

# HONG KONG PHARMACEUTICAL *JOURNAL*

VOL 33 NO 2 May - Aug 2026 ISSN 1727-2874



## News & Short Communications

Optimising Post-Approval Regulatory Change Management for Pharmaceutical Products in Hong Kong — Case Studies from China and the United States

Anticholinergic Burden in Older Adults (2 CE Units)

Quality Assurance of Community Pharmacy Services Across Jurisdictions: A Comparative Review of Governance Models and Structural Considerations for Hong Kong

From Dispensing to Clinical Practice - Navigating the Paradigm Shift in the United Kingdom's Primary Care Pharmacy for Hong Kong's Healthcare Evolution

Is the Pharmacy Profession Ready for Artificial Intelligence by 2030? – Insights from the Hong Kong Pharmacy Conference 2026 Plenary Session



*The Pharmaceutical Society of Hong Kong  
The Practising Pharmacists Association of Hong Kong  
The Society of Hospital Pharmacists of Hong Kong*

# HONG KONG PHARMACEUTICAL JOURNAL

VOL 33 NO 2 May - Aug 2026 ISSN 1727-2874

## EDITORIAL COMMITTEE

|                                        |                                                                                                   |
|----------------------------------------|---------------------------------------------------------------------------------------------------|
| Editor-in-Chief                        | LAM, May                                                                                          |
| Managing Editors                       | CHENG, Mary<br>TSANG, Warren                                                                      |
| Secretary                              | WONG, Bryan                                                                                       |
| Treasurer                              | LAM, Paul                                                                                         |
| Business Manager                       | Zoe Tsui                                                                                          |
| IT Manager                             | LI, Yvonne                                                                                        |
| Section Editors                        | WONG, Johnny                                                                                      |
| Pharmacy Education & Practice          | CHONG, Donald<br>LEUNG, Ann<br>LEUNG, Shek Ming<br>TAM, Eliza<br>CHOW, Tiffany (Review Assistant) |
| Drugs & Therapeutics                   | CHAN, Esther<br>LEUNG, Brian<br>LEUNG, Wilson<br>SUN, WY Kiwi<br>YUEN, Johnny                     |
| Primary Care, OTC & Health             | CHENG, WT Franco<br>LEE, Marco<br>TAM, Janice                                                     |
| Pharmaceutical Techniques & Technology | KWOK, Philip<br>TONG, Henry                                                                       |
| Herbal Medicines & Nutraceuticals      | CHEUNG, HY                                                                                        |
| Society Activities                     | YAU, Edward                                                                                       |
| New Products                           | LEUNG, Lucilla                                                                                    |

## EDITORIAL ADVISORY BOARD

|                             |                              |
|-----------------------------|------------------------------|
| Prof. CHAN, Hak-Kim         | Prof. CHANG, Pong            |
| Prof. CHERN, Ji-Wang        | Prof. CHIANG, Chiao-Hsi      |
| Prof. CHO, Chi-Hin          | Ms. CHIANG, Sau Chu          |
| Prof. LI, CH Paul           | Prof. LI, Wan-Po Alain       |
| Prof. LEE, An-Rong          | Prof. LEE, Hon-leung Vincent |
| Dr. MORGAN, Rae M.          | Prof. WONG Ian               |
| Prof. YANG, Chih-Hsin David | Prof. ZUO Zhong, Joan        |

The Hong Kong Pharmaceutical Journal, the publisher, the editorial board and the respective member societies are not responsible for the completeness and accuracy of the articles and advertisements contained in the Hong Kong Pharmaceutical Journal. The Journal will not be liable to any damages to persons and properties. Readers are advised to approach the respective authors and advertisers for information in case of doubts.

Copyright © 2026 by Hong Kong Pharmaceutical Journal  
All rights reserved. No part of this publication or its supplement may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording, or any information storage and retrieval system, without permission in writing from the Publisher.

All communications and enquiries should be directed to:  
**The Secretary, Hong Kong Pharmaceutical Journal,  
Room 1303, Rightful Centre, 12 Tak Hing Street,  
Jordan, Hong Kong.**

For all enquiries regarding advertisement, please contact:  
**Ms. Zoey Tsui (Tel. 9099 3100) or Ms. Yvonne Li (Tel: 2376 3090)**  
at the following email address: [admin@pshkk.hk](mailto:admin@pshkk.hk)

## INSTRUCTIONS FOR AUTHORS

The Hong Kong Pharmaceutical Journal is a journal of the pharmacists, for the pharmacists and by the pharmacists. Submissions are welcome for the following sections:

- Pharmacy Education & Practice
- Drugs & Therapeutics
- Primary Care, OTC & Health
- Pharmaceutical Techniques & Technology
- Medication Safety
- Herbal Medicines & Nutraceuticals
- Society Activities
- New Products

Comments on any aspects of the profession are also welcome as Letter to the Editor.

There is no restriction on the length of the articles to be submitted. They can be written in English or Chinese. The Editorial Committee may make editorial changes to the articles but major amendments will be communicated with the authors prior to publishing.

It is preferable to have original articles submitted as an electronic file, in Microsoft Word, typed in Arial 9pt. Files can be sent to the following address:

**e-mail: [editor@hkpj.org](mailto:editor@hkpj.org)**

**address: Room 1303, Rightful Centre,  
12 Tak Hing Street, Jordan,  
Hong Kong.**

For detail instructions for authors, please refer to the first issue of each volume of HKPJ.

## Editorial

LAM, May 41

## News & Short Communications

Daraxonrasib or Chemotherapy in Previously Treated Metastatic Pancreatic Cancer 42

Finerenone in Persons with Chronic Kidney Disease without Diabetes 42

Adjuvant Pembrolizumab-Belzutifan Improves Disease-free Survival for Patients with Clear-Cell Renal-Cell Carcinoma 43

Extended Dual Antiplatelet Therapy Reduces Composite Cardiovascular Deaths in Multivessel Coronary Artery Disease 43

Ralinepag for the Treatment of Pulmonary Arterial Hypertension 44

Perioperative Apalutamide Plus Androgen-Deprivation Therapy Provides Better Pathological Response in High-Risk Localized Prostate Cancer 44

## Pharmacy Education & Practice

Optimising Post-Approval Regulatory Change Management for Pharmaceutical Products in Hong Kong – Case Studies from China and the United States 45

CHAN, Philip Pan; KWONG, Rex Lok Fung

## Drugs & Therapeutics

Anticholinergic Burden in Older Adults(2 CE Units) 51

CHAN, Yi-Ming

## Primary Care, Over-the-Counter & Health

Quality Assurance of Community Pharmacy Services Across Jurisdictions: A Comparative Review of Governance Models and Structural Considerations for Hong Kong 59

LEE, Marco Tsun; LAW, Kitty Kit Ki; LEE, Tommy Ka Ho; CHEUNG, Gladys Daphne; LIU, Sharon Yin; CHENG, Franco Wing Tak; WAN, Eric Yuk Fai; CHEN, Timothy Frank; WONG, Ian Chi Kei

65

From Dispensing to Clinical Practice - Navigating the Paradigm Shift in the United Kingdom's Primary Care Pharmacy for Hong Kong's Healthcare Evolution

LEE, Tommy Ka-Ho; LO, Leo Kin-yip; LEE, Marco Tsun; LAW, Kitty Kit-Ki; CHEUNG, Gladys Daphne; WAN, Eric Yuk-Fai; PATEL, Nileshe; HUGHES, Carmel; WONG, Ian Chi-Kei

## Pharmaceutical Techniques & Technology

Is the Pharmacy Profession Ready for Artificial Intelligence by 2030? – Insights from the Hong Kong Pharmacy Conference 2026 Plenary Session 73

TONG, Jason; WONG, Vincent; WONG, Johnny; FUNG, Crystal; KWAN, William; HO, Sue; TSE, Hercules; LI, Cherrie

## Pharmacy 2.1—Systems, Safety, Community, and Technology



The publication of Volume 33, Issue 2 of the Hong Kong Pharmaceutical Journal reflects the diverse responsibilities of pharmacists in today's healthcare system. This issue spans regulatory frameworks, geriatric safety, community based preventive care and technological innovation. Together, these contributions illustrate how our profession is evolving to meet both systemic demands and patient centered outcomes.

### Regulatory Science: Post Approval Change Management

Beginning with policy and systems, the article on optimising post approval regulatory change management for pharmaceutical products in Hong Kong (p. 45) highlights the importance of regulatory vigilance. As medicines undergo manufacturing updates, labeling revisions and distribution adjustments, pharmacists play a critical role in ensuring continuity of safety and efficacy. In an era of biologics and advanced therapies, robust change management processes are indispensable. This work reminds us that clinical excellence must be anchored in regulatory stewardship.

### Clinical Practice: Anticholinergic Burden in Older Adults

The next article addresses the anticholinergic burden in older adults (p.51), a pressing issue in geriatric care. Polypharmacy and multimorbidity increase vulnerability to cognitive decline, falls and hospitalizations. Pharmacists are uniquely positioned to assess cumulative anticholinergic load, conduct medication reviews and implement deprescribing strategies. This contribution exemplifies how pharmacists translate pharmacological expertise into interventions that directly improve patient safety and quality of life.

### Community and Preventive Care: Expanding the Pharmacist's Reach

Two articles in this issue highlight the growing importance of community and preventive care.

The first article (p. 59) provides a comparative review of quality assurance (QA) systems for community pharmacy services across jurisdictions including Australia, Canada, Macau, Mainland China, Singapore, the United Kingdom and the United States. The analysis maps regulatory foundations, accreditation approaches, inspection practices and incentive alignment strategies. Findings show that while statutory regulation remains the baseline, mature systems incorporate structured quality programmes, incident reporting, external assessment and accreditation to support continuous improvement. The article suggests that Hong Kong may benefit from a phased QA model—strengthening statutory compliance in the short term, introducing peer review in the medium term and developing an independent, multi stakeholder accreditation pathway in the long term as community pharmacy expands within primary healthcare reform.

The second article (p. 65) draws on insights from a three week fellowship in the United Kingdom (UK) under the Primary Care Pharmacy Fellowship Scheme of the Jockey Club PHARM+ Community Medication Service Network Project.

Observations from the UK National Health Service (NHS) demonstrate how community pharmacists are integrated into primary care as clinical hubs. The article highlights operational bottlenecks—such as high volume technical workloads—that must be mitigated through enabling infrastructure like Original Pack Dispensing and hub and spoke systems. It further emphasizes the value of commissioning structured clinical services, including minor ailment triage and medication reviews within multidisciplinary teams, to enhance patient access and relieve frontline general practice pressures. While structural reforms in Hong Kong must be phased and context specific, the UK model offers a roadmap for collaborative chronic disease management and patient centered care, enabling community pharmacies to transition into sustainable healthcare providers.

Together, these contributions show that preventive care is not ancillary but central to our professional identity, positioning pharmacists as leaders in both individual and population health.

### Pharmaceutical Technology: Readiness for Artificial Intelligence

This issue also features an article under pharmaceutical technology, summarizing the plenary debate at the Hong Kong Pharmacy Conference 2026 (p. 73) on whether the profession is ready for artificial intelligence (AI) by 2030. The “For” team argued that infrastructure, professional evolution, governance frameworks and empirical evidence position pharmacy well for AI integration. The “Against” team highlighted regulatory gaps, data security concerns, ethical challenges and immature applications.

Adjudicated by AI experts, the debate underscored both global regulatory trends and local cybersecurity challenges, while stressing AI's potential role in clinical workflows. Importantly, it emphasized the need for proactive training, policy development and ethical safeguards to harness AI's promise without compromising patient safety. This article situates pharmacy at the intersection of technological optimism and cautious realism, reminding us that innovation must be balanced with accountability.

### Conclusion: A Profession Anchored in Accountability and Innovation

Taken together, the contributions in this issue illustrate the breadth of pharmacy's evolving mission: regulatory stewardship, geriatric safety, preventive care and technological innovation. The trajectory of Pharmacy 2.1 is clear. Our profession is moving toward a model where systemic vigilance and patient centered outcomes converge.

As Editor in Chief, I invite you to engage with these articles not only as scholarly discourse but as a roadmap for practice. By embracing innovation, strengthening regulatory frameworks and maintaining unwavering focus on patient safety, we will ensure that pharmacy remains at the heart of a resilient, evidence based healthcare system.

*May P S Lam*  
Editor-in-Chief  
September 2026

Prepared by Candice Leung & Anne Ng

### Daraxonrasib or Chemotherapy in Previously Treated Metastatic Pancreatic Cancer

Date: May 31, 2026

Metastatic pancreatic ductal adenocarcinoma (mPDAC) carries a dismal prognosis, with current second-line cytotoxic regimens yielding limited survival benefit. Oncogenic RAS mutations, present in the vast majority of these tumors, activate downstream proliferative and survival signaling. Daraxonrasib is a novel oral agent that suppresses RAS activity by binding to the active, GTP-bound conformation of both mutant and wild-type RAS isoforms.

This international, open-label phase 3 trial randomly assigned 500 patients with prior-treated mPDAC to either daraxonrasib (248 patients) or physician-selected standard chemotherapy (252 patients), with 91.8% of enrolled patients carrying RAS G12 alterations. The two primary efficacy measures were overall and progression-free survival specifically within the RAS G12-mutant subgroup, with secondary assessments encompassing the broader patient population (including G12, G13, Q61 mutations, and RAS wild-type), objective tumor response, and patient-reported outcomes.

In the RAS G12 population, daraxonrasib nearly doubled median overall survival compared with chemotherapy

(13.2 vs. 6.6 months), corresponding to a 60% relative reduction in the risk of death (hazard ratio, 0.40;  $P < 0.001$ ). Progression-free survival was similarly improved (7.3 vs. 3.5 months; hazard ratio, 0.45;  $P < 0.001$ ). Tumor shrinkage occurred in approximately one-third of daraxonrasib-treated patients, more than double the rate seen with chemotherapy (33.2% vs. 11.8%). Treatment-related grade 3 or higher toxicity were also less frequent with daraxonrasib (43.6%) than with chemotherapy (57.5%), and treatment cessation due to adverse effects was markedly lower (1.2% vs. 11.2%). The predominant daraxonrasib-related side effects were dermatologic and gastrointestinal in nature, typically low-grade and manageable with supportive care.

Daraxonrasib represents a significant therapeutic advance over conventional chemotherapy for previously treated mPDAC, affording substantial improvements in survival, disease control, and quality of life with a more favorable tolerability profile. These findings show that RAS(ON) inhibition is an effective precision-medicine strategy in this highly refractory malignancy.

Source: [www.nejm.org](http://www.nejm.org)

### Finerenone in Persons with Chronic Kidney Disease without Diabetes

Date: June 4, 2026

As a nonsteroidal mineralocorticoid receptor antagonist, Finerenone has demonstrated renoprotective and cardiovascular benefits in patients with type 2 diabetes and chronic kidney disease (CKD). However, its efficacy and safety profile in patients with non-diabetic CKD had not been established prior to this investigation.

This phase 3, international, double-blind, randomized, placebo-controlled trial enrolled 1584 adults with type 1 diabetes, CKD (those with estimated glomerular filtration rate [eGFR] 25 to  $< 90$  ml/min/1.73m<sup>2</sup>), and albuminuria (urinary albumin-to-creatinine ratio [UACR] 200 to  $< 3500$ ). Participants were randomly assigned to receive finerenone (10 or 20 mg daily) or matching placebo, alongside standard renin–angiotensin system inhibitor therapy (angiotensin-converting-enzyme (ACE) inhibitor or an angiotensin-receptor blocker (ARB)). The primary endpoint was the total eGFR slope—the average annual change in kidney function from baseline through month 32—analysed using a two-slope linear spline mixed-effects model.

Over a median treatment period exceeding 3 years, the annual eGFR decline was slowed by 0.7 ml/min/1.73m<sup>2</sup>

with finerenone compared with placebo ( $-3.3$  vs.  $-4.0$  ml/min/1.73m<sup>2</sup> annually; 95% CI for difference, 0.3 to 1.1;  $P < 0.001$ ). The composite kidney–cardiovascular outcome occurred less frequently with finerenone (13.9% vs. 16.9%; hazard ratio, 0.77; 95% CI, 0.60–0.99;  $P = 0.04$ ). Hyperkalemia was more common with finerenone (17.0% vs. 13.3%), however serious hyperkalemia was rare ( $< 1\%$ ) and led to treatment discontinuation in only 1.5% of finerenone recipients. Overall adverse event rates were comparable between groups.

In non-diabetic CKD patients already receiving RAS inhibitor therapy, finerenone slowed kidney function decline and reduced the risk of composite kidney–cardiovascular events compared with placebo, with a manageable safety profile. These findings provide additional evidence for finerenone's renoprotective benefits beyond the diabetic population, supporting its potential role as an additional therapeutic option in the broader CKD landscape.

Source: [www.nejm.org](http://www.nejm.org)

## Adjuvant Pembrolizumab-Belzutifan Improves Disease-free Survival for Patients with Clear-Cell Renal-Cell Carcinoma

Date: July 2, 2026

Adjuvant pembrolizumab serves as a standard-of-care therapy after nephrectomy for clear-cell renal-cell carcinoma (ccRCC) patients at increased risk for recurrence. However, disease recurrence or death still occurs in approximately 40% of high-risk patients within five years. Belzutifan, a potent and selective hypoxia-inducible factor 2  $\alpha$  inhibitor, is clinically proven to slow tumour growth in specific kidney cancers with low-grade toxic effects.

The phase 3, double-blinded LITESPARK-022 trial randomly assigned 1841 adult participants with resected clear-cell renal-cell carcinoma in a 1:1 ratio to receive intravenous pembrolizumab 400 mg every 6 weeks for up to 9 doses plus either (1) oral 120 mg daily belzutifan (n=921) or (2) placebo (n=920) for up to 1 year. Eligible participants had intermediate-to-high risk, high risk, or M1 with no evidence of disease following surgery. The primary outcome was investigator-assessed disease-free survival (DFS), while key secondary outcomes included overall survival (OS) and safety.

At a median follow-up of 28.4 months, DFS was significantly prolonged with pembrolizumab-belzutifan

compared to pembrolizumab-placebo (hazard ratio for recurrence or death=0.72, 95% confidence interval [CI], 0.59-0.87,  $P<0.001$ ), with 24-month DFS estimates of 80.7% versus 73.7%. Overall survival data remained immature (29% of target events) and showed no statistically significant difference between groups (hazard ratio for death=0.78, 95% confidence interval [CI], 0.51-1.19,  $P=0.24$ ). Regarding toxicity, Grade 3 or higher adverse events occurred in 52.1% of the pembrolizumab-belzutifan group compared to 30.2% in the pembrolizumab-placebo group, primarily driven by a higher incidence of anemia (84.0% vs. 11.4%) and hypoxia (7.0% vs. 0.1%).

In conclusion, adding belzutifan to adjuvant pembrolizumab significantly improves disease-free survival in patients with resected clear-cell renal-cell carcinoma at increased risk for recurrence. Although the combination carries a higher incidence of Grade 3 or higher toxicities, its overall safety profile remains consistent with the known toxicities of each drug.

Source: [www.nejm.org](http://www.nejm.org)

## Extended Dual Antiplatelet Therapy Reduces Composite Cardiovascular Deaths in Multivessel Coronary Artery Disease

Date: July 16, 2026

Multivessel coronary artery disease affects 40-60% of patients undergoing percutaneous coronary intervention (PCI), significantly elevating the risk of recurrent ischemic events and mortality from both treated and non-stented coronary segments. While 12 months of dual antiplatelet therapy (DAPT) with aspirin and a P2Y<sub>12</sub> inhibitor is currently the golden standard following drug-eluting stent placement, extended treatment benefits remain uncertain due to concerns over elevated bleeding risks.

The open-label, randomized DAPT-MVD trial enrolled 8250 patients aged 18 to 75 across 97 Chinese institutions who had remained event-free for 12 months after drug-eluting stenting for multivessel disease. Participants were randomly assigned 1:1 to receive an additional 12 months of extended DAPT (n=4125) or aspirin monotherapy (n=4125) as placebo. The primary efficacy end point was a composite of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke assessed in a time-to-event analysis. The primary safety end point was clinically relevant or major bleeding, classified with reference to Bleeding Academic Research Consortium (BARC) type 2 to 5.

Over a median follow-up of 34.3 months, extended DAPT significantly reduced primary efficacy events compared to aspirin monotherapy (5.8% vs. 6.8% 36-month cumulative incidence; Hazard Ratio=0.82, 95% confidence interval [CI], 0.69-0.98,  $P=0.03$ ), primarily driven by a lower rate of nonfatal myocardial infarction (1.8% vs. 2.5%; Hazard Ratio=0.68, 95% confidence interval [CI], 0.50-0.93). Importantly, extended DAPT did not significantly increase clinically relevant or major bleeding (1.4% vs. 1.5%; Hazard Ratio=0.89, 95% confidence interval [CI], 0.61-1.30,  $P=0.54$ ) or major BARC 3-5 bleeding (0.8% vs. 0.9%; Hazard Ratio=0.87, 95% confidence interval [CI], 0.53-1.43,  $P=0.59$ ). Overall serious adverse events were similarly balanced between groups (27.7% vs. 28.0%,  $P=0.77$ ).

