research managers, including protected research time and clear career pathways.
- Enable parallel processing of ethics, legal, PPB, and drug code applications; launch digital tracking systems with transparent timelines and fixed milestones.
- Standardize legal vetting, site procedures, and approval templates across hospitals to reduce repetition, inconsistency, and post-IRB delays.

1.3 Enhance the Value of Clinical Trials

- Position and promote clinical trials as a legitimate channel for early patient access to breakthrough therapies, enhancing Hong Kong's research reputation and attracting multinational investment.
- Use trial-generated real-world data (RWD) to support regulatory and reimbursement decisions, bridge standards, and foster a virtuous innovation cycle.
- Strengthen local investigator capacity and raise Hong Kong's international research profile.

1.4 Strengthen Real-World Data Integration

- Develop a secure, privacy-compliant mechanism for researchers to access anonymized public and private healthcare data.
- Formalize structured RWD use for regulatory approval, health technology assessment, and reimbursement decisions.
- Build analytical capabilities for long-term safety monitoring and outcomes tracking.

1.5 Expand Clinical Research Participation

- Establish a centralized patient referral system across public hospitals to improve trial matching efficiency.
- Expand recruitment through primary care, community engagement and GBA collaboration.
- Adopt more diverse and inclusive patient recruitment strategies.
- launch public education campaigns to improve awareness and participation in clinical research.

2. Pillar Two: Intellectual Property & Market Incentives

Strategic Goal

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The industry supports patent box and tax incentives; however, pharmaceutical innovation requires targeted, sector-specific protection. It is crucial to develop a pharmaceutical-focused IP and incentive framework that protects innovation, encourages R&D investment, and rewards high-value local clinical research.

Define clear criteria for success, such as increased patent filings and locally conducted trials.

2.1 Data Exclusivity as a Strategic Policy Tool

- Establish an internationally competitive data exclusivity framework benchmarked to global best practices.
- Link data exclusivity incentives to local clinical trial investment to encourage companies to conduct high-value research in Hong Kong.

2.2 Strengthen Patent Linkage and Enforcement

- Improve coordination between regulatory approval and patent systems to enhance predictability and investor confidence.
- Develop streamlined administrative dispute resolution and enforcement mechanisms to reduce the burden on originator companies, avoiding lengthy and costly court proceedings to revoke infringing product registrations.

3. Pillar Three: Regulatory Excellence & Approval Efficiency

Strategic Goal

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Create an efficient, predictable, transparent, and internationally recognized regulatory system that accelerates patient access while maintaining safety, quality, and efficacy. Set clear targets, such as reduced approval times and have more agencies to recognize Hong Kong regulatory approvals.

3.1 Improve Regulatory Efficiency and predictability.

- Further reduce the registration timelines including those 2 CPPs, 1+ and ensure the primary evaluation an efficient one by benchmark the region such as Singapore.
- Publish roadmap with fixed timelines and guidelines published.
- Expand review capacity and therapeutic expertise, including specialist review panels.
- Streamline regulatory pathways, referencing the EU “Do & Tell” model and simplifying LegCo vetting where appropriate.
- Develop an electronic product insert (ePI) platform under the Hong Kong Centre for Medical Products Regulation (CMPR).

3.2 Uphold International Standards

- Maintain alignment with ICH, PIC/S, and other global regulatory norms to reinforce Hong Kong’s role as an international gateway and trusted reference market.

3.3 Enhance the Value of Hong Kong Regulatory Approval

- Join international joint-evaluation platforms such as ACCESS and ORBIT.
- Develop a formal linkage between Hong Kong registration and boarder Mainland market access pathways (in addition to ‘Special Measures”)
- Establish a primary evaluation pathway to position Hong Kong as an APAC regulatory leader, where Hong Kong approval supports access to multiple regional markets.

4. Pillar Four: Sustainable Market Access & Value-Based Healthcare

Strategic Goal

Change the mindset that investment in health delivers high economic and social returns. Patient outcomes and people's quality of life in society shall be the core value of medicine and the entire healthcare system.