In conclusion, extending DAPT with clopidogrel and aspirin for an additional 12 months in stable, event-free patients with multivessel coronary artery disease after drug-eluting stent implantation significantly reduces major adverse cardiovascular events. Furthermore, this ischemic benefit was achieved without increasing the risk of clinically relevant or major bleeding.

Source: [www.nejm.org](http://www.nejm.org)

## Ralinepag for the Treatment of Pulmonary Arterial Hypertension

Date: July 28, 2026

Pulmonary arterial hypertension (PAH) remains a life-threatening disorder caused by increase in pulmonary vascular resistance, frequently resulting in right-sided heart failure and early mortality. Although the therapeutic landscape has expanded over recent decades, its prognosis remains suboptimal. Ralinepag is a novel oral prostacyclin IP receptor agonist administered once daily, using its vasodilatory and antiproliferative properties to control prostacyclin signalling.

This international, double-blind, placebo-controlled phase 3 study randomly assigned 687 patients with PAH to receive either Ralinepag (n=350) or matching placebo (n=337) on the basis of standard-of-care therapy. Dosing started at 50 µg daily with weekly up-titration to each patient's maximum tolerated level. The study population was predominantly on dual background PAH therapy (80%) and had a mean baseline 6-minute walk distance of 438.9 m. The primary outcome was the time from randomisation to the first clinical worsening event, a composite of death from any cause, admission to hospital due to worsening PAH or right heart failure, initiation of parenteral or inhaled prostacyclin-pathway therapy, disease progression, or any unsatisfactory long-term clinical response.

During the median observation period, the primary composite endpoint was reached in 18% of the Ralinepag arm versus 36% of the placebo arm, corresponding to a 55% relative risk reduction (hazard ratio, 0.45; 95% CI, 0.33–0.62;  $P<0.0001$ ). The treatment effect was most pronounced for components related to disease progression, prostacyclin-therapy intensification, and inadequate long-term response. Secondary analyses showed favourable shifts in NT-proBNP (24.3% relative reduction vs. placebo;  $P=0.0013$ ) and 6-minute walk distance (20.4 m treatment effect;  $P=0.003$ ). Tolerability concerns led to treatment cessation in 19% of Ralinepag recipients, which was substantially higher than the 3% observed with placebo, with most discontinuations occurring during the titration phase. Serious adverse event rates were comparable between groups (28% vs. 31%), and on-treatment mortality was similar (4% in each arm).

In a predominantly low-to-intermediate-risk PAH cohort receiving dual background therapy, Ralinepag presents a significant and clinically meaningful reduction in clinical worsening events, accompanied by improvements in haemodynamic biomarkers and functional capacity.

Source: [www.nejm.org](http://www.nejm.org)

## Perioperative Apalutamide Plus Androgen-Deprivation Therapy Provides Better Pathological Response in High-Risk Localized Prostate Cancer

Date: August 6, 2026

Patients diagnosed with high-risk localized or locally advanced prostate cancer face a significant risk of disease recurrence, with up to 50% experiencing a relapse within five years of undergoing a radical prostatectomy. Apalutamide, an oral nonsteroidal androgen receptor inhibitor, blocks the androgen-receptor pathway that binds testosterone to cancer cells. The efficacy and safety of apalutamide in addition to androgen-deprivation therapy (ADT) in perioperative setting among patients with potentially invasive localized prostate cancer is currently unknown.

The double-blind, placebo-controlled study randomized 2109 patients in a 1:1 ratio to receive either (1) ADT plus oral apalutamide 240mg daily (n=1057) or (2) ADT plus placebo (n=1052). The treatment regimen consisted of six 28-day cycles of neoadjuvant therapy before surgery and six cycles of adjuvant therapy following radical prostatectomy with pelvic lymph-node dissection. The trial utilized two dual primary efficacy end points: a composite of pathological complete response (pCR) or minimal residual disease (MRD), and metastasis-free survival (MFS) as determined via conventional imaging or PSMA PET. Key secondary outcomes included event-free survival (EFS), time to the first subsequent treatment, and safety, which was assessed through the tracking of adverse events graded by standard criteria.

Over a median follow-up of 61.7 months, the apalutamide group demonstrated significantly superior efficacy outcomes, achieving a pCR or MRD rate of 8.9% compared to 1.0% in the placebo cohort ( $P<0.001$ ). The 5-year MFS rate was also significantly higher with apalutamide at 78.2% versus 73.5% for placebo, representing a 20% reduction in the risk of distant metastasis or death (Hazard Ratio=0.80,  $P=0.02$ ). Secondary end points including EFS and time to subsequent therapy similarly favored the apalutamide arm ( $P<0.001$ ). Regarding safety, Grade 3 or 4 adverse events occurred in 39.6% of patients receiving apalutamide compared to 31.0% receiving placebo, a variance driven primarily by a higher incidence of skin rash in the apalutamide group.

To summarize, the addition of perioperative apalutamide to standard ADT significantly improves long-term oncologic outcomes and disease control for patients undergoing radical prostatectomy for high-risk prostate cancer. Although the treatment is associated with a higher incidence of adverse events, particularly rash, its robust clinical efficacy establishes it as a highly beneficial therapeutic strategy in this patient population.

Source: [www.nejm.org](http://www.nejm.org)

# Optimising Post-Approval Regulatory Change Management for Pharmaceutical Products in Hong Kong - Case Studies from China and the United States

CHAN, Philip Pan\*; KWONG, Rex Lok Fung

Fortune Pharmacal Co. Ltd., Block A & Block B, 50-68 Wang Lok Street, Yuen Long Industrial Estate, Yuen Long, New Territories, Hong Kong SAR, China

(\*Corresponding author)

## ABSTRACT

Post-approval changes are essential to ensuring that pharmaceutical products maintain quality, safety, and supply continuity throughout their lifecycle. Many regulatory authorities have adopted risk-based frameworks that classify changes according to their potential impact and apply proportionate controls. It ranges from prior approval for high-risk changes to notification or annual reporting for low-risk changes. These systems also avoid the routine withdrawal of safe pre-change stock, reducing waste and supporting stable supply chains.

In contrast, Hong Kong's current system requires pre-approval for all changes and mandatory full withdrawal of pre-change stock regardless of risk level, resulting in unnecessary delays, resource strain, and product destruction. This article examines risk-based post-approval change management and stock transition practices in China (NMPA) and the United States (FDA), highlighting their classification systems, timelines, and approaches to stock retention. It then outlines the practical benefits, implementation challenges, and key considerations for Hong Kong. Stakeholder collaboration among regulators, industry pharmacists, and academia is also essential to successful adoption.

**Keywords:** Post-Approval Regulatory Change Process, China's NMPA, US FDA

## INTRODUCTION

Post-drug registration approval change management is an inevitable part of a pharmaceutical product's lifecycle. These changes must be managed effectively to ensure quality, safety, and efficacy while maintaining supply continuity.

The International Council for Harmonisation (ICH) Q12 guideline, "Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management", provides a

framework for managing post-approval changes in a predictable and efficient manner<sup>(1)</sup>. Central to this framework is a risk-based approach that categorises changes according to their potential impact on product quality, safety, and efficacy, with three regulatory pathways: **prior approval**, **notification**, and **recording**. Such risk-based categorisation enables regulatory authorities to apply proportionate controls: low-risk changes face minimal regulatory oversight, while high-impact changes receive focused review.

Major authorities worldwide have adopted frameworks aligned with ICH Q12, using tiered systems to differentiate changes by risk. These include China's National Medical Products Administration (NMPA)<sup>(2)</sup>, the United States Food and Drug Administration (US FDA)<sup>(3)</sup>, the European Medicines Agency (EMA)<sup>(4)</sup>, Health Canada<sup>(5)</sup>, Taiwan FDA<sup>(6)</sup>, Singapore Health Sciences Authority (HSA)<sup>(7)</sup>, and South Korea Ministry of Food and Drug Safety (MFDS)<sup>(8)</sup>. Another common feature across these systems is that pre-change stock withdrawal is required only when changes affect quality, safety, or efficacy, not routinely for all approved changes.

In contrast, Hong Kong's current regulatory framework takes a conservative approach. It requires pre-approval for all changes and mandatory full withdrawal of pre-change stock, regardless of risk level or impact<sup>(9)</sup>.

In addition, locally, the Chief Executive's 2024 Policy Address envisions establishing a "Hong Kong FDA" (which is actually now named the Hong Kong Centre for Medical Products Regulation (CMPR)) to enhance competitiveness and foster the life and health technology industry<sup>(10)</sup>. Adopting a risk-based framework aligned with ICH Q12 would support this vision by aligning Hong Kong with international best practices, improving regulatory efficiency and facilitating potential regulatory collaboration.

This article aims to first examine the current regulatory landscape in Hong Kong. It then explores how two major regulators — China's NMPA and the United States FDA — have

implemented risk-based post-approval change frameworks in line with ICH Q12 principles to inform the development of relevant pathways in Hong Kong. It also discusses the potential benefits and drawbacks of such an approach, explores implementation considerations for Hong Kong, and describes how collaboration among regulators, industry, and pharmacists can support successful adoption.

HONG KONG REGULATORY CONTEXT

In Hong Kong, the regulatory framework governing pharmaceutical product changes is established under the Pharmacy and Poisons Regulations (Cap. 138A), and the relevant legislative provisions are set out in **Table 1** below<sup>(11)</sup>.

| Table 1: Relevant Legislative Provisions in Pharmacy and Poisons Regulations (Cap 138A) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Provision                                                                               | Text                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Cap 138A Part 8<br>Section 36 Paragraph 1B                                              | For the avoidance of any doubt, a pharmaceutical product or substance is registered with the Board, for the purposes of paragraph (1), if and only if its registrable particulars are those which correspond exactly with the registered particulars of a registered product or substance. (L.N. 366 of 1995)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Cap 138A Part 8<br>Section 36A<br>Paragraph 6                                           | Where the change is approved, it shall be approved to take effect from a certain date and the following provisions shall apply—<br>a) as from that date and without limiting the generality of regulation 36(1B), the product or substance having as its registrable particulars the registered particulars which are to be changed (hereinafter referred to as the product or substance to be replaced) shall not be regarded as registered with the Board;<br>b) the applicant shall, prior to that date, recall or cause to be recalled any product or substance to be replaced which may still be in the possession of any person to whom he supplied the product or substance;<br>c) where the product or substance to be replaced is to be recalled, the applicant shall, as soon as reasonably possible, replace or cause to be replaced such product or substance with the product or substance having the particulars changed as approved, or make such alternative arrangements as are agreed with the person to whom he supplied the product or substance. |

According to these regulations, any change to the registered particulars of a pharmaceutical product requires prior approval by the Pharmacy and Poisons Board of Hong Kong (PPBHK) before implementation, irrespective of the nature or impact of the proposed change.

Furthermore, Cap. 138A also mandates that all pre-change stocks must be fully recalled from the market before the effective date of an approved change. This policy applies even to low-risk changes such as non-substantive artwork updates or minor labelling modifications.

While this approach aims to ensure product integrity and patient safety, it results in several drawbacks including:

- 1. Prolonged Approval Timelines:** Even minor changes must navigate the same approval pathway as major changes, causing potential delays in change approval and implementation.
- 2. Inefficient Use of Regulatory Resources:** Limited resources are diverted from high-impact reviews to processing low-risk changes.
- 3. Unnecessary Destruction of Safe Medicines:** Routine mandatory recall of pre-change stock destroys safe, effective products regardless of whether the change affects quality, leading to financial losses for industry and contributing to pharmaceutical waste in landfills.

These drawbacks highlight the gap between Hong Kong’s current practice and the risk-based principles outlined in ICH Q12, which have been adopted by major regulators worldwide. The following sections will examine how two major regulators — China’s NMPA and the US FDA — have implemented these principles in practice.

POST-APPROVAL REGULATORY CHANGES PROCESS IN CHINA

China’s NMPA adopts a risk-based three-tier classification system for post-approval changes, which can streamline regulatory processes while ensuring product quality and safety<sup>(12)</sup>. The three categories are<sup>(2)</sup>:

- 1. Major changes (重大變更):** Require an application with approval before implementation. These apply to significant modifications, such as active ingredient alterations or major process changes, which could critically affect product performance.
- 2. Moderate changes (中等變更):** Require filing for record (notification) before the change implementation to the province level authority. In general, a public announcement for the changes can be found in authority websites within 5 days, indicating the approval of change implementation. Further technical review may be initiated after the public announcement. These typically apply to changes with moderate risk, such as changes to shelf life or tightening of product specifications<sup>(13)</sup>.

- Minor changes (微小變更):** Reported via annual report only, with no prior approval needed. These apply to changes that pose minimal risk and examples are corrections to package insert typographical errors or changes to pack size.

In addition, pre-change stocks do not require recall unless the changes are related to quality, safety, or efficacy defects, a practice that differs from Hong Kong's current approach. Drawing from our direct experience in managing changes

for products registered in China, manufacturing equipment changes that preserve the same working principle, as well as changes to excipients, are typically classified as minor changes and do not necessitate stock withdrawal. Similarly, package insert updates may be classified as minor or moderate depending on the context and likewise do not mandate the withdrawal of pre-change stock. **Table 2** below provides the review timeframe and categorisation of specific change types under the NMPA system<sup>(14)</sup>.

| Table 2: Change Category Example of Post-Approval Regulatory Change Process in China |                                                                                                                              |                                                                                                                                           |                                                                                                                                                                                                                                 |
|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Change Category                                                                      | Major Change                                                                                                                 | Moderate Change                                                                                                                           | Minor Change                                                                                                                                                                                                                    |
| Requirement                                                                          | A supplementary application is required - subject to official approval.                                                      | A filing application is required at the province level. Change can be implemented after public announcement.                              | Only it needs to be recorded in the annual report. No approval is required for implementation.                                                                                                                                  |
| Approval Time                                                                        | 60 –200 days depending on the nature and complexity of the major changes                                                     | Public announcement within 5 days of submission. The authority has up to 30 days to review and may reject the filing if issues are found. | Not applicable                                                                                                                                                                                                                  |
| Package insert or Labelling Change                                                   | Changes to the indication and other content in the package insert that may increase safety risks.                            | In accordance with the requirements of NMPA announcement to revise content uniformly (e.g., adding safety warnings).                      | Adding (removing, changing) non-drug approval documents such as telephone numbers, company websites, electronic supervision codes, barcodes, QR code colors, patterns, and registered trademarks to the instructions or labels. |
| Specification Change                                                                 | Testing method change, relax specification, delete testing item                                                              | Added testing items, tightened limits of specification                                                                                    | Not applicable                                                                                                                                                                                                                  |
| Shelf-life Change                                                                    | Changes in the shelf-life due to changes in the drug's manufacturing process, formulation, quality standards, etc.           | Extend shelf-life based on stability study                                                                                                | Not applicable                                                                                                                                                                                                                  |
| Pack Size change                                                                     | Not applicable                                                                                                               | Multi-dose packaging, such as the number of tablets per bottle                                                                            | Single-dose packaged formulations, such as the number of vials per box of injections                                                                                                                                            |
| Change in Manufacturing Site                                                         | The master formula, production processes, and batch sizes are changed during the transfer from the old site to the new site. | The master formula, production processes, and batch sizes remain consistent between the old and new sites.                                | Not applicable                                                                                                                                                                                                                  |

## POST-APPROVAL REGULATORY CHANGE PROCESS IN THE UNITED STATES

The US FDA employs a similar 3-tier categorisation system for Chemistry, Manufacturing and Controls (CMC) post-approval changes, based on their potential impact on the product's identity, strength, quality, purity, or potency (ISQPP)<sup>(3)</sup>. The three categories are:

- Major changes:** Require a "Prior Approval Supplement" (PAS) that must receive an US FDA approval before distributing any product made with the change, which have substantial potential to adversely affect product quality, safety, or efficacy (such as manufacturing site changes, master formula changes or new container closure systems)
- Moderate changes:** Require a "Changes Being Effectuated" (CBE) supplement. CBE-30 submissions (e.g., certain process optimisations or analytical method changes) can be implemented 30 days after US FDA receipt unless objected to, while lower-risk CBE-0 changes (e.g., some labelling or minor equipment updates) allow immediate implementation upon submission. The change should pose a moderate potential impact on ISQPP of Product
- Minor changes:** Only described in the next annual report, requiring no prior US FDA review or approval, presenting minimal risk to product quality (such as editorial labelling updates or alternative analytical procedures providing equivalent assurance).

Apart from the change system, there is no requirement for a mandatory withdrawal of pre-change stock unless defects are identified. This approach reduces regulatory burden and

facilitates timely product updates, supporting manufacturers' competitiveness and enhancing patient access to improved therapies.

**Table 3 shows some examples of classification system for post-approval changes in USA <sup>(3)</sup>**

|                             | Major Change                                                                                                                                        | Moderate Change                                                                                                                                                                                       |                                                                                                                                                                                                                                          | Minor Change                                                                                                                                                                                    |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Impact on ISQPP of Product? | Substantial Potential                                                                                                                               | Moderate Potential                                                                                                                                                                                    |                                                                                                                                                                                                                                          | Minimal Potential                                                                                                                                                                               |
| Requirement                 | <b>Prior Approval Supplement (PAS):</b><br>Requires submission and approval prior to distribution:                                                  | <b>Change Being Effected in 30 Days (CBE-30):</b><br>Requires submission at least 30 days before distribution                                                                                         | <b>Change Being Effected (CBE-0):</b><br>Distribution can occur when US FDA receives the supplement                                                                                                                                      | Describe minor changes in next Annual Report                                                                                                                                                    |
| Components and Composition  | Qualitative or quantitative formulation, including inactive ingredients                                                                             | N/A                                                                                                                                                                                                   | N/A                                                                                                                                                                                                                                      | Deletion or reduction of an ingredient intended to affect only the colour of the drug product                                                                                                   |
| Labelling                   | Changes based on post marketing study results, including, but not limited to, labelling changes associated with new indications and usage.          | N/A                                                                                                                                                                                                   | Addition of an adverse event due to information reported to the applicant or Agency/ Addition of a precaution arising out of a post marketing study.                                                                                     | Changes in the layout of the package or container label that are consistent with US FDA regulations (e.g., 21 CFR part 201) without a change in the content of the labelling./Editorial changes |
| Specifications              | Relaxing an acceptance criterion/Deleting any part of a specification                                                                               | Relaxing an acceptance criterion or deleting a test to comply with an official compendium that is consistent with US FDA statutory and regulatory requirements                                        | An addition to a specification that provides increased assurance that the drug substance or drug product will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess. | Tightening of acceptance criteria/Any change in a specification made to comply with an official compendium                                                                                      |
| Manufacturing Site          | Move to a new manufacturing site (when the new manufacturing site has never been inspected by US FDA for the type of operation that is being moved) | Move to a different manufacturing site for the primary packaging of (1) any drug product that is not otherwise listed as a major change and (2) modified-release solid oral dosage form drug products | A move to a different manufacturing site for the manufacture or processing of the final intermediate.                                                                                                                                    | Move to a different manufacturing site for secondary packaging/ Labelling                                                                                                                       |

## POTENTIAL BENEFITS OF THE RISK-BASED APPROACH

A risk-based approach to manage post-approval changes application offers several distinct advantages over Hong Kong's current approach.

### Reduced Wastage and Improved Stock Transition

Risk-based pre-change product withdrawal significantly decreases destruction of safe and quality products that remain on the market, thereby reducing environmental impact from waste disposal, supporting stable drug supply chains and minimising economic losses for manufacturers.

### Accelerated Implementation for Low-Risk Changes

Faster handling of low-risk changes enables shorter implementation timelines, delivering more up-to-date products

to patients quickly while enhancing competitiveness for local manufacturers and importers. This is exemplified by NMPA's minor change annual reporting category and US FDA's CBE-0 immediate-effect category, which provide predictable regulatory outcomes and enable manufacturers to plan and respond to market demands efficiently.

### Optimised Resource Allocation

Categorising changes by risk allows regulatory authorities to allocate resources efficiently, enabling them to focus detailed scientific review on major post-approval changes, generic drug applications, and new chemical or biological entity applications that potentially have a higher impact on quality, safety, or efficacy. Moderate and minor changes can follow streamlined notification or annual reporting routes without delaying supply. In this way, resource utilisation and regulatory capacity are optimised.

## IMPLEMENTATION CONSIDERATIONS IN HONG KONG

Adopting a risk-based post-approval change management system in Hong Kong presents several challenges that must be addressed to ensure successful implementation. These include legislative constraints, public confidence, transition management, and digital infrastructure limitations.

### Legislative Constraints

The Pharmacy and Poisons Ordinance currently lack explicit provisions permitting risk-based stock retention for low-risk post-approval changes, creating a major legislative obstacle. Amending the regulations is necessary to permit selective stock transition, for example, retaining pre-change batches when no quality or safety defects are present. This would align Hong Kong with ICH Q12 lifecycle principles and international best practices, while reducing environmental impact and maintaining patient safety.

### Public Confidence and Safety Oversight

A risk-based system depends on companies' internal judgment rather than direct regulatory review. This creates a vulnerability: a high-risk change misclassified as minor may escape proper scrutiny. As a result, problematic products could reach the market before issues are detected. Problems may only emerge later through complaints, adverse events, or inspections, potentially leading to more recalls and greater public health risks. Beyond these safety concerns, public confidence may also suffer if misclassification or quality oversights raise alarm.

To address this, the regulatory authority can issue clear guidelines with concrete examples of risk categories. Hosting industry seminars and webinars would help train stakeholders on risk assessment, fostering transparency and showing that patient safety remains the priority.

### Regional Classification Variation

Although ICH Q12 provides a harmonisation framework, regional differences across regulators remain a practical consideration for Hong Kong. Companies operating in multiple markets may face classification inconsistencies. For instance, a minor change under the NMPA may be considered a moderate change (requiring CBE-30 submission) under the US FDA.

This variation is not a flaw of the risk-based system itself, but it is a reality that Hong Kong regulators should consider when designing classification criteria. Aligning Hong Kong's framework with internationally recognised categories can help reduce submission burdens for companies managing changes across multiple markets.

### Transition Management

Transitioning to a risk-based system demands significant upfront planning for resources, training, and cross-functional change management. Consulting industry associations enables

the development of a practicable timeline. Pilot programmes focused on low-risk changes can be introduced to ensure a smooth rollout without overwhelming operations.

### Digital Infrastructure Limitations

Hong Kong currently uses the Pharmaceuticals Registration System 2.0 (PRS 2.0) for online application submissions. However, the platform is not designed for tiered submissions, posing a technical barrier to adoption. It handles uniform "change of particulars" application but cannot distinguish between different routes. Revamping PRS 2.0 with modular workflows such as instant minor change acknowledgments and dashboards can enable streamlined operations and data integrity.

## COLLABORATION OF STAKEHOLDERS

Successful implementation of a risk-based framework will require active collaboration among regulators, industry, and pharmacists. Each stakeholder group brings unique expertise that can contribute to a well-designed and practical system.

### Technical Contribution

Pharmacists from both industry and academia can contribute to framework design by applying their practical chemistry, manufacturing, and controls (CMC) knowledge and regulatory expertise to define precise risk categories tailored to Hong Kong's pharmaceutical landscape. For instance, they can help establish criteria that distinguish major changes—such as a change in manufacturing sites—from minor ones, like the addition of pack sizes or minor label modifications.

Using tools such as Failure Mode and Effects Analysis (FMEA) helps quantify impacts on product quality and patient safety. This input ensures that categories reflect real-world scenarios, preventing overly conservative classifications that could compromise regulatory efficiency.

### Effective Stock Transition and Communication

Industry pharmacists play a key role in planning and overseeing stock transitions. They can help evaluate whether withdrawal of pre-change inventory is necessary, which is required only when an impact assessment identifies quality or safety defects.

They also coordinate batch disposition decisions, liaise with distributors and customers through clear change notifications, and minimise confusion. Furthermore, the industry can gather and share feedback on post-approval changes, helping regulators build confidence in low-risk stock retention and develop practical stock management guidelines.

### Post-Marketing Surveillance and Continuous Improvement

Pharmacists and industry serve as frontline reporters of adverse events and quality complaints within Hong Kong's pharmacovigilance system. They provide regulators with data to assess whether specific post-approval changes or stock

practices introduce risk. Through annual reports or joint working groups, their feedback enables continuous improvement of the risk-based framework, allowing classifications and stock guidance to be adjusted in response to emerging trends.

## CONCLUSION

Risk-based categorisation of post-approval regulatory changes, combined with pragmatic stock transition rules, offers a clear pathway to reduce product wastage, shorten regulatory timelines, and optimise resource utilisation without compromising product quality, safety, or efficacy. The case studies from China and the United States demonstrate the feasibility and advantages of such systems.

Hong Kong stands to benefit by adapting these principles to its own regulatory environment. This would not only align the territory with international best practices but also enhance its competitiveness and support its ambition to become a regional hub for life and health technologies.

However, successful implementation will require careful planning. Key considerations include addressing legislative constraints, maintaining public confidence, managing the transition effectively, and upgrading digital infrastructure to support tiered submissions.

Most importantly, success will depend on sustained collaboration among regulatory authorities, industry, and the pharmacy profession. By working together, these stakeholders can design and implement an optimised post-approval regulatory change framework that serves both public health and Hong Kong's strategic development goals.

## Acknowledgement

We sincerely thank Cindy Cheung, Regulatory and Medical Affairs Manager at Fortune Pharmacal Co., Ltd., for sharing her detailed insights on the regulatory frameworks of the Hong Kong SAR, China NMPA, and the US FDA.

### Author's background

**CHAN, Philip Pan** is currently the Quality Assurance Manager at Fortune Pharmacal Co. Ltd in Hong Kong. His email address is [philip.chan.pan@fortunepharm.com](mailto:philip.chan.pan@fortunepharm.com)

**KWONG, Rex Lok Fung** is currently the Assistant Quality Assurance Pharmacist at Fortune Pharmacal Co. Ltd in Hong Kong. His email address is [rex.kwong@fortunepharm.com](mailto:rex.kwong@fortunepharm.com)

## References

1. International Council For Harmonisation of Technical Requirements for Pharmaceutical for Human Use. ICH Harmonised Guideline - Technical And Regulatory Considerations for Pharmaceutical Product Lifecycle Management Q12 [Internet]. 2019 Nov 19 [cited 2026 Mar 13]. Available from: <https://www.ich.org/page/quality-guidelines>
2. 中華人民共和國司法部. 药品注册管理办法 [Internet]. 2020 [cited 2026 Mar 27]. Available from: [https://www.moj.gov.cn/pub/sfbgw/flfggz/flfggzbmzg/202101/t20210105\\_146465.html](https://www.moj.gov.cn/pub/sfbgw/flfggz/flfggzbmzg/202101/t20210105_146465.html)
3. U.S. Department of Health and Human Services Food and Drug Administration. Guidance for Industry - Changes to an Approved NDA or ANDA [Internet]. 2004 [cited 2026 Mar 27]. Available from: <https://www.fda.gov/media/71846/download>
4. European Commission. COMMISSION REGULATION (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorizations for medicinal products for human use [Internet]. 2008 [cited 2026 Mar 27]. Available from: <https://eur-lex.europa.eu/eli/reg/2008/1234>
5. Health Canada. Guidance Document: Post-Notice of Compliance (NOC) Changes: Quality Document [Internet]. 2018. [cited 2026 Mar 27]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/post-notice-compliance-changes/quality-document/guidance.html#t2.1>
6. 全國法規資料庫 - 藥品查驗登記審查準則 [Internet]. 2026 [cited 2026 Mar 27]. Available from: <https://law.moj.gov.tw/LawClass/LawAll.aspx?pcode=L0030057>
7. Health Sciences Authority. Overview of variation application types [Internet]. [cited 2026 Mar 27]. Available from: <https://www.hsa.gov.sg/therapeutic-products/variation-application/overview>
8. Ministry of Food and Drug Safety. Guideline on Post Approval Change Management of Pharmaceutical Manufacturing Process [Internet]. 2024 [cited 2026 Mar 27]. Available from: [https://www.mfds.go.kr/eng/brd/m\\_1127/view.do?seq=6&srchFr=&srchTo=&srchWord=&srchTp=&itm\\_seq\\_1=0&itm\\_seq\\_2=0&multi\\_itm\\_seq=0&company\\_cd=&company\\_nm=&page=1](https://www.mfds.go.kr/eng/brd/m_1127/view.do?seq=6&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1)
9. Pharmacy and Poisons Board of Hong Kong. Guidance Notes on Change of Registered Particulars of Registered Pharmaceutical Products/Substances [Internet]. 2025 [cited 2026 Mar 27]. Available from: [https://www.ppbhk.org.hk/eng/doc/guidelines\\_forms/copGuide\\_en.pdf?v=9bpohs](https://www.ppbhk.org.hk/eng/doc/guidelines_forms/copGuide_en.pdf?v=9bpohs)
10. The Chief Executive's 2024 Policy Address [Internet]. 2024 [cited 2026 Mar 27]. Available from: <https://www.policyaddress.gov.hk/2024/en/policy.html>
11. Cap. 138A Pharmacy and Poisons Regulations [Internet]. [cited 2026 Mar 13]. Available from: [https://www.elegislation.gov.hk/hk/cap138A?xid=ID\\_1438402707439\\_002](https://www.elegislation.gov.hk/hk/cap138A?xid=ID_1438402707439_002)
12. National Medical Products Administration. 药品上市后变更管理办法(试行) [Internet]. 2021 [cited 2026 Mar 13]. Available from: <https://www.nmpa.gov.cn/yaopin/ypggtg/20210113142301136.html?type=pc&m=>
13. 广东省药品监督管理局. 广东省药品监督管理局关于印发《广东省药品监督管理局药品上市后变更管理实施细则》的通知 [Internet]. 2023 May 15 [cited 2026 Mar 27]. Available from: [https://mpa.gd.gov.cn/zwgk/gzwj/content/post\\_4180938.html](https://mpa.gd.gov.cn/zwgk/gzwj/content/post_4180938.html)
14. Centre For Drug Evaluation, NMPA. 已上市化学药品药学变更研究技术指导原则(试行) [Internet]. 2021 Feb 10 [cited 2026 Mar 27]. Available from: <https://www.cde.org.cn/main/news/viewInfoCommon/4ec3dca752a82347bdf24ad3d3e85113>

# Anticholinergic Burden in Older Adults

CHAN, Yi-Ming

Department of Pharmacy, Queen Elizabeth Hospital, 30 Gascoigne Road, Kowloon, Hong Kong SAR, China

## ABSTRACT

The use of medications with anticholinergic activity in older adults is not uncommon because of age-related physiological changes and multiple morbidities. Anticholinergic agents bind to muscarinic receptors located in central nervous system and peripheral effector organs, and may cause diversified adverse effects due to their wide distribution in human body. The older population is particularly susceptible to the anticholinergic adverse effects, which may lead to decrement in physical functioning, falls and fractures, acute delirium and chronic cognitive deficits. The cumulative effect of using multiple medications with anticholinergic properties is referred to as “Anticholinergic burden”. It is increasingly being recognised as potentially inappropriate in older adults that warrants medication review. This article discusses the pharmacology of anticholinergic agents and the associated central and peripheral adverse effects, tools to quantify anticholinergic burden and to minimize negative impact of anticholinergic effects in elderly.

**Keywords:** Anticholinergic activity, Anticholinergic burden, Muscarinic receptor antagonists, Anticholinergic drug scales

## INTRODUCTION

Medications with anticholinergic properties have been used for a variety of medical conditions, such as urinary incontinence, sleep disorders, motion sickness, depression and parkinsonism.<sup>(1)</sup> Use of anticholinergic drugs in the older population is not uncommon for symptomatic management of these medical problems that often occur in later life. However, their use has been associated with central adverse effects of cognitive impairment and functional decline, and thus denoted as potentially inappropriate for older adults.<sup>(1,2,3)</sup> Physicians often prescribe medicines based on the anticipated therapeutic benefits, for instance, the use of oxybutynin for urinary incontinence and paroxetine for depression, and might have overlooked the risk of cumulative anticholinergic effects. The cumulative exposure to medicines with anticholinergic properties is referred to as “anticholinergic burden”.<sup>(3)</sup> This article discusses the pharmacology of anticholinergic agents,

methods to quantify the anticholinergic burden and to minimize anticholinergic adverse effects in elderly patients.

## PHARMACOLOGY OF ANTICHOLINERGIC AGENTS

Anticholinergic drugs inhibit acetylcholine-mediated responses by competitively binding cholinergic receptors. There are two main types of cholinergic receptors – nicotinic and muscarinic receptors (Figure 1).<sup>(4)</sup> Nicotinic receptors are ligand-gated ion channels mainly located in skeletal muscles and autonomic ganglia. Muscarinic receptors are G-protein coupled receptors found in the central nervous system and peripheral autonomic effector cells innervated by postganglionic parasympathetic nerves, such as smooth muscles and cardiac muscles.<sup>(4)</sup> Anticholinergic agents predominantly act on muscarinic receptors. Hence, the term “muscarinic receptor antagonist” would better describe the receptors involved and the clinical profile of the medications.<sup>(1,4)</sup>

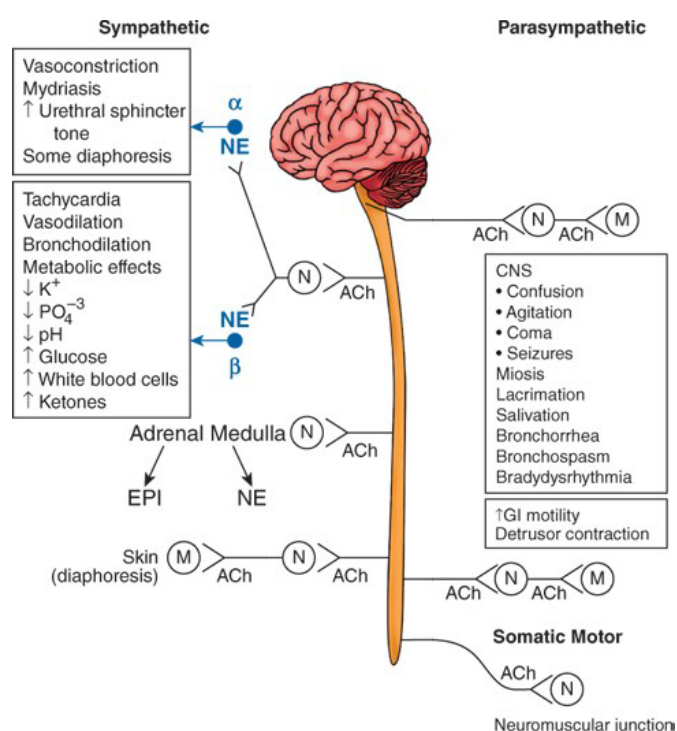


**Figure 1:** Diagram of the cholinergic nervous system. Acetylcholine (ACh) binds to various nicotinic receptors (N) in CNS, in sympathetic and parasympathetic ganglia, and the adrenal glands; also binds to various subtypes of muscarinic (M) receptors in the CNS and on effector organs innervated by postsynaptic parasympathetic neurons and to sweat glands.<sup>(5)</sup>

There are five subtypes of muscarinic receptors, namely M1 to M5. All five subtypes are expressed in human brain, with potential interplay between the excitatory (M1, M3, M5) and inhibitory (M2, M4) receptor subtypes.<sup>(1)</sup> As the predominant subtype involved in higher cognitive processes, the M1 receptor's antagonism leads to impaired memory and learning processes. Muscarinic receptors are also involved in the modulation of neurotransmission: M2 receptors modulate acetylcholine homeostasis by pre-synaptic regulation of acetylcholine release, M4 and M5 receptors alter regulation of other neurotransmitters such as dopamine. In the periphery, expression of muscarinic receptors is organ specific. Some subtypes may co-exist but one dominant subtype mediates the primary physiological response. For instance, M2 in the heart lowers heart rate and slows conduction, whereas M3 in smooth muscles and exocrine glands stimulates muscle contraction and promotes secretion.<sup>(6)</sup> Most anticholinergic medicines are non-selective antimuscarinic agents, which bind all receptor subtypes and inhibit the cholinergic responses involved in the complex mechanisms of neurotransmission, autonomic regulation and cognitive functions.<sup>(1)</sup>

## ANTICHOLINERGIC ADVERSE EFFECTS

Muscarinic receptors are located centrally in human brain and peripherally in effector organs such as the eyes, heart, lungs, gastrointestinal tract, genitourinary tracts and secretory glands.<sup>(4)</sup> The wide distribution leads to diversified clinical presentation of adverse effects. Peripheral side effects include mydriasis and blurred vision, decreased sweating, dry mouth, decreased peristalsis, constipation and increased bladder tone.<sup>(4)</sup> Anticholinergics that cross the blood-brain barrier induce central adverse effects, which could be acute delirium or chronic cognitive deficits. Delirium is frequently identified by disorientation, altered consciousness, disorganized thinking and fluctuating alertness, whereas chronic cognitive deficits can present as cognitive impairment in area of orientation, memory, attention and language, worsening dementia or new diagnosis of dementia.<sup>(2)</sup> Acute cognitive impairment is generally dose-dependent, related to a sudden surge in drug concentration and considered reversible on discontinuation of anticholinergic therapy; chronic cognitive decline is likely driven by duration-dependent, cumulative exposure over years that may induce pathological changes in the brain.<sup>(7,8)</sup> Reduced executive function, altered emotion and behavioral disturbance are also found to be related to central cholinergic inhibition.<sup>(1)</sup>

## SENSITIVITY TO ANTICHOLINERGIC EFFECTS

The chronic negative impact of anticholinergic medicines on cognitive performance in elderly is often unrecognized and easily misinterpreted as a natural consequence of aging.<sup>(1)</sup> In fact, the older population is more susceptible to anticholinergic adverse effects due to declined cholinergic reserve caused by age-related decrease in cholinergic neurons or receptors in the brain, reduction in hepatic metabolism and renal excretion of drugs, and increased permeability of the blood-brain barrier to drugs secondary to epithelial shrinkage and the opening of tight junctions.<sup>(1,2,4)</sup> Apart from normal aging-related physiological

changes, there is inter-individual variability in the susceptibility to central cholinergic blockade. Genetic polymorphism at receptor level, variability in cholinergic reserves and the extent of tolerance which could be developed after cumulative anticholinergic drug exposure are possible factors.<sup>(1)</sup> Evidences suggested that patients with Alzheimer's disease are predisposed to increased vulnerability to central cholinergic antagonism due to impaired cholinergic neurotransmission resulted from neuron degeneration.<sup>(1)</sup> Patients with Alzheimer-type or vascular dementia appear to be more sensitive to central anticholinergic effects than age-matched controls.<sup>(1,9)</sup>

## QUANTIFYING ANTICHOLINERGIC BURDEN

*In vitro* method and anticholinergic drug scales have been published in an attempt to assess the anticholinergic burden, to predict risk for central adverse effect and as a sensible approach to reduce negative cognitive impact of drug therapy in elderly.

Serum anticholinergic activity (SAA) is an *in vitro* measurement of the anticholinergic activity towards the muscarinic receptors of rat forebrain in an individual person's serum.<sup>(1)</sup> It can potentially identify individuals with high anticholinergic load and hence at increased risk of adverse effects. It may also quantify and compare the anticholinergic activity of different drugs in the same therapeutic class, and provide evidences to choose between equally efficacious medications. Nevertheless, SAA is a measure of the peripheral anticholinergic activity in serum and may not reflect the level in the central nervous system. It cannot differentiate anticholinergic activity caused by drugs, endogenous substances or stress responses.<sup>(1)</sup> Furthermore, the complexity of testing procedure with inter-laboratory heterogeneity in assay standard limits the widespread acceptance of SAA as a bioassay for anticholinergic adverse effects.<sup>(1,2)</sup>

Anticholinergic drug scales are expert-opinion derived risk scales developed to quantify the anticholinergic burden. Variations exist between different scales and some of the well-recognized tools from the United States are described as examples in **Table 1**. The Anticholinergic Drug Scale (ADS) is the first scale developed based on expert consensus and available rating of *in vitro* anticholinergic activity of drugs. The Anticholinergic Cognitive Burden Scale (ACB) and Anticholinergic Risk Scale (ARS) are developed based on literature review of the drug's anticholinergic potential.<sup>(1,3)</sup> The ACB assesses the cognitive impact of anticholinergic agents, whereas ARS evaluates the risk of both central and peripheral anticholinergic adverse effects as well as the affinity of the drug to the muscarinic receptors.<sup>(1,3)</sup> These scales rank the anticholinergic activity of medications in an ordinal fashion from 0 to 3, with 0 indicating no known anticholinergic activity and 3 signifying definite / high anticholinergic activity.<sup>(2,3)</sup> Some examples of medication with potential anticholinergic activity are tabulated in **Table 2**. The anticholinergic burden of an individual is determined by summation of each drug's anticholinergic rating, which highlights that attention should be paid to the cumulative anticholinergic effects of all medicines taken by the patient instead of to individual drug score.