Build a transparent, value-based market that rewards innovation, ensures sustainable healthcare financing, supports a multi-payer system, and improves Drug Formulary transparency and efficiency. Establish treat-to-goal mindset, prioritize resources to high-risk patients with optimal diagnosis and treatment, maximize the value of innovation.

4.1 Maximize the value of innovation.

- Reward innovation based on therapeutic value, not just upfront cost.
- Use treat-to-goal mindset, prioritize resources to high-risk patients with optimal diagnosis and treatment by evidence-based clinical guidelines for patients to optimize resource allocation.
- Shift from a single-payer model to a sustainable multi-payer system (enhanced VHIS, private insurance, and health financing reform).
- Strengthen multi-stakeholder collaboration: patients, industry, government, and insurers.

4.2 Value-based Drug Enlistment (HADF)

- Establish transparent HA reimbursement and formulary processes that reflect real-world value: clinical outcomes, quality of life, and societal benefit.
- Strengthen assessment criteria, ensure transparent decisions, and adopt value-based evaluation.
- Provide fast-track DAC/HA pathways for drugs supported by Hong Kong trial data.
- Incorporate innovation value principles and align with the best international practices.
- Define clear timelines, rationales, and structured engagement and appeal mechanisms, and ensure it is transparent.

4.3 Adopt International Benchmark Evaluation

- Benchmark against advanced economies and leading innovation hubs.
- Use evidence-based decision-making, horizon scanning, and international frameworks.
- Establish clear prerequisites for expedited pathways (the Office of Introduction to Innovative Medicine and Devices).

4.4 Embrace Advanced Technology

- Deploy AI, digital tools, ePI, electronic platforms, and integrated health data, to ensure the efficiency of the system.
- Build an open data ecosystem to support drug evaluation, reimbursement, and innovative pricing.

4.5 Adopt Innovative Funding Solutions

- Implement multi-innovative funding models, i.e. Managed entry agreements, risk-sharing arrangements, and outcomes-based contracts.
- Improve access while maintaining budget sustainability.

5. Pillar Five: Cross-Sector Collaboration & GBA Strategy

Strategic Goal

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Institutionalize structured cooperation among government, academic, and industry. Leveraging on the GBA strategy and expanding Hong Kong's role as super connector between global innovation and the Mainland. Establish clear measures, such as increased cross-sector projects and regional partnerships.

5.1 Establish Transparent Collaboration Platforms

- Create formal dialogue platforms, advisory councils, and regular strategic roundtables.
- Implement early scientific advice mechanisms.
- Develop shared roadmaps for innovation priorities.

Structured communication improves policy alignment and speeds up access to innovative therapies.

5.2 Greater Bay Area (GBA) Synergies

- Build cross-border clinical trial networks and multi-centered research platforms.
- Promote the use of Hong Kong real-world data as a credible reference for Mainland drug registration and reimbursement.
- Expand the GBA “Medical Connect” drug list and designated hospitals to increase market reach.

6. Cross-Cutting Enablers

All initiatives will be guided by:

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- Transparency and policy predictability
- Clear timelines and measurable performance indicators
- Efficient, flexible administrative systems
- Patient-centered and inclusive healthcare principles
- Recognition of the long-term economic and social value of biomedical innovation

7. Conclusion

Hong Kong stands at a strategic inflexion point. By strengthening its clinical research ecosystem, reinforcing intellectual property protections, advancing regulatory excellence, modernizing market access through value-based care, and institutionalizing cross-sector and cross-border collaboration, Hong Kong will emerge as a premier global biomedical innovation hub.

This transformation will attract multinational R&D investment, accelerate early patient access to cutting-edge therapies, and ensure the long-term sustainability of Hong Kong's healthcare system. Through coordinated implementation of this five-pillar framework, Hong Kong will move beyond incremental reform to become a globally competitive, trusted, and vibrant center for pharmaceutical innovation.