**Table 1: Examples of expert opinion-based rating scales**

| Expert opinion-based rating scales | Description                                                                                                                                                                          | Number of anticholinergic medicines listed |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Carnahan et al, 2006 <sup>10</sup> | <b>Anticholinergic Drug Scale</b> is a four-point (0-3) scale that ranks anticholinergic drugs based on expert opinion and serum anticholinergic activity measurements               | 117                                        |
| Rudolph et al, 2008 <sup>11</sup>  | <b>Anticholinergic Risk Scale</b> is a four-point (0-3) scale based on literature review and expert opinion, evaluated on both reported central and peripheral effects               | 49                                         |
| Boustani et al, 2008 <sup>12</sup> | <b>Anticholinergic Cognitive Burden Scale</b> is a four-point (0-3) scale based on published data and expert opinion, prioritizing for central nervous system and cognitive outcomes | 88                                         |

**Table 2: Examples of drugs with potential anticholinergic activity**

| Drug class                   | Medium or high anticholinergic activity *                                                                                              | Low anticholinergic activity#                                                                                                                |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Antidepressants              | Amitriptyline, Amoxapine, Clomipramine, Desipramine, Doxepin, Imipramine, Nortriptyline, Paroxetine, Trimipramine                      | Bupropion, Fluoxetine, Fluvoxamine, Mirtazapine, Sertraline, Trazodone                                                                       |
| Antihistamines               | Brompheniramine, Chlorpheniramine, Cyproheptadine, Dimenhydrinate, Diphenhydramine, Hydroxyzine, Meclizine, Triprolidine, Promethazine | /                                                                                                                                            |
| Drugs for overactive bladder | Darifenacin, Oxybutynin, Tolterodine, Solifenacin, Trospium                                                                            | /                                                                                                                                            |
| Antiparkinson agents         | Amantadine, Benztropine, Trihexyphenidyl                                                                                               | Bromocriptine, Carbidopa/Levodopa, Entacapone, Pramipexole, Selegiline                                                                       |
| Antipsychotics               | Clomipramine, Chlorpromazine, Clozapine, Fluphenazine, Loxapine, Olanzapine, Perphenazine, Pimozide, Quetiapine, Trifluoperazine       | Haloperidol, Risperidone, Ziprasidone                                                                                                        |
| Antiepileptics               | Carbamazepine, Oxcarbazepine                                                                                                           | Valproic acid                                                                                                                                |
| Benzodiazepines              | /                                                                                                                                      | Alprazolam, Chlordiazepoxide, Clonazepam, Clorazepate, Diazepam, Flurazepam, Lorazepam, Midazolam, Oxazepam, Temazepam, Triazolam            |
| Cardiovascular agents        | Disopyramide                                                                                                                           | Atenolol, Captopril, Chlorthalidone, Digoxin, Diltiazem, Furosemide, Hydralazine, Isosorbide, Metoprolol, Nifedipine, Quinidine, Triamterene |
| Gastrointestinal agents      | Atropine, Belladonna, Cimetidine, Dicyclomine, Hyoscyamine, Loperamide, Prochlorperazine, Ranitidine, Scopolamine                      | Famotidine, Metoclopramide                                                                                                                   |
| Muscle relaxants             | Baclofen, Carisoprodol, Cyclobenzaprine, Methocarbamol, Orphenadrine, Tizanidine                                                       | /                                                                                                                                            |
| Opioids                      | Meperidine                                                                                                                             | Codeine, Fentanyl, Morphine, Oxycodone, Tramadol                                                                                             |
| Others                       | /                                                                                                                                      | Colchicine, Dipyridamole, Warfarin                                                                                                           |

Remark: This list is not exhaustive and should be used as a general guide only as there is inconsistency in anticholinergic rankings between sources.

\* Drugs in this column are considered at least score '2' in one or more of the following: ACB, ARS, or ADS, or listed by American Geriatrics Society Beers Criteria as exhibiting strong anticholinergic properties

# Drugs in this column are considered score '1' in one or more of the following: ACB, ARS, or ADS

Modified from Reference<sup>(13)</sup>

Numerous studies have demonstrated correlation between anticholinergic burden and adverse outcomes in physical and cognitive function in older population. Mini-Mental State Examination (MMSE) is a 30-point screening tool used to assess global cognitive function, covering five core domains including orientation, memory, attention and calculation, language and visuospatial abilities.<sup>(14)</sup> Fox et al revealed an association between a total ACB score of 5 or higher with a MMSE score of 0.70 points lower in elderly aged over 65 than those without anticholinergic drug use. The use of definite anticholinergics or a ACB score of 4 or higher was found to have a decline in MMSE score of 0.33 point more than those without anticholinergics over 2 years.<sup>(15)</sup> Although the drop in score was a small incremental loss that might not be clinically meaningful on an individual basis, it was statistically significant at population level, signalling anticholinergic exposure pose a genuine increased risk of accelerated cognitive deterioration. An increase in mortality at the end of the 2-year follow-up period was also observed, suggesting a possible link, although evidence on mortality is limited from other studies.<sup>(15,16)</sup> Central and peripheral anticholinergic effects, in particular sedation, blurred vision and dizziness, can also affect mobility and functioning of elderly, contributing to an increased risk of falls and fractures.<sup>(8)</sup> Landi et al suggested that the use of anticholinergic drugs is associated with impaired physical performance and functional status after adjusting for age and comorbidities.<sup>(17)</sup> The validated anticholinergic drug scales hence provide guidance for which drug to be withdrawn in order to optimize drug therapy for older adults.

Nevertheless, it should be noted that the calculation of anticholinergic burden is based on the assumption that the

anticholinergic activity of different drugs is linear and additive, which is unlikely in reality given that there may be synergistic or antagonistic effect on different muscarinic receptor subtypes or possible development of tolerance to anticholinergic effects.<sup>(1,3)</sup> The number and rating of the anticholinergic agents also vary among different scales, and there is no single “gold standard” to aid in conducting medication review.<sup>(3)</sup>

## REDUCING ANTICHOLINERGIC BURDEN IN ELDERLY

Regular medication review with consideration of anticholinergic burden is important in reducing the risk of anticholinergic adverse effects. The American Geriatrics Society (AGS) Beers Criteria and the Screening Tool of Older Persons’ Prescriptions (STOPP criteria) include explicit list of potentially inappropriate medications to be avoided in older adults aged 65 or above, and identify specific diseases or syndromes that can be exacerbated by these drugs.<sup>(18,19)</sup> **Table 3** summarizes AGS explicit criteria involving medications with anticholinergic activities, the rationale for potential inappropriateness and expert panel recommendation with quality of evidence and strength of recommendation ratings. In particular, the rationale for anticholinergic drugs to avoid has been expanded in 2023 updates to recognize the risks associated with concurrent use, as compared with the 2019 criteria. Conditions that can be exacerbated by drugs with anticholinergic activity, due to drug-disease/syndrome interactions, are shown in **Table 4**. The STOPP criteria is the European counterpart designed to support identification of potentially inappropriate medications in older adults. Similar criteria that pinpoint concerns for drugs with anticholinergic/antimuscarinic effects are included, which are outlined in **Table 5**.

**Table 3: Explicit criteria of drugs with anticholinergic activity, adopted from AGS Beers Criteria 2023<sup>(18)</sup>**

| Organ system, therapeutic category, drug(s)                                                                                                                                                                           | Rationale                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Recommendation | Quality of evidence | Strength of recommendation |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|---------------------|----------------------------|
| <b>Antihistamines</b>                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                |                     |                            |
| <b>First-generation antihistamines</b><br>Brompheniramine<br>Chlorpheniramine<br>Cyproheptadine<br>Dimenhydrinate<br>Diphenhydramine (oral)<br>Doxylamine<br>Hydroxyzine<br>Meclizine<br>Promethazine<br>Triprolidine | Highly anticholinergic; clearance reduced with advanced age, and tolerance develops when used as hypnotic; risk of confusion, dry mouth, constipation, and other anticholinergic effects or toxicity. Cumulative exposure to anticholinergic drugs is associated with an increased risk of falls, delirium, and dementia, even in younger adults.<br><br>Consider total anticholinergic burden during regular medication reviews and be cautious in “young-old” as well as “old-old” adults.<br><br>Use of diphenhydramine in situations such as acute treatment of severe allergic reactions may be appropriate. | Avoid          | Moderate            | Strong                     |

| <b>Central nervous system</b>                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |       |          |        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|----------|--------|
| <b>Antidepressants with strong anticholinergic activity,</b><br>alone or in combination<br>Amitriptyline<br>Amoxapine<br>Clomipramine<br>Desipramine<br>Doxepin >6 mg/day<br>Imipramine<br>Nortriptyline<br>Paroxetine | Highly anticholinergic, sedating, and cause orthostatic hypotension; the safety profile of low-dose doxepin ( $\leq 6$ mg/day) is comparable to that of placebo.                                                                                                                                                                                                                                                                                                                   | Avoid | High     | Strong |
| <b>Antiparkinsonian agents with strong anticholinergic activity</b><br>Benztropine (oral)<br>Trihexyphenidyl                                                                                                           | Not recommended for prevention or treatment of extrapyramidal symptoms due to antipsychotics; more effective agents available for the treatment of Parkinson disease.                                                                                                                                                                                                                                                                                                              | Avoid | Moderate | Strong |
| <b>Gastrointestinal</b>                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |       |          |        |
| <b>GI antispasmodics with strong anticholinergic activity</b><br>Atropine (excludes ophthalmic)<br>Clidinium-chlordiazepoxide<br>Dicyclomine<br>Hyoscyamine<br>Scopolamine                                             | Highly anticholinergic, uncertain effectiveness.                                                                                                                                                                                                                                                                                                                                                                                                                                   | Avoid | Moderate | Strong |
| <b>Pain medications</b>                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |       |          |        |
| <b>Skeletal muscle relaxants</b><br>Carisoprodol<br>Chlorzoxazone<br>Cyclobenzaprine<br>Metaxalone<br>Methocarbamol<br>Orphenadrine                                                                                    | Muscle relaxants typically used to treat musculoskeletal complaints are poorly tolerated by older adults due to anticholinergic adverse effects, sedation, and increased risk of fractures; effectiveness at dosages tolerated by older adults is questionable.<br><br>This criterion does not apply to skeletal muscle relaxants typically used for the management of spasticity (i.e., baclofen and tizanidine) although these drugs can also cause substantial adverse effects. | Avoid | Moderate | Strong |

| <b>Table 4: Diseases and syndromes that can be exacerbated by drugs with anticholinergic activity, adopted from AGS Beers Criteria 2023<sup>(18)</sup></b> |                                                                                |                                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|--------------------------------------------------------|
| <b>Disease or syndrome</b>                                                                                                                                 | <b>Rationale</b>                                                               | <b>Recommendation on anticholinergics</b>              |
| <b>Delirium</b>                                                                                                                                            | Potential of inducing or worsening delirium.                                   | Avoid in older adults with or at high risk of delirium |
| <b>Dementia or cognitive impairment</b>                                                                                                                    | Adverse CNS effects.                                                           | Avoid                                                  |
| <b>History of falls or fractures</b>                                                                                                                       | May cause ataxia, impaired psychomotor function, syncope, or additional falls. | Avoid unless safer alternatives are not available.     |
| <b>Lower urinary tract symptoms, benign prostatic hyperplasia</b><br>(except antimuscarinics for urinary incontinence)                                     | May decrease urinary flow and cause urinary retention                          | Avoid in men                                           |

**Table 5: Selected sections from STOPP criteria version 3, adopted from Reference<sup>(19, 20)</sup>**

| Section                     | STOPP criteria                                                                                                                                                                                                                                                                                                                                                       | Clinical concern                                                                                                                                                                                                                                                           | Alternative management®                                                                                                                                                                                                                                                                                                                         |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Central nervous system      | Anticholinergics/Antimuscarinics (e.g. orphenadrine, trihexyphenidyl) to treat extrapyramidal side effects of antipsychotic medications                                                                                                                                                                                                                              | Risk of anticholinergic toxicity                                                                                                                                                                                                                                           | Decrease antipsychotic dose or discontinue; switch to atypical antipsychotic                                                                                                                                                                                                                                                                    |
|                             | Drugs with potent anticholinergic/antimuscarinic effects in patients with delirium or dementia                                                                                                                                                                                                                                                                       | Risk of exacerbation of cognitive impairment                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                 |
| Gastrointestinal system     | Drugs likely to cause constipation (e.g. systemic antimuscarinics, opioid, oral iron) in patients with chronic constipation where non-constipating alternatives are available                                                                                                                                                                                        | Risk of worsening constipation                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                 |
| Respiratory system          | Long-acting muscarinic antagonists (e.g. tiotropium, aclidinium, umeclidinium, glycopyrronium) in patients with history of narrow angle glaucoma or bladder outflow obstruction                                                                                                                                                                                      | May exacerbate glaucoma or cause urinary retention                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                 |
| Urogenital system           | Antimuscarinic drugs (e.g. oxybutynin, tolterodine, trospium) in patients with: <ul style="list-style-type: none"> <li>dementia or chronic cognitive impairment;</li> <li>narrow angle glaucoma;</li> <li>lower urinary tract symptoms with benign prostatic hyperplasia (BPH) and high post-void residual volume i.e. &gt; 200 ml;</li> <li>constipation</li> </ul> | <ul style="list-style-type: none"> <li>Risk of increased confusion, agitation;</li> <li>Risk of acute exacerbation of glaucoma;</li> <li>Uncertain efficacy and increased risk of urinary retention in older men;</li> <li>risk of exacerbation of constipation</li> </ul> | <u>For urge incontinence:</u> Behavioral therapy e.g. bladder retraining                                                                                                                                                                                                                                                                        |
| Anticholinergic drug burden | Concomitant use of two or more drugs with antimuscarinic/anticholinergic properties (e.g. bladder antispasmodics, intestinal antispasmodics, tricyclic antidepressants, first generation antihistamines, antipsychotics)                                                                                                                                             | Risk of increased antimuscarinic/anticholinergic toxicity                                                                                                                                                                                                                  | <u>Alternative antihistamine:</u> Consider second generation e.g. cetirizine, loratadine but note some degree of anticholinergic activity expected<br><br><u>For sleep:</u> non-drug approach e.g. sleep hygiene<br><br><u>For depression:</u> Avoid paroxetine. Consider Selective Serotonin Reuptake Inhibitor but be cautious for fall risk. |

® Therapeutic alternative adopted from Reference<sup>(21)</sup>

These tools could be applied in clinical practice to identify red flags that might require intervention. Medications listed are best to be avoided if a safer alternative or non-pharmacological approach is available. However, these tools are not meant to supersede clinical judgment or individual's needs (such as in hospice and end-of-life care settings) and preference.<sup>(18)</sup> Medication review to optimize pharmacotherapy should always be individualized. Pharmacists providing geriatric pharmacy service at Queen Elizabeth Hospital often utilize the explicit

criteria to assess appropriateness of medication use. The anticholinergic drug scales provide valuable reference to identify culprit drugs contributing to anticholinergic load. With additional aids of corporate list of Fall Risk Increasing Drugs in Hospital Authority and freely accessible online resources such as the ACB calculator, pharmacists can effectively screen regimens for potential risks, evaluate treatment options and collaborate with clinicians on tailored pharmaceutical care plans.<sup>(22,23)</sup>

## CONCLUSION

The use of anticholinergic drugs is associated with impaired cognitive and physical function in older population, which can be acute or chronic in nature. Individuals who take multiple medications with low anticholinergic activity may also be at increased risk of adverse effects due to the cumulative anticholinergic burden. Regular medication review is recommended for every elderly patient. It could be challenging to balance the therapeutic effects and the adverse effects of anticholinergic medicines. Validated tools, such as the anticholinergic drug scales and criteria for potentially inappropriate medications, are available to provide guidance for assessment and optimization of drug therapy. Careful monitoring of adverse effects and regular review on the need of therapy should be conducted if the use of medicines with anticholinergic properties are deemed necessary.

### Author's background

**CHAN, Yi-Ming** graduated from the School of Pharmacy of the Chinese University of Hong Kong. She is currently a pharmacist at the Queen Elizabeth Hospital. Her corresponding e-mail address is [cym226@ha.org.hk](mailto:cym226@ha.org.hk).

### References

1. Kersten H, Wyller TB. (2014). Anticholinergic drug burden in older people's brain - how well is it measured? *Basic & Clinical Pharmacology & Toxicology*, 114(2):151-9.
2. Campbell N et al. (2009). The cognitive impact of anticholinergics: a clinical review. *Clinical Interventions in Aging*, 4:225-33.
3. Salahudeen MS et al. (2015). Anticholinergic burden quantified by anticholinergic risk scales and adverse outcomes in older people: a systematic review. *BMC Geriatrics*, 25:15:31.
4. Persaud M and Holroyd-Leduc JM. (2014). Anticholinergic medications in the older adult: a hidden burden. *Canadian Geriatrics Society Journal of CME*, Volume 4, Issue 2; 4-7.
5. The Fundamental Principles of Medical Toxicology. In: Goldfrank's Toxicologic Emergencies. 11e, 2019. [Accessed 20th May 2025]
6. Abrams P et al. (2006). Muscarinic receptors: their distribution and function in body systems, and the implications for treating overactive bladder. *British Journal of Pharmacology*, 148(5):565-78.
7. Gray SL et al. (2015). Cumulative Use of Strong Anticholinergics and Incident Dementia: A Prospective Cohort Study. *JAMA Internal Medicine*, 175(3):401-407.
8. BPAC NZ Limited (2024). Anticholinergic burden in older people. Available from: <https://bpac.org.nz/2024/anticholinergic.aspx#5> [Accessed 15th Apr 2025]
9. Coupland CAC et al. (2019). Anticholinergic Drug Exposure and the Risk of Dementia: A Nested Case-Control Study. *JAMA Internal Medicine*, 179(8):1084-1093.
10. Carnahan RM et al. (2006). The Anticholinergic Drug Scale as a measure of drug-related anticholinergic burden: associations with serum anticholinergic activity. *Journal of Clinical Pharmacology*, 46(12):1481-6.
11. Rudolph JL et al. (2008). The anticholinergic risk scale and anticholinergic adverse effects in older persons. *Archives of Internal Medicine*, 168(5):508-13.
12. Boustani M et al. (2008). Impact of anticholinergics on the aging brain: a review and practical application. *Aging Health*, 4(3):311-20.
13. PL Detail-Document. (2011). Drugs with Anticholinergic Activity. *Pharmacist's Letter / Prescriber's Letter*. December 2011.
14. Mendez MF. (2026). Mental status scales to evaluate cognition. UpToDate, DeKosky ST, Wiltedink JL (Ed), Wolters Kluwer. [Accessed 14th Aug 2026].
15. Fox C et al. (2011). Anticholinergic medication use and cognitive impairment in the older population: the medical research council cognitive function and ageing study. *Journal of the American Geriatrics Society*, 59(8):1477-83.
16. Fox C et al. (2014). Effect of medications with anti-cholinergic properties on cognitive function, delirium, physical function and mortality: a systematic review. *Age and Ageing*, 43(5): 604-615.
17. Landi F et al. (2007). Anticholinergic drugs and physical function among frail elderly population. *Clinical Pharmacology and Therapeutics*, 81(2):235-41.
18. The 2023 American Geriatrics Society Beers Criteria Update Expert Panel. (2023). American Geriatrics Society 2023 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *Journal of the American Geriatrics Society*, 71(7):2052-2081.
19. O'Mahony D et al. (2023). STOPP/START criteria for potentially inappropriate prescribing in older people: version 3. *European Geriatric Medicine*, 14:625-632.
20. O'Mahony D et al. (2023). STOPP/START criteria for potentially inappropriate prescribing in older people: version 3. Supplementary data. Available from: [https://static-content.springer.com/esm/art%3A10.1007%2Fs41999-023-00777-y/MediaObjects/41999\\_2023\\_777\\_MOESM1\\_ESM.pdf](https://static-content.springer.com/esm/art%3A10.1007%2Fs41999-023-00777-y/MediaObjects/41999_2023_777_MOESM1_ESM.pdf) [Accessed 15th Apr 2025]
21. PL Detail-Document. (2011). STARTing and STOPping Medications in the Elderly. *Pharmacist's Letter/Prescriber's Letter*. September 2011.
22. Chief Pharmacist's Office, Hospital Authority. (2024) Fall Risk Increasing Drugs (FRIDs) Commonly Prescribed in Hospital Authority. Available from: <http://cpo.home/Doc/Resources/Other%20useful%20information/Fall%20Risk%20Increasing%20Drugs%20Commonly%20Prescribed%20in%20HA.pdf> [Accessed 14th Aug 2026]
23. King R, Rabino S. ACB Calculator. <http://www.acbcalc.com> [Accessed 14th Aug 2026]

# Questions for Pharmacy Continuing Education Program

1. Which of the following terms best describe the pharmacology of anticholinergic drugs?

- a. Nicotinic receptor agonist
- b. Nicotinic receptor antagonist
- c. Muscarinic receptor agonist
- d. Muscarinic receptor antagonist

2. Which of the following statements about muscarinic receptors is true?

- a. Muscarinic receptors are ligand-gated ion channels found in the central nervous system.
- b. Acetylcholine binds to muscarinic receptors in neuromuscular junction to control skeletal muscle contraction.
- c. M1 receptor is involved in higher cognitive processes such as memory and learning.
- d. Only excitatory M1, M3 and M5 receptors are expressed in human brain.

3. Which of the followings is not a peripheral adverse effect of anticholinergics?

- a. Decreased salivation
- b. Miosis
- c. Urinary retention
- d. Constipation

4. Which of the following factors may affect the susceptibility to anticholinergic adverse effects?

- a. Genetic polymorphism at receptor level
- b. Inter-individual variability in cholinergic reserves
- c. Extent of tolerance developed after cumulative exposure
- d. All of the above

5. Which of the following statements is false regarding the susceptibility of elderly to anticholinergic adverse effects?

- a. Reduction in hepatic metabolism and renal excretion may increase drug exposure and adverse effects.
- b. Neuron degeneration impairs cholinergic neurotransmission and increases vulnerability to cognitive side effects.
- c. Opening of tight junctions decreases permeability of the blood-brain barrier and reduces peripheral adverse effects.
- d. Tolerance to adverse effects may develop after cumulative anticholinergic drug exposure.

6. Which of the following is NOT a sign or symptom of cytokine release syndrome?

- a. It is an in vitro measurement of the anticholinergic activity towards the muscarinic receptors of rat forebrain in an individual's serum.
- b. It measures the anticholinergic activity in the central nervous system.
- c. It cannot differentiate anticholinergic activity caused by medicines, endogenous substances or stress responses.
- d. There exists inter-laboratory heterogeneity in assay standard.



2 CE Units  
**Anticholinergic Burden  
in Older Adults**

7. Which of the following statements is true regarding anticholinergic drug scales?

- (i) Drugs with rating "3" is considered exhibiting higher anticholinergic activity than drugs with rating "1" by expert opinion.
- (ii) Anticholinergic burden is determined by summation of each drug's anticholinergic rating.
- (iii) Anticholinergic Drug Scale (ADS) by Carnahan et al has taken into account the in vitro anticholinergic activity of

drugs and serves as the gold standard in calculating anticholinergic burden.

- a. (i) only
- b. (i) and (ii) only
- c. (i) and (iii) only
- d. (i), (ii) and (iii)

8. Cumulative exposure to anticholinergic drugs is associated with:

- (i) increased risk of falls
  - (ii) potential of inducing or worsening delirium
  - (iii) a decline in Mini-Mental State Examination score
- a. (i) only
  - b. (ii) only
  - c. (i) and (ii) only
  - d. (i), (ii) and (iii)

9. Which of the following statements is false?

- a. AGS Beers Criteria and STOPP criteria are explicit criteria which identify potentially inappropriate medications to be avoided in older adults aged 65 or above.
- b. Explicit criteria should be applied to adults 65 years old and older in all ambulatory, acute and institutionalized settings of care including hospice and end-of-life care settings.
- c. Total anticholinergic burden should be considered as concomitant use of drugs with anticholinergic properties increases the risk of anticholinergic toxicity.
- d. Non-pharmacological approach or safer alternatives should be considered to replace highly anticholinergic medicines.

10. Which of the following statements is true when conducting medication review?

- a. Explicit criteria serve as a tool to identify red flags that might require intervention.
- b. Explicit criteria should not supersede clinical judgment or individual's needs and preference.
- c. Anticholinergic burden should be assessed in patients at risk of anticholinergic adverse effects and attempt be made to optimize therapy with less anticholinergic activity.
- d. All of the above

Answers will be released in the next issue of HKPJ.

Answers for CE Questions for HKPJ Vol331(D&T)

Use of Aprocitan and Spironolactone in Resistant Hypertension Management

1. D    2. B    3. B    4. A    5. D    6. D    7. A    8. D    9. B    10. B

# Quality Assurance of Community Pharmacy Services Across Jurisdictions: A Comparative Review of Governance Models and Structural Considerations for Hong Kong

LEE, Marco Tsun<sup>a</sup>; LAW, Kitty Kit Ki<sup>a</sup>; LEE, Tommy Ka Hoa; CHEUNG, Gladys Daphne<sup>a</sup>; LIU, Sharon Yin<sup>a</sup>; CHENG, Franco Wing Tak<sup>a</sup>; WAN, Eric Yuk Fai<sup>a,b</sup>; CHEN, Timothy Frank<sup>c</sup>; WONG, Ian Chi Kei<sup>a\*</sup>

<sup>a</sup> Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Hong Kong SAR, China

<sup>b</sup> Department of Family Medicine and Primary Care, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Hong Kong SAR, China

<sup>c</sup> School of Pharmacy, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia  
(\*Corresponding author)

## ABSTRACT

As community pharmacy practice expands beyond traditional dispensing into preventive care, chronic disease management, screening services, and other pharmaceutical services, quality assurance (QA) systems must evolve to safeguard patient safety, professional accountability, and service effectiveness. This comparative review used a jurisdictional scan to map QA mechanisms for community pharmacy services in Australia, Canada, Macau, Chinese Mainland with Shenzhen as an illustrative example, Singapore, the United Kingdom, and the United States. The analysis compared regulatory foundations, accreditation approaches, inspection and audit practices, and incentive alignment strategies. Across jurisdictions, QA systems ranged from regulator-led compliance models to accreditation-based clinical governance arrangements and incentive-linked quality schemes. Statutory regulation remained the baseline mechanism, while more mature systems incorporated structured quality programmes, incident reporting, external assessment, and accreditation to support continuous quality improvement. The findings suggest that Hong Kong may benefit from a phased QA model that strengthens statutory compliance in the short term, introduces learning-oriented peer review in the medium term, and develops an independent, multi-stakeholder accreditation pathway in the long term as community pharmacy services expand within primary healthcare reform.

**Keywords:** Community pharmacy; Primary healthcare; Quality assurance; Medication safety; Continuous quality improvement; Hong Kong

## INTRODUCTION

**Community pharmacy** has undergone a sustained shift from product supply toward more patient-facing and clinical roles in many health systems. In addition to medication dispensing, pharmacists increasingly provide more clinical services such as medication management services, chronic disease management, minor ailment service and immunisation, in collaboration with doctors and other primary healthcare service providers.<sup>1</sup> As responsibilities broaden, quality assurance (QA) should extend beyond premises and product controls to include service governance, workforce competency, workflow safety, documentation standards, incident reporting and learning systems, and routine monitoring of service performance.

In Hong Kong, primary healthcare reform has explicitly signalled a stronger role for community pharmacies. The Hong Kong Government's Primary Healthcare Blueprint in 2022 recommended enhancing community pharmacy functions, and subsequent policy directions announced the development of a Community Drug Formulary and a Community Pharmacy Programme to support access to affordable primary healthcare medicines through a community network.<sup>2,3</sup> In parallel, the Guidelines of Practice for Community Pharmacy situate standards-setting as an enabling condition for primary healthcare initiatives.<sup>4</sup> These policy directions underscore the importance of considering what form of QA architecture can effectively support service expansion in community pharmacies while maintaining public confidence and operational feasibility. This article aims to map and compare QA mechanisms for community pharmacy services across selected jurisdictions, and synthesise governance design features that may inform Hong Kong as community pharmacy services expand within primary healthcare reform.

METHODS

A comparative review was conducted using a jurisdictional scan to map QA mechanisms for community pharmacy services. The jurisdictions were selected to reflect variation in governance arrangements and in the maturity of community pharmacy service development. The review included Australia, Canada, Macau, Chinese Mainland (with Shenzhen as an illustrative example), Singapore, the United Kingdom, and the United States. For each jurisdiction, the review described the responsible organisations, the baseline requirements for licensing and standards, the mechanisms used for ongoing monitoring and quality improvement, and any incentives or accreditation arrangements linked to quality. Information was drawn primarily from publicly available publications by regulators, government agencies, professional organisations, and accreditation bodies. Expert consultation within the author

group was used to verify interpretations and ensure that the descriptions reflected operational realities. Formal risk-of-bias appraisal and quantitative synthesis were not performed because the purpose of the review was to map governance structures rather than to estimate intervention effects.

RESULTS

Overview of QA governance models across jurisdictions

**Table 1** summarises the key QA mechanisms identified across the selected jurisdictions.<sup>5-23</sup> Overall, the findings show that statutory regulation remains the common foundation of community pharmacy QA, but jurisdictions differ in the extent to which they incorporate accreditation, structured quality programmes, incident reporting, external assessment, and incentive-linked mechanisms.

| Table 1. Comparative Overview of QA Mechanisms for Community Pharmacy Services Across Jurisdictions |                                                                                                   |                                                                                                                               |                                                                                                                                                                                            |                                                                                                  |                                               |
|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-----------------------------------------------|
| Jurisdiction                                                                                        | Primary Regulator(s)                                                                              | Accreditation or Quality Scheme                                                                                               | Ongoing QA Mechanisms                                                                                                                                                                      | Incentive or Participation Linkage                                                               | QA Governance Model                           |
| Australia                                                                                           | Pharmacy Board of Australia; state or territory health authorities; sector-led quality programmes | QCPP, aligned with AS 85000                                                                                                   | External assessment cycle; standards-based documentation review; quality improvement requirements within the programme                                                                     | Quality programme alignment used to support participation expectations under national agreements | Accreditation embedded                        |
| Canada (selected provinces)                                                                         | Provincial pharmacy regulators                                                                    | Mandatory QA components; NAPRA model standards as harmonising reference                                                       | Practice review; self-assessment and reflective learning; competence assessment; continuing professional development portfolios; incident reporting and learning systems in some provinces | Continuing competence requirements linked to licensure maintenance                               | Professional QA embedded                      |
| Macau                                                                                               | Government medicines and pharmacy authority                                                       | No formal service accreditation identified                                                                                    | Regulator-led inspection and compliance oversight                                                                                                                                          | No incentive linkage identified                                                                  | Regulatory compliance                         |
| Chinese Mainland (Shenzhen example)                                                                 | Medical security authority                                                                        | Contract-based performance grading                                                                                            | Data-enabled monitoring; audits; on-site inspection                                                                                                                                        | Contract renewal and administrative consequences linked to performance grading                   | Contractual compliance                        |
| Singapore                                                                                           | Health Sciences Authority; Singapore Pharmacy Council                                             | No national community pharmacy service accreditation identified; SS 644 provides standards for medication supply and delivery | Regulatory audits and inspections; targeted standards for specific contexts including online supply and delivery arrangements                                                              | Limited incentive linkage identified                                                             | Regulatory compliance with targeted standards |
| The United Kingdom (England)                                                                        | General Pharmaceutical Council; NHS England; NHS Business Services Authority                      | PQS                                                                                                                           | CPAF; contractual monitoring; audit and assurance activity                                                                                                                                 | Quality payments linked to achievement of defined PQS criteria                                   | Mixed compliance and incentive                |

|                                                                                                                                                                                                                                                                                                                                          |                          |                                                                             |                                                                                     |                                                                                                                |                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|---------------------------------------|
| The United States                                                                                                                                                                                                                                                                                                                        | State Boards of Pharmacy | NABP Community Pharmacy Accreditation; URAC Pharmacy Services Accreditation | Standards-based documentation review; site assessment; periodic reassessment cycles | Accreditation commonly used to demonstrate eligibility for programme participation or contracting requirements | Independent third-party accreditation |
| <b>Abbreviations:</b> CPAF, Community Pharmacy Assurance Framework; NAPRA, National Association of Pharmacy Regulatory Authorities; NABP, National Association of Boards of Pharmacy; NHS, National Health Service; PQS, Pharmacy Quality Scheme; QCPP, Quality Care Pharmacy Program; URAC, Utilization Review Accreditation Commission |                          |                                                                             |                                                                                     |                                                                                                                |                                       |

### Compliance-based regulatory QA as the baseline model

Compliance-based regulatory oversight remains the foundational layer of community pharmacy quality assurance across the jurisdictions examined in this review. Across jurisdictions, statutory licensing of pharmacy premises and professional registration underpins baseline QA.<sup>1</sup> Such regulation typically sets minimum requirements for premises, storage conditions, staffing, documentation, and professional conduct, and is enforced through inspection and sanctions when needed. In Singapore, the Health Sciences Authority regulates retail pharmacy licensing and conducts product quality surveillance and compliance monitoring across the supply chain, including retailers, to ensure the quality and safety of therapeutic products in the market.<sup>5</sup> Professional governance is further supported through the Singapore Pharmacy Council's pharmacist registration framework, competency standards, and assessment requirements for pharmacy practitioners.<sup>6</sup> Singapore has also strengthened supply-and-delivery safeguards through national standards such as SS 644:2025, which provides requirements for medication supply and delivery arrangements, including collection points and institutional delivery contexts.<sup>7</sup> In Macau, pharmacy governance is predominantly regulator-led, with inspection and enforcement functions embedded within governmental structures overseeing medicine regulation and pharmacy activities.<sup>8</sup> In Chinese Mainland, particularly in Shenzhen, designated retail pharmacies participating in medical insurance are governed through a contractual and supervisory model. National rules specify oversight tools such as on-site inspection, spot checks, and intelligent monitoring, including data analytics, and provide mechanisms for handling non-compliance.<sup>9</sup> Shenzhen additionally operationalises graded performance assessment, explicitly linking assessment outcomes to contract renewal and administrative consequences, thereby strengthening payer-led accountability.<sup>10</sup> These compliance models are effective for establishing minimum safety and legality but may be less equipped on their own to cultivate continuous improvement culture or to standardise complex clinical services that require governance above baseline legal requirements.

### Accreditation and structured quality programmes for expanded services

Several jurisdictions complement statutory regulation with accreditation or structured quality programmes that embed clinical governance requirements into routine practice. In England, the Community Pharmacy Contractual Framework provides a national structure within which a multi-layered

quality assurance mechanism is embedded. The Community Pharmacy Assurance Framework (CPAF) is the primary tool for NHS England to monitor essential and advanced services and contractual compliance, while the Pharmacy Quality Scheme (PQS) is an incentive-based mechanism that rewards pharmacies for achieving higher quality criteria across clinical effectiveness, patient safety, and patient experience dimensions.<sup>11,12</sup> This approach uses incentive alignment to encourage adoption of governance and safety requirements that may exceed minimum legal standards. In Australia, accreditation is a prominent pillar. The Quality Care Pharmacy Program (QCPP) is a national QA programme aligned with the Australian community pharmacy quality standards, including the AS 85000 series, supporting structured governance and regular assessment cycles.<sup>13,14</sup> Quality accreditation is also referenced within national agreements governing community pharmacy programmes and is used to support clinical safety and quality expectations.<sup>15</sup> In Canada, QA is commonly embedded within provincial pharmacy regulators' continuing competence frameworks. Nationwide model standards of practice developed by National Association of Pharmacy Regulatory Authorities (NAPRA) provide a common framework that provinces can adopt or adapt, thereby supporting consistency across jurisdictions.<sup>16</sup> At the provincial level, Ontario's QA programme is directed primarily at pharmacy professionals rather than pharmacy organisations. It includes self-assessment, knowledge assessment, and learning portfolio maintenance and practice assessment. The practice assessment focuses on patient assessment, decision making, documentation, and communication and education. Participation in these components is linked to professional expectations and regulatory oversight.<sup>17,18</sup> This differs from models in jurisdictions such as England and Australia, where QA mechanisms more explicitly incorporate organisational or service-level assessment of community pharmacy practice.

### Incident reporting and continuous quality improvement mechanisms

In Canada, medication incident reporting in community pharmacy has increasingly been embedded within provincial quality improvement programmes and standards. Several provinces require pharmacies to participate in structured reporting systems that contribute anonymised data to Institute for Safe Medication Practices (ISMP) Canada's National Incident Data Repository for Community Pharmacies, thereby supporting shared learning and medication safety improvement at a national level. British Columbia provides one example through Continuous Improvement, Reporting, Collaborating, and Learning (CIRCL), a provincial programme designed to

facilitate incident reporting, shared learning, and continuous quality improvement in pharmacy practice.<sup>19</sup> A consistent feature across these systems is that quality is framed not only as regulatory compliance but as clinical governance. This is supported by standardised processes, defined competency expectations, incident learning, and periodic assessment cycles that embed continuous improvement in routine community pharmacy practice.

### **Independent third-party accreditation and service-specific QA**

Independent, third-party accreditation is a governance approach in which an external accrediting organisation develops service standards, evaluates implementation against those standards, and awards accreditation through periodic external evaluation and reassessment, in accordance with internationally recognised evaluation principles.<sup>20</sup> It is intended to complement statutory regulation by addressing dimensions of service quality that are often under-specified in licensure requirements, including clinical governance arrangements, workforce competency, documentation practices, and Continuous Quality Improvement (CQI) mechanisms. By distinguishing minimum legal compliance from quality development, accreditation can enhance transparency and support a learning-oriented improvement culture while maintaining accountability. An illustrative example is the United States, where state boards of pharmacy regulate practice through licensure and enforcement of state pharmacy law, while independent organisations offer service-specific accreditation programmes.<sup>21-23</sup> Accrediting bodies such as the Utilization Review Accreditation Commission (URAC) and the National Association of Boards of Pharmacy publish standards for programmes including community dispensing, drug therapy management, point-of-care testing, and vaccine administration.<sup>22,23</sup> These programmes commonly apply structured assessment methods that include standards-based documentation review, site assessment, and reassessment cycles.<sup>22</sup> Although accreditation is often voluntary, it is frequently used to demonstrate readiness for programme participation, contracting requirements, or other eligibility criteria, which can strengthen adoption of governance and quality systems in routine practice.

## **DISCUSSION**

### **Principal Findings**

This comparative review identified several key findings. First, statutory regulation, including pharmacy premises licensing, professional registration, inspection, and compliance monitoring, remains the baseline QA mechanism across all jurisdictions reviewed. Second, jurisdictions with more mature community pharmacy service models have introduced additional QA layers, such as accreditation, structured practice review, incident reporting systems, external assessment, and incentive-linked quality schemes. Third, as community pharmacy services expand beyond dispensing into clinical and preventive care, QA systems increasingly need to address service governance, workforce competency, documentation standards, patient safety, and continuous quality improvement.

These findings suggest that Hong Kong's future QA model should not rely solely on regulatory inspection, but should develop progressively towards a layered system that combines compliance, peer learning, and service accreditation.

### **Multi-Stakeholder Accreditation and Functional Differentiation as Governance Architecture**

From a governance perspective, accreditation models are often strengthened when standards development and oversight incorporate multi-stakeholder input. This can be formalised through consortium-style arrangements that include professional, academic, service provider, and health system representatives. This can ensure service standards remain clinically credible, operationally feasible, and responsive to system priorities. Internationally, this principle can be seen in several forms. In the United Kingdom, QA for community pharmacy reflects a distributed governance arrangement involving the regulator [the General Pharmaceutical Council (GPhC)], the commissioners (NHS England and Integrated Care Boards), and Community Pharmacy England (CPE) as the representative body.<sup>24-27</sup> In this model, the GPhC serves as the statutory regulator, establishing the “floor” of minimum safety and legal compliance. Simultaneously, NHS England develops clinical quality mechanisms, while CPE ensures these standards remain operationally realistic and achievable for contractors. In Australia, the community pharmacy quality standard that underpins QCPP accreditation was developed with stakeholder associations and is operationalised through recurring external assessment against a national standard.<sup>13,14</sup> In the United States, independent accreditation programmes provide a further example, with service-specific accreditation standards and advisory structures that incorporate subject matter expertise in standards development and review.<sup>21-23</sup> Such arrangements support timely updating of standards as service models evolve and help translate complex service activities into auditable governance requirements that complement licensure-based oversight.

A further recurring feature across more mature systems is functional differentiation. Statutory regulation establishes minimum safety and legal compliance, while accreditation and continuous quality improvement mechanisms drive quality development beyond baseline requirements.<sup>28</sup> This separation can reduce tension between enforcement and learning functions. Where a single authority is expected to both enforce compliance and lead developmental improvement, psychological safety for reporting and learning may be undermined, particularly for incident reporting systems that depend on trust, standardised feedback loops, and non-punitive learning frameworks. This provides a practical reference point for considering how a future independent, multi-stakeholder accreditation pathway could be developed in Hong Kong as community pharmacy services expand in scope and public relevance.

### **Proposed phased QA pathway for Hong Kong**

Hong Kong's current QA framework for community pharmacies is predominantly regulatory and is anchored in statutory

licensing and inspection requirements, setting the legal basis for pharmacy registration and the control of pharmaceutical products.<sup>29,30</sup> In parallel, primary healthcare reform is expanding expectations for community pharmacy participation in publicly oriented clinical services.<sup>2-4</sup> A key structural consideration is how to strengthen service governance without duplicating regulator functions or creating disproportionate administrative burden for pharmacies at different levels of readiness. A layered model combining statutory regulation, learning-oriented peer review, and progressive accreditation offers a neutral, internationally consistent approach (Figure 1). In this model, regulation continues to safeguard baseline legality and minimum safety requirements. Continuous quality improvement mechanisms support learning from incidents and standardising internal quality systems. Accreditation, potentially administered by an independent multi-stakeholder structure, provides service-specific governance and external validation that can be scaled as services mature. Incentive alignment can then be introduced to accelerate uptake and sustain improvement once standards and reporting maturity are established.

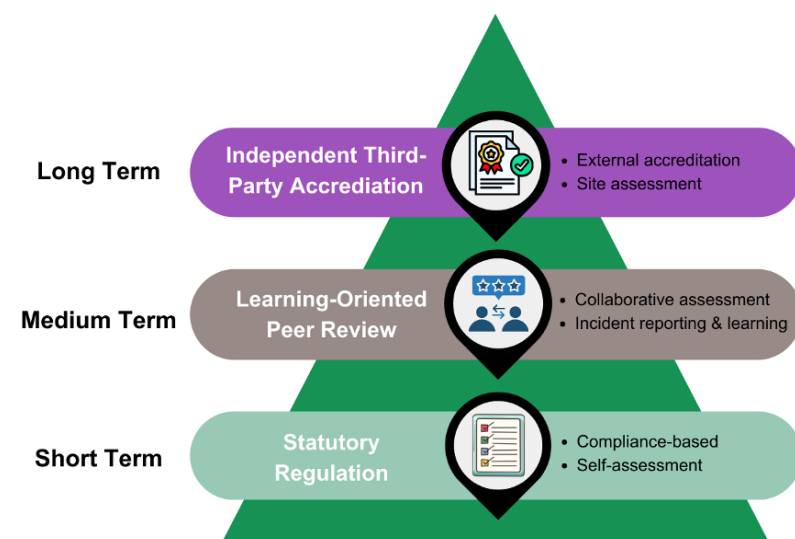


**Figure 1:** Layered governance model to strengthen QA for community pharmacy services in Hong Kong.

In the short term, Hong Kong could prioritise strengthening a consistent compliance baseline and supporting structured self-assessment for service readiness. This can include standardised self-assessment checklists aligned with the Guidelines of Practice for Community Pharmacy and any programme requirements under emerging primary healthcare initiatives, coupled with simple evidence templates and corrective action planning.<sup>4</sup> Such an approach is practical, low-cost, and capacity-building, particularly for pharmacies that are at an early stage of service transformation.

In the medium term, Hong Kong could introduce peer review and collaborative assessment mechanisms to support learning-oriented quality improvement. Peer review models can be designed to provide formative feedback on workflows, documentation quality, incident learning practices, and service governance. Internationally, many continuing competence and practice review frameworks embed reflective learning and

structured feedback as core mechanisms for improvement.<sup>17,18</sup> This phase would also benefit from establishing shared incident reporting norms and feedback loops, which are central to medication safety improvement and continuous quality culture.<sup>19</sup>

In the long term, as community pharmacy services become a durable component of primary healthcare delivery, Hong Kong could consider formalising an accreditation pathway for service governance. International experience suggests that independent or consortium-based accreditation can complement statutory oversight by focusing on service standards, governance, and periodic reassessment, particularly for services such as vaccination and point-of-care testing that require explicit programme controls and documentation expectations.<sup>22</sup> Accreditation could be implemented progressively, beginning with high-impact services and moving toward broader scope as data infrastructure and sector readiness mature. Alignment between accreditation status and participation in publicly funded programmes may then be considered as a policy lever, in keeping with approaches used in other jurisdictions that link quality schemes to programme participation or incentives.<sup>10,12,15</sup>

### Strengths and Limitations

This review has several strengths, including its comparative focus across jurisdictions with different regulatory, accreditation, and incentive-linked QA models, and its direct relevance to Hong Kong's evolving primary healthcare context. However, several limitations should be noted. This was not a systematic review, and the analysis relied mainly on publicly available documents and expert interpretation. The selected jurisdictions may not capture all possible QA approaches, and the review did not quantitatively assess the effectiveness or impact of different QA models on service quality, patient safety, or clinical outcomes.

### CONCLUSION

Across jurisdictions, QA systems for community pharmacy increasingly extend beyond statutory inspection alone. Accreditation frameworks, structured quality programmes, incident learning systems, and incentive-linked quality schemes have emerged as complementary governance mechanisms as pharmacy services expand into broader clinical and preventive roles. In Hong Kong, where primary healthcare reform anticipates greater community pharmacy participation, a phased approach that begins with compliance strengthening and structured self-assessment in the short term, progresses to peer review and collaborative improvement in the medium term, and advances toward service accreditation supported by an independent multi-stakeholder structure in the long term provides a practical pathway to strengthen service quality and public trust and to support sustainable scale-up of community pharmacy services.

### Author's background

**LEE, Marco Tsun** is the Senior Pharmacist at the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. His email is [marcolt@hku.hk](mailto:marcolt@hku.hk)

**LAW, Kitty Kit Ki** is the Pharmacist at the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. Her email is [kittykk@hku.hk](mailto:kittykk@hku.hk)

**LEE, Tommy Ka Ho** is the Pharmacist at the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. His email is [tkhlee@hku.hk](mailto:tkhlee@hku.hk)

**CHEUNG, Gladys Daphne** is the Clinical Assistant Professor at the Department of Medicine, the University of Hong Kong. Her email is [lungyi@hku.hk](mailto:lungyi@hku.hk)

**LIU, Sharon Yin** is the Senior Research Assistant at the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. Her email is [syinliu@hku.hk](mailto:syinliu@hku.hk)

**CHENG, Franco Wing Tak** is the Lecturer at the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. His email is [francowt@hku.hk](mailto:francowt@hku.hk)

**WAN, Eric Yuk Fai** is the Associate Professor at the Department of Family Medicine and Primary Care and the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. His email is [yfwan@hku.hk](mailto:yfwan@hku.hk)

**CHEN, Timothy Frank** is the Professor at School of Pharmacy, Faculty of Medicine and Health, The University of Sydney, Sydney. His email is [timothy.chen@sydney.edu.au](mailto:timothy.chen@sydney.edu.au)

**WONG, Ian Chi Kei** is the Professor at the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. His email is [wongick@hku.hk](mailto:wongick@hku.hk)

### References

1. International Pharmaceutical Federation; World Health Organization. Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: Forty-fifth report. WHO Technical Report Series, No. 961, Annex 8. World Health Organization; 2011. Accessed February 28, 2026.
2. Health Bureau, Government of the Hong Kong Special Administrative Region. Primary Healthcare Blueprint. 2022. Accessed February 28, 2026.
3. Government of the Hong Kong Special Administrative Region. The Chief Executive's 2024 Policy Address. Published 2024. Accessed February 28, 2026.
4. Health Bureau, Government of the Hong Kong Special Administrative Region. Guidelines of practice for community pharmacy. Primary Healthcare Commission; 2025. Accessed February 28, 2026.
5. <https://www.hsa.gov.sg/therapeutic-products/retail-pharmacy-licence/overview>Health Sciences Authority, Singapore. Product quality surveillance for therapeutic products. Accessed February 28, 2026.
6. <https://www.spc.gov.sg/for-professionals/standards-exams/pre-registration-pharmacist-local-training-and-assessment/>Singapore Pharmacy Council. Competency standards and examination/assessment. Accessed February 28, 2026.
7. Singapore Standards Council. SS 644:2025 supply and delivery of medication standard. 2025. Accessed February 28, 2026.
8. Macao Special Administrative Region. Administrative Regulation No. 35/2021: organisation and operation of the pharmaceutical administration authority. 2021. Accessed February 28, 2026.
9. National Healthcare Security Administration, People's Republic of China. Interim measures for designated management of retail pharmacies under medical insurance. 2021. Accessed February 28, 2026.
10. Shenzhen Municipal Medical Security Administration. Performance assessment measures for designated retail medical institutions. 2024. Accessed February 28, 2026.
11. NHS Business Services Authority. Community Pharmacy Assurance Framework (CPAF). NHSBSA. Accessed February 28, 2026.
12. NHS Business Services Authority. Pharmacy Quality Scheme (PQS). NHSBSA. Accessed February 28, 2026.
13. The Pharmacy Guild of Australia. Quality Care Pharmacy Program (QCPP). Accessed February 28, 2026.
14. Standards Australia. AS 85000:2024 community pharmacy quality standard. Standards Australia; 2024.
15. Australian Government Department of Health and Aged Care. Eighth Community Pharmacy Agreement (8CPA). 2024. Accessed February 28, 2026.
16. National Association of Pharmacy Regulatory Authorities. Model standards of practice for pharmacists and pharmacy technicians in Canada. Published February 2022. Accessed February 28, 2026.
17. Ontario College of Pharmacists. Quality assurance program overview. Accessed February 28, 2026.
18. Ontario College of Pharmacists. Community pharmacist practice assessments. Accessed February 28, 2026.
19. <https://www.bcpharmacists.org/CIRCL-program-overview>Institute for Safe Medication Practices Canada. Community pharmacy reporting programs. Accessed February 28, 2026.
20. International Society for Quality in Health Care. ISQua Guidelines and Standards for External Evaluation Organisations. 5th ed. Accessed February 28, 2026. <https://acreditacionensalud.org.co/wp-content/uploads/2020/07/ISQua-Guide-Standards-External-Evaluat-Organis-5th-Ed-v1.0.pdf>
21. National Association of Boards of Pharmacy. Model State Pharmacy Act and Model Rules. Accessed February 28, 2026.
22. Utilization Review Accreditation Commission. Pharmacy services accreditation. Accessed February 28, 2026.
23. National Association of Boards of Pharmacy. Community pharmacy accreditation. Accessed February 28, 2026.
24. General Pharmaceutical Council. About us. Accessed February 28, 2026.
25. Community Pharmacy England. Community Pharmacy Contractual Framework. Accessed February 28, 2026.
26. Community Pharmacy England. Integrated Care Systems. Accessed February 28, 2026.
27. Community Pharmacy England. Pharmacy representation. Accessed February 28, 2026.
28. World Health Organization. Handbook for national quality policy and strategy: a practical approach for developing policy and strategy to improve quality of care. Published 2018. Accessed February 28, 2026.
29. Department of Justice, Hong Kong Special Administrative Region. Pharmacy and Poisons Ordinance (Cap. 138). Hong Kong e-Legislation. Accessed February 28, 2026.
30. Pharmacy and Poisons Board of Hong Kong. Code of Practice for Authorized Sellers of Poisons. Department of Health, Hong Kong Special Administrative Region. Accessed February 28, 2026.

# From Dispensing to Clinical Practice - Navigating the Paradigm Shift in the United Kingdom's Primary Care Pharmacy for Hong Kong's Healthcare Evolution

LEE, Tommy Ka-Ho<sup>a</sup>; LO, Leo Kin-yip<sup>b</sup>; LEE, Marco Tsun<sup>a</sup>; LAW, Kitty Kit-Ki<sup>a</sup>; CHEUNG, Gladys Daphne<sup>a</sup>; WAN, Eric Yuk-Fai<sup>a,c</sup>; PATEL, Nilesh<sup>d</sup>; HUGHES, Carmel<sup>e</sup>; WONG, Ian Chi-Kei<sup>a\*</sup>

<sup>a</sup> Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong, L02-56, 2/F, Laboratory Block, 21 Sassoon Road, Pokfulam, Hong Kong SAR, China

<sup>b</sup> PHARM+ St. James' Settlement Community Pharmacy, St. James' Settlement, 9/F, 383 King's Road, North Point, Hong Kong SAR, China

<sup>c</sup> Department of Family Medicine and Primary Care, Li Ka Shing Faculty of Medicine, The University of Hong Kong, 3/F, Ap Lei Chau Clinic, 161 Main Street, Ap Lei Chau, Hong Kong SAR, China

<sup>d</sup> Institute of Pharmaceutical Science, King's College London, Waterloo Bridge Wing, Franklin Wilkins Building, Stamford Street, SE1 9NH, United Kingdom

<sup>e</sup> School of Pharmacy, Queen's University Belfast, Medical Biology Centre, 97 Lisburn Road, Belfast, BT9 7BL, United Kingdom

(\* Corresponding author)

## ABSTRACT

Hong Kong's primary healthcare system faces mounting pressures from an ageing population and a rising chronic disease burden, necessitating a strategic pivot towards community-based care. Drawing from a three-week fellowship in the United Kingdom (UK) under the Primary Care Pharmacy Fellowship Scheme of the Jockey Club PHARM+ Community Medication Service Network Project — initiated and funded by The Hong Kong Jockey Club Charities Trust — this article examines the mature integration of community pharmacists into the UK National Health Service (NHS).

Observations demonstrate that transforming community pharmacies into effective clinical hubs requires addressing fundamental operational bottlenecks. High-volume technical workloads must be mitigated through enabling infrastructure, such as Original Pack Dispensing and hub-and-spoke systems, to liberate pharmacists for patient-facing care. Furthermore, commissioning structured clinical services such as minor ailment triage and structured medication reviews executed within multidisciplinary teams could substantially enhance patient access and relieve frontline general practice pressures.

While structural reforms require phased, context-specific exploration in Hong Kong, the underlying clinical competencies of the UK model offer an essential roadmap. Adopting collaborative chronic disease management protocols and patient-centered care enables community

pharmacies to transition successfully from traditional dispensaries into vital, sustainable healthcare providers in primary healthcare.

**Keywords:** Primary Healthcare, Community Pharmacy, Chronic Disease Management, Interprofessional Collaboration, Independent Prescribing

## INTRODUCTION

The landscape of primary healthcare in Hong Kong is at a historic crossroads. With the release of the Primary Healthcare Blueprint in 2022, the Hong Kong Special Administrative Region government has signaled a definitive shift towards a “prevention-centric” system, placing community-based care at the heart of the city's health strategy<sup>(1)</sup>. Spearheaded by the rollout of District Health Centres (DHCs) and DHC Expresses (DHCEs) across all 18 districts, this systemic evolution presents an unprecedented opportunity to expand the scope and impact of community pharmacy. Within this ecosystem, community pharmacists are increasingly recognised as accessible, medication-expert professionals poised to expand their clinical footprint in synergy with these strategic initiatives.

## BACKGROUND

As a catalyst of the professional transformation, the Jockey Club PHARM+ Community Medication Service Network Project (the Project) has driven local service innovation<sup>(2)</sup>. To complement this effort and expose Hong Kong pharmacists to advanced international models, The Primary Care Pharmacy Fellowship Scheme under Jockey Club PHARM+ Community

Medication Service Network Project funded by The Hong Kong Jockey Club Charities Trust, was organised by the Department of Pharmacology and Pharmacy at The University of Hong Kong under the Project. The three-week fellowship in the United Kingdom (UK) was conducted in October 2025 in London and Belfast, coordinated by the King's College London and the Queen's University Belfast respectively. The UK fellowship focused on the mature integration of pharmacists into the UK National Health Service (NHS) framework, allowing fellows to immerse themselves in various advanced primary healthcare pharmacy models – from urban general practice to community-based clinical services.

Key highlights included:

- Clinical empowerment and advanced pharmacy practice in different primary healthcare facilities
- Operational efficiency and modern infrastructure of a community pharmacy that streamline high-volume dispensing services
- Professional competency and continuous education

By synthesising these observations, this article aims to provide a translational roadmap for Hong Kong, identifying evidence-based UK practices that can be adapted to maximise the clinical impact and sustainability of the community pharmacy.

## THE NHS PHARMACY FRAMEWORK – A PILLAR OF INTEGRATED CARE

To appreciate the translational potential of the UK model, one must first understand the structural role of community pharmacy within the NHS. Unlike the diversified market-driven retail model often seen in Hong Kong, the UK community pharmacies strive to operate as an integrated, contracted extension of the public healthcare system.

### Professional Governance: A Unified Standard of Safety

The community pharmacy models in England and Northern Ireland operate as public-private partnerships, where pharmacies function as independent contractors commissioned by the administrative regions to deliver essential healthcare. While England's operations are governed by the Community Pharmacy Contractual Framework (CPCF), Northern Ireland follows a distinct commissioning plan negotiated between the Department of Health (Northern Ireland) and Community Pharmacy Northern Ireland (CPNI). Despite the separate administrative tracks, both administrative regions share a unified vision: transforming community pharmacy from a traditional dispensary into an accessible primary healthcare hub that alleviates burdens on healthcare systems.

## Structural Integration: The Contracted Service Model

Community pharmacies are recognised as clinical service hubs rather than mere retail outlets. These contractual frameworks remunerate community pharmacies not only for dispensing services, but also a wide range of advanced clinical services<sup>(3)</sup>. In this system, almost all prescriptions, whether initiated by a general practitioner in a local clinic or subsequently prescribed by a general practitioner via a hospital discharge, are channeled through community pharmacies for dispensing.

This high-volume environment has necessitated a clear operational distinction between technical assembly of medications and face-to-face clinical consultations. While pharmacists are legally and professionally integrated into the patient's care pathway, the system has evolved to support them with robust clinical governance and evolving digital infrastructure such as electronic prescription services and a targeted data-sharing system, though universal access to complete patient health records across different care settings remains a work in progress. This integration serves as a bedrock that allows UK community pharmacies to continuously evolve — a transition that Hong Kong is currently beginning to navigate.

## THE ENABLING FACTORS FOR CLINICAL CARE IN COMMUNITY PHARMACY

The transformation in the UK is underpinned by a robust operational infrastructure. The innovations are the enabling factors that facilitate the strategic utilisation of pharmacists in providing more clinical services at the frontline of the pharmacy counter and in a consultation room (Figure 1). By streamlining and modernising routine dispensing workflows such as through electronic prescription routing and supportive technical staff, the system enables pharmacists to be released from administrative bottlenecks, allowing their specialised clinical expertise to be effectively utilised.

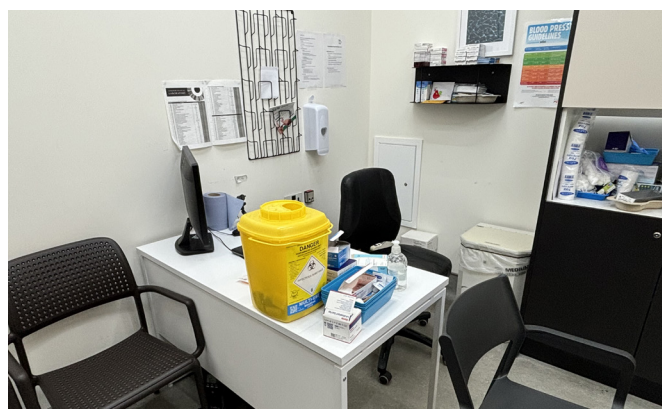


**Figure 1:** Consultation room in a community pharmacy which can support multiple clinical services.

## Original Pack Dispensing

A striking operational difference in the UK is the near universal adoption of Original Pack Dispensing (OPD). Medications are dispensed in manufacturer-sealed, patient-ready packaging, complete with standardised quantities, community pharmacy system-generated medication label, and the original patient information leaflet<sup>(4)</sup>. This practice is supported by UK legal provisions allowing up to a 10% variance from prescribed quantities for most prescription-only medicines. This regulatory flexibility integrates seamlessly with robotic systems and maintains traceability from manufacturer to patient via intact batch numbers and expiry dates.

In Hong Kong, significant pharmacist time is consumed by cutting blister strips and repackaging medications into plastic pouches. Adopting OPD would enhance dispensing efficiency by reducing the ‘technical’ time per prescription, minimising contamination risks, and strengthening medication safety by ensuring patients receive full branding and instructions. More importantly, this operational shift is not merely a matter of convenience; it is a strategic prerequisite. By eliminating the manual burden of pill-counting and repackaging, pharmacists gain the operational capacity required to exercise advanced professional judgement, manage chronic disease pathways, and ensure continuity of patient care. This is a highly viable pathway for Hong Kong pharmacists to dedicate their intensive focus to patient-centered clinical care and chronic disease management.

## Automated Dispensing System

The UK has moved beyond manual labor by leveraging automated dispensing systems to handle high-volume, repetitive dispensing tasks in community pharmacy. In some community pharmacies, automated medication cabinets and robotic dispensing arms are deployed to streamline the assembly of repeat prescriptions. By automating the mechanical sorting, counting, and labeling processes, pharmacies drastically reduce human error associated with repetitive manual tasks and accelerate transaction throughput during peak operational hours.

## Hub and Spoke Model

The dispensing efficiency is further optimised through the Hub and Spoke model, where a centralised “Hub” pharmacy utilises large-scale automation to dispense prescriptions for multiple “Spoke” community pharmacies<sup>(3)</sup>. In this system, the “Hub” pharmacy

handles the technical assembly, labeling, and accuracy checking of medications at scale (Figure 2), while the “Spoke” pharmacy receive these patient-ready orders for final distribution. Where implemented, centralising this technical workload transforms community pharmacies into clinical hubs, liberating pharmacists from the dispensary to focus on patient-facing services. While currently scaling up across major chain stores and progressive networks following recent regulatory expansions, wider adoption across the entire independent sector remains an ongoing transition.



**Figure 2:** A ‘Hub’ community pharmacy integrated with one-stop dispensing system.

## Digital Integration: Electronic Prescription Service

The clinical transformation of pharmacy practice is impossible without a digital infrastructure that ensures data integrity and reduces administrative friction. The UK demonstrates a tiered approach to this evolution, offering two distinct stages of digital maturity.

In Northern Ireland, where paper remains a component of the workflow, risk is mitigated through standardised printed prescriptions, unlike the handwritten prescription or diversified formats often encountered in Hong Kong which are prone to illegibility and transcription errors. A key feature is the integration of unique prescription identifiers and QR codes. By scanning these codes, pharmacy management systems can automatically populate patient profiles and synchronise directly with the robotic dispensing machine, where one is available. This eliminates manual data entry, drastically improving workflow efficiency and ensuring that the technical dispensing process is fueled by accurate, digital data.

England represents the next frontier: the Electronic Prescription Service (EPS)<sup>(6)</sup>. EPS allows prescribers to send prescriptions electronically to a community pharmacy nominated by the patient. This makes the prescribing and dispensing process more efficient and

allows pharmacy to prepare medications in advance of the patient's arrival.

Medication Delivery and 24/7 Automated Collection

As observed in one of the community pharmacies in Belfast, the implementation of external automated collection points of medications represents a significant evolution in pharmaceutical logistics. This automated machine allows patients to conveniently drop off their paper prescriptions and securely collect their dispensed medications via a secure, unique code at their convenience (Figure 3).

Continuous Pharmacy Education (CPE)

Across the UK, professional practice and revalidation are governed by statutory regulators, specifically the General Pharmaceutical Council (GPhC) in Great Britain<sup>(7)</sup> and the Pharmaceutical Society of Northern Ireland (PSNI) for Northern Ireland<sup>(8)</sup>. Table 1 shows the continuing pharmacy education framework of different administrative regions.



Figure 3: Prescription drop-off & collection point is available even when the pharmacy is closed.

| Table 1: Comparison of different CPE models in Great Britain and Northern Ireland. |                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                    | Great Britain                                                                                                                                                                                                                                            | Northern Ireland                                                                                                                                                                                                                                                                                                |
| Regulatory Body                                                                    | GPhC                                                                                                                                                                                                                                                     | PSNI                                                                                                                                                                                                                                                                                                            |
| Framework Type                                                                     | Revalidation model: Focus on continuous learning paired with peer review and portfolio reflection against professional standards                                                                                                                         | Continuing professional development (CPD) framework: Focus on structured learning – reflection, planning, action and evaluation                                                                                                                                                                                 |
| Key Requirement                                                                    | <ul style="list-style-type: none"><li>• four continuing professional development records</li><li>• one peer discussion record</li><li>• one reflective account record, reflecting against any of the nine standards for pharmacy professionals</li></ul> | <p>Submission of annual CDP portfolio:</p> <ul style="list-style-type: none"><li>• Minimum of 30 hours of CPD activity</li><li>• 4 to 10 CPD cycles</li><li>• Minimum 75% of cycles must relate to current scope of practice</li><li>• Minimum of 75% of cycles must be evaluated in current practice</li></ul> |

Translating elements of the UK model to Hong Kong’s evolving continuous pharmacy education system, there are a few key insights:

- Shift from passive attendance to active reflection: Traditional CPE often relies on accumulating lecture credits. Adopting a proactive model that allows structured self-reflection and peer review ensures that education directly translates into safe, quality-assured clinical behaviors rather than just compliance.
- Workplace-based blended learning: In Northern Ireland, the Northern Ireland Centre for Pharmacy Learning & Development, which is a

statutory educational body commissioned by the Department of Health (Northern Ireland) to develop and deliver a range of workforce development programmes and CPD opportunities, has launched an Enhanced Pharmacy Practice Programme. This integrates academic learning with clinical supervision from experienced practitioners to equip prescribing pharmacists with the skills, knowledge, experience and behaviours required for working at pre-advanced level [9]. Hong Kong can model similar mentorship structures to build frontline confidence in managing minor ailments and chronic disease.

## STRATEGIC SYNTHESIS: OPTIMISING COMMUNITY PHARMACY PRACTICE IN HONG KONG

As Hong Kong embarks on the transformative initiative to shift dispensing from hospital into the community<sup>(10)</sup>, the insights gained from the UK practice offer a valuable blueprint for operational excellence and risk mitigation.

### Safety Always Come First

In the UK, the implementation of OPD was driven as much by a commitment to patient safety as by a drive for operational throughput. The traditional practice of manually cutting blister strips and repackaging introduces avoidable latent failures, including human error and potential environmental contamination. OPD is not merely convenient, but it is a foundational clinical governance standard. By institutionalising OPD, technical dispensing risks are significantly mitigated, thereby enabling the pharmacist's final clinical validation to shift its focus from verification of pill counts to a rigorous evaluation of the therapy's clinical appropriateness and patient-centered outcomes.

### Modernisation and Sustainability

The Hub-and-Spoke model emerged in the UK because individual community pharmacies reached a saturation point where they could no longer sustain high-volume dispensing while simultaneously providing quality clinical consultations.

As Hong Kong embarks on the transformative initiative to shift dispensing from hospital into the community, the insights gained from the UK practice offer a valuable blueprint for operational excellence and risk mitigation.

## THE FRONTIERS OF CLINICAL EMPOWERMENT

### Pharmacy First: Collaborative Management of Common Conditions

Pharmacy First is a nationally commissioned NHS clinical service that redefines community pharmacies as the initial point of care for common, low-acuity

conditions<sup>(11)</sup>. In conventional healthcare systems, patients presenting with minor ailments such as acute sinusitis, sore throats, acute otitis media, infected insect bites, impetigo, shingles, or uncomplicated urinary tract infections routinely burden general practitioner surgeries and emergency departments. Figure 4 and figure 5 illustrate the scope of services in England and Northern Ireland respectively. Under the Pharmacy First framework, participating community pharmacists conduct formal clinical assessments, utilise standardised clinical pathways, and supply necessary medications directly via Patient Group Directions.

Crucially, the success of Pharmacy First relies heavily on robust interprofessional collaboration rather than operating in isolation. The service is designed to incorporate structured electronic referral and communication pathways that connect community pharmacists with general practitioners. When a patient presents with “red flag” symptoms or requires escalation beyond the pharmacist's scope of practice, the system enables a direct, secure transfer of clinical notes and patient history back to the primary care team.

In practice, real-world implementation often encounters IT fragmentation. When a patient presents with “red flag” symptoms requiring escalation, pharmacists sometimes navigate these technological gaps using pragmatic workarounds such as secure NHS emails or direct telephone calls to ensure the safe and timely handover of clinical notes. Despite these transitional communication hurdles, this service formally embeds community pharmacy within the primary care referral loop, actively builds interprofessional collaboration, and lays the essential groundwork for a more fully integrated healthcare system.

By empowering community pharmacists to triage, assess, and manage a defined scope of minor conditions — supported by seamless interprofessional collaboration with medical practitioners — the healthcare system can optimise resource utilisation, foster genuine interprofessional teamwork, and establish community pharmacies as integral, accessible frontline triage hubs.



**Figure 4:** Scope of Pharmacy First in England. (Reprinted with permission from Community Pharmacy England)<sup>(11)</sup>



**Figure 5:** Scope of Pharmacy First in Northern Ireland. (Adapted from Health and Social Care Business Services Organisation)<sup>(12)</sup>

## Community Pharmacy Contributions to Public Health

The availability of vaccination services within the UK community pharmacies represents a decade-long strategic expansion of primary care capacity. Nationally commissioned by the NHS as an “Advanced Service” since 2015, the program initially focused on adult influenza vaccinations to relieve winter pressures on general practitioners<sup>(13)</sup>. The pharmacy operational agility was demonstrated during the COVID-19 pandemic, during which over 1,500 community pharmacies were

integrated into the national network, administering more than 22 million doses in a single year.

Building on the success, the clinical scope has expanded beyond seasonal influenza vaccine such as respiratory syncytial virus (RSV) vaccine, and travel health vaccines. This established infrastructure demonstrates how a community pharmacy can be systematically transformed into one of the accessible components of overall preventative healthcare strategy.



**Figure 6:** Consultation room is available in community pharmacy for vaccination service to support public health initiative.

## Advanced Pharmacy Practice

The integration of advanced pharmacy practice including independent prescribing represents a definitive evolution in professional practice within the UK. Prescribing pharmacists are legally authorised to assume full responsibility for clinical assessment, diagnosis, and the formulation of clinical management plans, including the initiation, adjustment, or discontinuation of prescription-only medicines. Historically, independent prescribing was restricted to a post-registration credentialing route, requiring experienced pharmacists to complete additional postgraduate training. However, reflecting a

monumental shift in national healthcare policy, the GPhC implemented structural changes to pharmacy education and pre-registration training standards. Consequently, newly qualified pharmacists joining the register in 2026 automatically qualify as independent prescribers from day one<sup>(14)</sup>.

In England, prescribing pharmacists working in Primary Care Networks and general practice surgeries leverage on their clinical autonomy to conduct structured medication reviews<sup>(15)</sup> (Figure 7). Prescribing pharmacists utilise their clinical autonomy to comprehensively evaluate patients with complex multi-morbidity and polypharmacy, optimising regimens, resolving drug-related problems, and directly addressing medication safety. The primary benefits include significantly enhanced patient access to timely medication management, streamlined chronic disease pathways (e.g. hypertension, diabetes mellitus, and chronic respiratory diseases), and a reduction in general practitioner's overwhelming workloads.

While independent prescribing warrants further exploration in Hong Kong, the underlying clinical competencies of primary care model offer practical lessons. Drawing insights on how UK prescribing pharmacists function within multidisciplinary primary care teams, Hong Kong can investigate and adapt these core competencies such as advanced clinical assessment and structured medication reviews into collaborative chronic disease management frameworks. Pharmacists are well-positioned to be empowered through structured collaborative protocols to monitor chronic diseases, screen for drug-related problems, and provide ongoing medication management in tandem with family doctors. This approach applies advanced clinical skills safely within a shared care team, allowing community pharmacists to become trusted, capable partners who actively help relieve the burden of chronic disease care. Given that community-based clinical frameworks are still evolving locally, foundational infrastructure such as dedicated private consultation spaces, interoperable electronic health record systems and sustainable financial models must be systematically established before these expanded clinical services can be reliably and meaningfully scaled across the sector.



**Figure 7:** General practice setting where clinical pharmacists work alongside general practitioners within primary care clinics.

## CONCLUSION

This article synthesises observations and insights from a three-week Primary Care Pharmacy Fellowship Scheme conducted in London and Belfast in October 2025, coordinated by King's College London and Queen's University Belfast. The fellowship evaluated advanced practice models, operational frameworks, and clinical empowerment strategies across urban and regional healthcare facilities.

The UK model demonstrates that transforming community pharmacies into vital clinical hubs requires both operational enablers and structured clinical services frameworks. By aligning these lessons with local initiatives and government policy, Hong Kong can continuously foster interprofessional teamwork, and build a sustainable, prevention-centric primary care system.

## Acknowledgements

The Hong Kong delegation in the Primary Care Pharmacy Fellowship Scheme extends their sincere gratitude to all who made this transformative journey possible. We are especially thankful to the Hong Kong Jockey Club Charities Trust for their generous funding and strategic guidance in advancing primary care pharmacy through this scheme.

We also wish to express our deep appreciation to the team at King's College London and Queen's University Belfast, whose generous hospitality, expert guidance, and thoughtful coordination created a rich and inspiring learning environment throughout our visit.

### Author's background

**LEE, Tommy Ka-Ho** is the Pharmacist at the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. His email is [tkhlee@hku.hk](mailto:tkhlee@hku.hk)

**LO, Leo Kin-yip** is the Senior Pharmacist of PHARM+ St. James' Settlement Community Pharmacy, St. James' Settlement. His email is [leo.lo@sjs.org.hk](mailto:leo.lo@sjs.org.hk)

**LEE, Marco Tsun** is the Senior Pharmacist at the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. His email is [marcolt@hku.hk](mailto:marcolt@hku.hk)

**LAW, Kitty Kit-Ki** is the Pharmacist at the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. Her email is [kittylkk@hku.hk](mailto:kittylkk@hku.hk)

**CHEUNG, Gladys Daphne** is the Pharmacist at the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. Her email is [gdcheung@hku.hk](mailto:gdcheung@hku.hk)

**WAN, Eric Yuk-Fai** is the Associate Professor at the Department of Family Medicine and Primary Care and the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. His email is [yfwan@hku.hk](mailto:yfwan@hku.hk)

**PATEL, Nilesh** is the Reader in Clinical Pharmacy and Director of Clinical Pharmacy at Institute of Pharmaceutical Science, King's College London. His email is [nilesh.patel@kcl.ac.uk](mailto:nilesh.patel@kcl.ac.uk)

**HUGHES, Carmel** is the Professor of Primary Care Pharmacy at Queen's University Belfast, United Kingdom. Her email is [c.hughes@qub.ac.uk](mailto:c.hughes@qub.ac.uk)

**WONG, Ian Chi-Kei** is the Professor at the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. His email is [wongick@hku.hk](mailto:wongick@hku.hk)

### References

1. Health Bureau, Government of the Hong Kong Special Administrative Region. Primary Healthcare Blueprint Supplement [Internet]. Hong Kong: Health Bureau; 2022 [cited 2026 Jul 21]. Available from: [https://www.primaryhealthcare.gov.hk/bp/cms-assets/Primary\\_Healthcare\\_Blueprint\\_Supplement\\_Perfect\\_Binding\\_Eng\\_291a55714a.pdf](https://www.primaryhealthcare.gov.hk/bp/cms-assets/Primary_Healthcare_Blueprint_Supplement_Perfect_Binding_Eng_291a55714a.pdf)
2. LEE TKH, CHEUNG GD, LAW KK, LEE MT, WONG IC. Introduction to Jockey Club PHARM+ Community Medication Service Network Project. HKPJ. 2024;31(3):68.
3. NHS England. Community pharmacy contractual framework [Internet]. [cited 2026 Jul 21]. Available from: <https://www.england.nhs.uk/primary-care/pharmacy/community-pharmacy-contractual-framework/>
4. Community Pharmacy England. Original pack dispensing [Internet]. [cited 2026 Jul 21]. Available from: <https://cpe.org.uk/dispensing-and-supply/prescription-processing/original-pack-dispensing/>
5. Community Pharmacy England. Hub and spoke dispensing [Internet]. [cited 2026 Jul 21]. Available from: <https://cpe.org.uk/quality-and-regulations/hub-spoke-opd-supervision/hub-spoke/>
6. NHS Digital. Electronic Prescription Service (EPS) [Internet]. [cited 2026 Jul 21]. Available from: <https://digital.nhs.uk/services/electronic-prescription-service>
7. General Pharmaceutical Council. Revalidation renewal [Internet]. [cited 2026 Jul 21]. Available from: <https://www.pharmacyregulation.org/pharmacists/revalidation-renewal>
8. Pharmaceutical Society of Northern Ireland. Continuing Professional Development (CPD) [Internet]. [cited 2026 Jul 24]. Available from: <https://psni.org.uk/cpd/>
9. Northern Ireland Centre for Pharmacy Learning and Development. Enhanced Pharmacy Practice Programme [Internet]. [cited 2026 Jul 21]. Available from: <https://www.nicpld.org/courses/postreg-fp/plans.asp>
10. The Government of the Hong Kong Special Administrative Region. Primary Healthcare Commission announces Community Drug Formulary mechanism and Guidelines of Practice for Community Pharmacy to pave way for launch of Community Pharmacy Programme next year [Internet]. 2025 Oct 30 [cited 2026 Jul 21]. Available from: <https://www.info.gov.hk/gia/general/202510/30/P2025103000223.htm>
11. Community Pharmacy England. Pharmacy First Service [Internet]. [cited 2026 Jul 21]. Available from: <https://cpe.org.uk/national-pharmacy-services/advanced-services/pharmacy-first-service/>
12. Health and Social Care Business Services Organisation. Pharmacy First - Everyday Health Conditions [Internet]. [cited 2026 Jul 21]. Available from: <https://bso.hscni.net/directorates/operations/family-practitioner-services/pharmacy/contractor-information/contractor-communications/hscb-services-and-guidance/pharmacy-first-service/pharmacy-first-everyday-health-conditions/>
13. Community Pharmacy England. NHS flu vaccination service [Internet]. [cited 2026 Jul 21]. Available from: <https://cpe.org.uk/national-pharmacy-services/advanced-services/flu-vaccination-service/>
14. General Pharmaceutical Council. Advice for newly qualified pharmacists [Internet]. [cited 2026 Jul 21]. Available from: [https://assets.pharmacyregulation.org/files/2026-06/Advice-for-newly-qualified-pharmacists-June-2026.pdf?VersionId=fB1eal.LM.W9p\\_Cy5wv4vmgBSfGJirVa](https://assets.pharmacyregulation.org/files/2026-06/Advice-for-newly-qualified-pharmacists-June-2026.pdf?VersionId=fB1eal.LM.W9p_Cy5wv4vmgBSfGJirVa)
15. Royal College of General Practitioners. Policy areas: Pharmacists in Primary Care Networks [Internet]. [cited 2026 Jul 21]. Available from: <https://www.rcgp.org.uk/representing-you/policy-areas/pharmacists>

# Is the Pharmacy Profession Ready for Artificial Intelligence by 2030? – Insights from the Hong Kong Pharmacy Conference 2026 Plenary Session

TONG, Jason<sup>a</sup>; WONG, Vincent<sup>b</sup>; WONG, Johnny<sup>b</sup>; FUNG, Crystal<sup>b</sup>; KWAN, William<sup>c</sup>; HO, Sue<sup>d</sup>; TSE, Hercules<sup>a</sup>; LI, Cherrie<sup>a</sup>

<sup>a</sup> Pharmacists Connect, PO Box no.: 196, Shatin Central Post Office

<sup>b</sup> The Society of Hospital Pharmacists of Hong Kong, 13/F, Kingsfield Centre, 18 Shell Street, North Point, Hong Kong

<sup>c</sup> Scribo Limited, Unit 1017, 10/F, Building 19W, No. 19 Science Park West Avenue, Hong Kong Science Park, Pak Shek Kok, N.T.

<sup>d</sup> Hong Kong Social Enterprise Pharma Shop 33, G/F Mei Lam Commercial Centre, Tai Wai

## ABSTRACT

The Hong Kong Pharmacy Conference 2026 featured a plenary session debate on whether the pharmacy profession in Hong Kong is ready for artificial intelligence (AI) by 2030. The “For” team, comprising Mr. Johnny Wong, Ms. Crystal Fung, and Mr. William Kwan, argued that existing infrastructure, professional evolution, governance frameworks, and empirical evidence position the profession well for AI integration. In contrast, the “Against” team, including Ms. Sue Ho, Mr. Hercules Tse, and Ms. Cherrie Li, contended that regulatory gaps, data security issues, ethical concerns, and immature applications render the profession unprepared. Adjudicated by renowned AI experts Professor Andy Chun and Professor Joshua Ho, the debate highlighted macro-level global regulations, local cybersecurity challenges, AI’s role in clinical workflows, and the need for balanced adoption. This article summarizes the arguments, rebuttals, and implications, emphasizing the tension between technological optimism and cautious realism in Hong Kong’s pharmacy landscape. It underscores the profession’s need for proactive training, policy development, and ethical oversight to harness AI’s potential without compromising patient safety. Ultimately, the discussion aims to foster continuous, evidence-based, and multidisciplinary dialogue among pharmacy professionals, policymakers, and technologists to enable more fruitful collaboration and informed decision-making as the profession advances toward 2030.

**Keywords:** Artificial Intelligence, Pharmacy Practice, Healthcare Governance, Digital Health Readiness, Hong Kong Healthcare, Ethical AI Implementation

## INTRODUCTION

In an era where artificial intelligence (AI) is rapidly transforming healthcare, the pharmacy profession stands at a crossroads.<sup>(1)</sup> The Hong Kong Pharmacy Conference, held on 31 January - 1 February 2026, brought together pharmacists from different sectors to discuss pressing issues in pharmaceutical care. A highlight was the plenary session debate titled “Is the Pharmacy Profession Ready for Artificial Intelligence by 2030?” This topic is particularly pertinent in Hong Kong, where the healthcare system grapples with an aging population, rising chronic disease burdens, and resource constraints.<sup>(2,3)</sup>

The “For” team advocated readiness based on institutional foundations, while the “Against” team highlighted unpreparedness due to risks and gaps. Adjudicators Professor Andy Chun (expert in AI applications) and Professor Joshua Ho (specialist in bioinformatics and health informatics) provided impartial oversight.

This article recaps the debate, elaborating on key arguments to provide a comprehensive overview for Hong Kong pharmacists. By drawing on the speakers’ points, it aims to foster informed dialogue on AI adoption, aligning with the Hong Kong Government’s 2025 Policy Address emphasis on AI as a core industry.<sup>(4)</sup>



Photo 1. Title slide of the debate

## EVENT OVERVIEW

The debate occurred during the conference's plenary session on 1 February, 2026, at the Hong Kong Convention and Exhibition Centre, attended by over 700 pharmacists, healthcare professionals, and stakeholders. Moderated by Mr. Vincent Wong, the format included opening statements, presentations, rebuttals, and a Q&A segment. Each team had 3 minutes per segment to present and counter arguments.

The “For” team consisted of:

- Mr. Johnny Wong, The Society of Hospital Pharmacists of Hong Kong
- Ms. Crystal Fung, The Society of Hospital Pharmacists of Hong Kong
- Mr. William Kwan, Scribo Limited

The “Against” team included:

- Ms. Sue Ho, Hong Kong Social Enterprise Pharma
- Mr. Hercules Tse, Pharmacists Connect
- Ms. Cherrie Li, Pharmacists Connect

The debate was adjudicated by two eminent AI experts: Professor Andy Chun, a renowned AI visionary and Professor of Practice in Digital Innovation and Emerging Technologies at the Hong Kong Polytechnic University, with over 30 years of experience in leading technological advancements across academia, industry, and consulting, including pioneering Hong Kong's first commercial AI system and developing solutions that enhance social services and economic development; and Professor Joshua Ho, Associate Professor at the University of Hong Kong's Li Ka Shing Faculty of Medicine, Assistant Dean for Innovation and Technology Transfer, Co-Director of the Master of Biomedical Innovation, and a specialist in bioinformatics, digital health, and medical AI, with over 155 publications in top journals such as Nature and Genome Biology, backed by extensive research in single-cell analytics and AI applications in medicine. They were invited to evaluate the debate teams based on the strength of evidence, logical coherence, and relevance to Hong Kong's context.



**Photo 2.** Debate panelists engaging in lively discussion during the plenary session at the Hong Kong Pharmacy Conference 2026.

## “FOR” TEAM ARGUMENTS

The “For” team responded with measured optimism, contending that Hong Kong pharmacists can achieve functional AI readiness

by 2030. Their argument unfolded through institutional, professional, regulatory, and empirical perspectives, positioning artificial intelligence not as a disruptive force but as a natural extension of existing healthcare systems.

## Institutional and infrastructure readiness

Mr. Johnny Wong argued that Hong Kong's healthcare infrastructure already provides a robust foundation for AI integration. The Hospital Authority (HA) has established a comprehensive digital ecosystem encompassing the Electronic Health Record Sharing System (eHRSS), Clinical Management System (CMS), Clinical Data Analysis and Reporting System (CDARS).

Pharmacy, inherently data-intensive, stands to benefit directly from these platforms. Applications such as AI-assisted prescription vetting, dosage optimization, drug interaction alerts, and inventory forecasting exemplify “high-value” use cases that supplement the pharmacist's analytical capabilities.<sup>(1)</sup>

He further positioned AI as a workflow amplifier rather than an overhaul mechanism. He provided examples that in medication review, AI can pre-screen for high-risk drug combinations and renal dose adjustments; in patient safety, predictive algorithms can identify error-prone processes; in antimicrobial stewardship, real-time analytics enable timely intervention.<sup>(5)</sup>

Citing the 2025 introduction of the Community Drug Formulary and the 2026 Community Pharmacy Programme (CPP), Johnny described a developing “public-private AI loop” whereby interoperable data, shared via eHRSS, facilitates adherence monitoring and personalized dosing. For him, readiness does not imply perfection but pragmatic functionality—continuous improvement over the remaining four-year horizon to 2030. Hong Kong's unified data environment, underpinned by “1+” drug registration mechanisms and Centre for the Medical Products Regulation (CMPR) oversight, provides fertile ground for scenario-based AI development.

## Complementary roles of pharmacists and AI

Ms. Crystal Fung further elaborated on Johnny's point that AI should not be seen as a replacement for pharmacists but rather as an augmentation of their professional scope. AI excels in pattern detection, computational accuracy, and large-scale data synthesis, whereas pharmacists contribute irreplaceable clinical judgment, contextual reasoning, ethical accountability, and empathetic patient communication. These domains are complementary: AI enhances efficiency and consistency, while pharmacists safeguard patient-centered care through discernment and human oversight.<sup>(6)</sup>

Over the past decade, Hong Kong's pharmacy services have undergone a profound transition from dispensing-oriented operations toward clinical risk management and participation in multidisciplinary care. The profession's focus

has evolved from dispensing speed to patient-centricity of clinical decisions.<sup>(7)</sup> Crystal proposed that this trajectory positions pharmacists to take on pivotal roles in supervising AI applications—auditing training data, validating outputs, and ensuring ethical deployment.

Addressing concerns that AI might erode professional judgment, she argued that such outcomes are failures of governance, not inevitabilities of technology. Pharmacy's well-established institutional safeguards and delineated scopes of accountability can prevent over-standardization and skill atrophy. She cautioned against the "policy fallacy" of assuming readiness requires unanimity: if a risk-conscious profession such as pharmacy cannot safely operationalize AI, then few others can.

### **Governance and risk-oriented culture**

Mr. William Kwan emphasized that AI readiness is defined as much by governance structures and cultural preparedness as by technical capability. Pharmacy's ingrained commitment to risk mitigation, error prevention, and continuous quality improvement through PDCA (Plan–Do–Check–Act) cycles aligns closely with AI's ethical challenges—privacy, bias, transparency, and accountability.

Government support reinforces this alignment. The 2025 Policy Address positioned AI development as a national strategic priority, announcing HK\$10 billion in funding for an AI Research Institute and establishing new policy frameworks under the Digital Policy Office and the Office of the Privacy Commissioner for Personal Data (PCPD).<sup>(4)</sup> William stressed that pharmacists need not master algorithmic coding any more than they must understand molecular synthesis to assess a drug's efficacy. Instead, competency lies in evaluating AI's clinical implications, outcomes, and biases.

He cited a 2025 Productivity Bureau study indicating that 90% of local enterprises had adopted some form of AI, accompanied by a surge in retraining initiatives.<sup>(8)</sup> Drawing on Zhuangzi's reflections on living with continual change, skillfully adapting to particular circumstances, and ensuring that tools remain subordinate to human judgement, he reminded that professional evolution has always accompanied innovation. Continuous professional development (CPD) and cross-disciplinary collaboration, he argued, are sufficient to equip pharmacists with the literacy needed to question, calibrate, and ethically govern AI.

### **Empirical evidence and emerging trends**

William also offered empirical evidence to substantiate AI's value proposition. International and local studies suggest that AI integration reduces hospital dispensing errors by up to 75% and enhances adverse drug reaction detection by 65%.<sup>(9)</sup> Community settings have reported improved medication adherence of approximately 40% and a 55% reduction in missed refills.<sup>(9)</sup> Within the HA, data-driven initiatives via the Laboratory of Data Discovery for Health (D<sup>2</sup>4H)

already support noncommunicable disease surveillance and therapeutic optimization.

Furthermore, cross-border collaborations under the Greater Bay Area framework and harmonized regulatory mechanisms—such as the "1+" strategy and CMPR oversight—accelerate AI validation cycles. Countering critiques of limited clinical evidence, William argued that meaningful proof accumulates incrementally, echoing the early stages of digital health adoption. Hong Kong's unified health record architecture uniquely positions it to generate rapid, high-quality evidence and to assert regional leadership in AI-enabled pharmacy practice.

The "For" team's position was clear: by 2030, Hong Kong's pharmacy profession can achieve operational AI readiness through institutional foundations, complementary human–AI roles, governance maturity, and accumulating empirical support. Readiness, in this framing, is not technological perfection but controlled, evidence-informed progression—using digitized infrastructure as the launchpad for a responsible and adaptive AI-pharmacy ecosystem.

### **"AGAINST" TEAM ARGUMENTS**

The "Against" team opened with a firm stance: By 2030, Hong Kong pharmacists are not ready for comprehensive AI use in workplaces. Ms. Sue Ho set the tone by clarifying that the discussion centered on generative AI, and emphasized the distinction between personal and professional AI application. She began her argument by engaging the audience with an interactive poll, revealing a striking contrast—while personal adoption of AI tools is widespread, workplace integration remains limited, underscoring the readiness gap central to the debate.

### **Global context and ethical framing**

Sue began with a macro-level perspective, observing that global momentum on AI adoption is decelerating amid growing ethical and governance concerns. She cited South Korea's AI Basic Act—enacted in January 2025 and effective from January 2026—as the world's first comprehensive AI legislation.<sup>(10)</sup> The Act mandates labeling of generative AI outputs, explainability requirements for high-risk systems, and user risk notifications. Similarly, the European Union's AI Act introduces stringent oversight of medical AI, reflecting rising apprehension that technological progress outpaces regulatory safeguards.<sup>(11)</sup> These measures, she argued, respond to documented harms such as algorithmic bias and diagnostic errors disproportionately affecting underrepresented groups.

In contrast, Hong Kong currently lacks comparable legal or ethical frameworks.<sup>(12)</sup> This absence, Sue contended, reflects systemic unpreparedness rather than innovation restraint. The current global "pause" represents a measured response to ethical imperatives—particularly the potential for AI systems trained on biased data to exacerbate health inequities. For pharmacists, this risk extends beyond fairness to the integrity

of clinical decisions; without appropriate safeguards, AI could inadvertently prioritize cost efficiency over patient-centered care, especially within Hong Kong's resource-limited public healthcare setting.

### Local readiness and cybersecurity risks

Turning to local challenges, Sue identified cybersecurity vulnerabilities as a fundamental barrier. Government data from 2025 reported 15,877 network security incidents, a 27% year-on-year increase, with phishing attacks comprising 57% of cases<sup>(13)</sup>. Vulnerable systems expanded by over threefold. Against this backdrop, delegating sensitive patient data, prescriptions, and clinical records to AI-driven cloud platforms would be, she argued, premature and potentially hazardous. The reliance of most AI models on cloud-based infrastructures also amplifies data breach risks, especially amid regional geopolitical uncertainties. For healthcare institutions, such lapses could invite Health Insurance Portability and Accountability Act (HIPAA)-equivalent violations, undermining both patient trust and institutional credibility. Sue further elaborated that these are not merely technical flaws but symptoms of structural fragility that currently render widespread AI adoption unsafe.

#### Practical and regulatory limitations

At the operational level, Sue questioned AI's immediate applicability across pharmacy sectors—whether community, hospital, or industrial. Hong Kong's limited innovation ecosystem, small market scale, and short-term funding culture constrain the development of locally tailored AI solutions, often making manual workflows more economical and contextually appropriate. Historical precedents of failed health technology implementations demonstrate how hype can eclipse efficacy, particularly where local linguistic and cultural diversity complicates algorithmic interpretation.

Even beyond technical readiness, Sue highlighted unresolved legal and governance gaps. AI systems influencing clinical decisions may qualify as medical devices, requiring formal validation and post-market surveillance. Yet Hong Kong lacks a distinct regulatory framework to define these responsibilities, exposing practitioners to legal ambiguity. Cases overseas illustrate the potential for liability disputes following AI-enabled errors, a deterrent in risk-averse professions such as pharmacy.

### Infrastructure and sustainability concerns

Sue also drew attention to logistical constraints often overlooked in policy discussions. Privacy-preserving AI usually necessitates on-premise data hosting, which demands costly hardware investments, high energy consumption, and advanced processing units—resources already strained by global semiconductor supply chain disruptions.

### Ethical and professional implications

Mr. Hercules Tse reinforced these arguments with a technical perspective. Citing the World Health Organization's 2024 Guidance on Ethics and Governance of Artificial Intelligence for Health, he underscored that “a model is only as robust as the data that train it.”<sup>(14)</sup> Systemic underrepresentation of vulnerable populations amplifies bias, which is more difficult to detect and correct in AI systems than in conventional clinical processes. Within pharmacy practice, such bias could manifest in drug interaction alerts or dosing recommendations that fail to account for local population diversities.

He further referenced a 2026 Stanford–Microsoft study evaluating large language models (LLMs) across medical tasks: while LLMs demonstrated strong reasoning capabilities, they exhibited inconsistent performance across clinical contexts, struggled with quantitative tasks, and incurred prohibitive computational costs.<sup>(15)</sup> Invoking the “no free lunch theorem,” Hercules argued that no single model can perform optimally across all domains; rigorous local validation in Hong Kong's linguistic and clinical settings remains essential.

### Reframing AI readiness

Ms. Cherrie Li concluded the argument by clarifying that skepticism toward immediate AI adoption does not equate to opposition to innovation. Instead, she urged reframing the discourse from “Can we use AI?” to “How can we use AI safely and responsibly?”. She highlighted persistent vulnerabilities including data leakage from unauthorized uploads and reactive cybersecurity practices—evidenced by the rise in data loss prevention (DLP) system adoption from 31% to 54% within a year. The WHO continues to stress that legal and governance infrastructure must precede large-scale implementation.<sup>(16)</sup> To that end, Cherrie called for design thinking approaches, institutional training, and interdisciplinary collaboration to build competency before deployment.

The “Against” team thus presented a tempered, evidence-based argument: familiarity with AI in daily life does not imply institutional readiness for its clinical and operational integration. Without mature governance, secure infrastructure, and ethical frameworks, the profession risks adopting technology faster than it can manage its consequences. As of now, AI in pharmacy should evolve through structured adaptation rather than premature integration.

### ADJUDICATORS' COMMENTS

Following the presentations and rebuttals, adjudicators offered insightful commentary, blending agreement with forward-looking perspectives. They emphasized the imperative for proactive change, noting that maintaining the status quo would result in stagnation: “If we adhere to the status quo, nothing will

fundamentally change in the pharmacy profession's approach to AI integration." They concurred with elements of the "Against" team's arguments, particularly Sue's observations on Hong Kong's relatively small market size. Professor Chun highlighted that AI models must be economically viable and cost-effective to achieve widespread adoption. They further elaborated that public and private sector models may diverge significantly due to differing patient demographics—public systems often serve a broader, more diverse population with varying socioeconomic backgrounds, while private models might cater to more affluent or specialized groups, necessitating tailored approaches to ensure equity and efficacy.

The adjudicators also pointed to regional advantages that could accelerate progress. They noted China's robust ecosystem of open-source AI resources, which substantially lowers barriers to development by providing accessible tools, frameworks, and datasets for customization in healthcare applications. This proximity to mainland innovations positions Hong Kong favorably for collaborative advancements. Moreover, Professor Ho praised the advanced state of AI research in Hong Kong's universities, describing the region as "a fortunate hub" where five out of its eight universities funded by the University Grants Committee rank among the global top 50 in AI research output and impact, according to recent international benchmarks. This academic strength, they argued, could drive localized AI solutions for pharmacy, fostering interdisciplinary partnerships between academia, industry, and healthcare providers to bridge current gaps.

Their comments underscored a balanced view: While acknowledging risks and market constraints, they advocated leveraging Hong Kong's academic prowess and regional ties to propel the profession toward readiness by 2030, provided there is concerted effort beyond complacency.



**Photo 3.** Adjudicators Professor Andy Chun and Professor Joshua Ho providing feedback on AI governance.

## DISCUSSION

The debate illuminated a nuanced divide. The "Against" team's caution resonates amid global AI slowdowns and local cybersecurity woes, where risks like biases and breaches could undermine trust. Their emphasis on ethical guidelines and studies underscores that AI's "black box" and data dependencies demand scrutiny, especially in Hong Kong's

diverse population, which varies in age, ethnicity, language, socioeconomic circumstances, and levels of health and digital literacy. Furthermore, biases in AI could disproportionately affect ethnic minorities or elderly patients, common in pharmacy consultations, potentially widening health disparities. Labor fears are valid; while laws mandate pharmacists, AI might reduce entry-level roles, necessitating upskilling.

Conversely, the "For" team's optimism leverages Hong Kong's strengths: HA's digitization and policies like community pharmacy program could create data-rich environments for AI. Their "co-pilot" metaphor aligns with pharmacy's evolution, where AI augments clinical judgment. Empirical data from pilots suggests tangible benefits, like error reduction, crucial in high-volume settings. Rebuttals effectively frame risks as manageable via governance, not barriers.

The adjudicators' insights add depth, reinforcing that economic viability and demographic considerations are pivotal. By highlighting open-source resources from China and Hong Kong's top-tier AI research universities, they suggest pathways for overcoming market limitations—such as through cost-shared academic-industry collaborations or adapting open-source models to local needs. This could differentiate public models of focusing on scalability for mass populations from private ones of emphasizing personalization for niche demographics, ensuring AI's cost-effectiveness. Their call against status quo inertia aligns with the debate's overarching theme: From Insight to Impact.

Implications include urgent needs for AI-specific CPD, regulatory clarity (e.g., adapting Medical Device Ordinance), and small-scale pilots. Multistakeholder collaboration—government, HA, pharmaceutical societies, and universities—could bridge divides, ensuring AI enhances pharmaceutical care equitably. For instance, leveraging the top-ranked universities' expertise could lead to bespoke AI tools for Cantonese-language processing or region-specific drug interaction databases, addressing multilingual challenges raised by the "Against" team.

## CONCLUSION

The 2026 debate underscores that AI readiness is multifaceted, balancing innovation with safeguards. It highlights that realizing AI's benefits in pharmacy will depend as much on governance, ethics, and workforce capability as on technology itself. While challenges persist, Hong Kong's infrastructure, professional ethos, and academic strengths—bolstered by regional open-source access—position it favorably by 2030. Pharmacists must engage proactively: advocate for policies, pursue training, and pilot AI ethically, with clear human oversight and accountability. Building on the momentum of this plenary, the profession should actively foster continuous, evidence-based, and multidisciplinary dialogue among practitioners, policymakers, educators, patients, and technologists, so that AI adoption in Hong Kong pharmacy is not only innovative and efficient but also trustworthy, equitable, and sustainable.



**Photo 4.** Organizing Committee of HKPC2026

## Acknowledgment

Thanks to the Hong Kong Pharmacy Conference organizers, adjudicators and panelists for facilitating this vital discussion.

## Disclaimer

The views and opinions expressed in this article are those of the individual speakers and do not necessarily reflect the official positions, policies, or perspectives of their respective work organizations, institutions, or affiliated bodies.

### Author's background

**TONG Jason** is the President and co-founder of Pharmacists Connect. For enquiries, please contact him through the email address: [contact.pharmacistsconnect@gmail.com](mailto:contact.pharmacistsconnect@gmail.com)

**WONG Vincent** is a member at The Society of Hospital Pharmacists of Hong Kong. For enquiries, please contact him through the email address: [info@shphk.org.hk](mailto:info@shphk.org.hk)

**WONG Johnny** is the Vice President at The Society of Hospital Pharmacists of Hong Kong. For enquiries, please contact him through the email address: [info@shphk.org.hk](mailto:info@shphk.org.hk)

**FUNG Crystal** is a general committee member at The Society of Hospital Pharmacists of Hong Kong. For enquiries, please contact her through the email address: [info@shphk.org.hk](mailto:info@shphk.org.hk)

**KWAN William** is the technical director of Scribo Limited. For enquiries, please contact him through the email address: [kwanhimshek@gmail.com](mailto:kwanhimshek@gmail.com)

**HO Sue** is the cofounder of Hong Kong Social Enterprise Pharma. For enquiries, please contact her through the email address: [susan.ho@hksep.org](mailto:susan.ho@hksep.org)

**TSE Hercules** is a committee member of Pharmacists Connect. For enquiries, please contact him through the email address: [contact.pharmacistsconnect@gmail.com](mailto:contact.pharmacistsconnect@gmail.com)

**LI Cherrie** is a member of Pharmacists Connect. For enquiries, please contact her through the email address: [contact.pharmacistsconnect@gmail.com](mailto:contact.pharmacistsconnect@gmail.com)

## References

- Chalasani SH, Syed J, Ramesh M, Patil V, Pramod Kumar TM. Artificial intelligence in the field of pharmacy practice: A literature review. *Explor Res Clin Soc Pharm*. 2023 Oct 21;12:100346. doi: 10.1016/j.rcsop.2023.100346.
- Chen C. Analysis on Hong Kong's current medical service under the aging population. *Open J Soc Sci*. 2017;5(4):294-302.

- Hospital Authority. Strategic Service Framework for Chronic Disease Management. Hong Kong; 2024.
- The Government of the Hong Kong Special Administrative Region. The 2025 Policy Address. Hong Kong; 2025.
- De Micco F, Di Palma G, Ferorelli D, et al. Artificial intelligence in healthcare: transforming patient safety with intelligent systems—A systematic review. *Front Med (Lausanne)*. 2025;12:1537648.
- Bu F, Sun H, Li L, Tang F, Zhang X, Yan J, et al. Artificial intelligence-based internet hospital pharmacy services in China: Perspective based on a case study. *Front Pharmacol*. 2022;13:1049583.
- Lee CP. Health care system and pharmacy practice in Hong Kong. *Can J Hosp Pharm*. 2018;71(2):140-148
- Hong Kong Productivity Council. HKPC announces "AI Readiness in the Workplace Survey 2025" results: over 80% of enterprises ready to adopt AI, while "data privacy" and "technical expertise" remain key challenges [Internet]. Hong Kong: HKPC; 2025 Feb 11 [cited 2026 Apr 8]. Available from: <https://www.hkpc.org/en/about-us/media-centre/press-releases/2025/ai-readiness-in-workplace-survey-2025>
- Simpson MD, Qasim HS. Clinical and operational applications of artificial intelligence and machine learning in pharmacy: a narrative review of real-world applications. *Pharmacy (Basel)*. 2025 Mar 7;13(2):41. doi:10.3390/pharmacy13020041.
- National Artificial Intelligence Committee. AI Basic Act [Internet]. Seoul: Ministry of Science and ICT; [cited 2026 Apr 8]. Available from: <https://aibasicact.kr/>
- European Commission. Artificial intelligence in healthcare [Internet]. Brussels: European Commission; [updated 2024; cited 2026 Apr 8]. Available from: [https://health.ec.europa.eu/ehealth-digital-health-and-care/artificial-intelligence-healthcare\\_en](https://health.ec.europa.eu/ehealth-digital-health-and-care/artificial-intelligence-healthcare_en)
- White & Case. AI watch: global regulatory tracker - Hong Kong [Internet]. New York: White & Case LLP; 2024 [updated 2024 Nov 12; cited 2026 Apr 8]. Available from: <https://www.whitecase.com/insight-our-thinking/ai-watch-global-regulatory-tracker-hong-kong>
- Hong Kong Computer Emergency Response Team Coordination Centre. HKCERT releases Hong Kong cybersecurity outlook 2026: security incidents hit record high with 27% annual increase; AI-related attacks and supply chain risks emerge as top concerns [Internet]. Hong Kong: HKCERT; 2026 Feb 10 [cited 2026 Apr 8]. Available from: <https://www.hkcert.org/press-centre/hkcert-releases-hong-kong-cybersecurity-outlook-2026-security-incidents-hit-record-high-with-27-annual-increase-ai-related-attacks-and-supply-chain-risks-emerge-as-top-concerns-nearly-30-of-enterprises-lack-dedicated-cybersecurity-personnel>
- World Health Organization. Ethics and governance of artificial intelligence for health: guidance on large multi-modal models [Internet]. Geneva: World Health Organization; 2024 Jan 18 [cited 2026 Apr 8]. Available from: <https://www.who.int/publications/i/item/9789240084759>
- Liang P, Bommasani R, Lee T, Liao K, Srivastava A. Holistic evaluation of large language models for medical applications [Internet]. Stanford (CA): Stanford Institute for Human-Centered AI (HAI); 2024 Jun 13 [cited 2026 Apr 8]. Available from: <https://hai.stanford.edu/news/holistic-evaluation-of-large-language-models-for-medical-applications>
- Gioulekas F, Stamatidis E, Tzikas A, Gounaris K, Georgiadou A, Michalitsi-Psarrou A, Doukas G, Kontoulis M, Nikoloudakis Y, Marin S, Cabecinha R, Ntanos C. A cybersecurity culture survey targeting healthcare critical infrastructures. *Healthcare (Basel)*. 2022 Feb 9;10(2):327. doi:10.3390/healthcare10020327.