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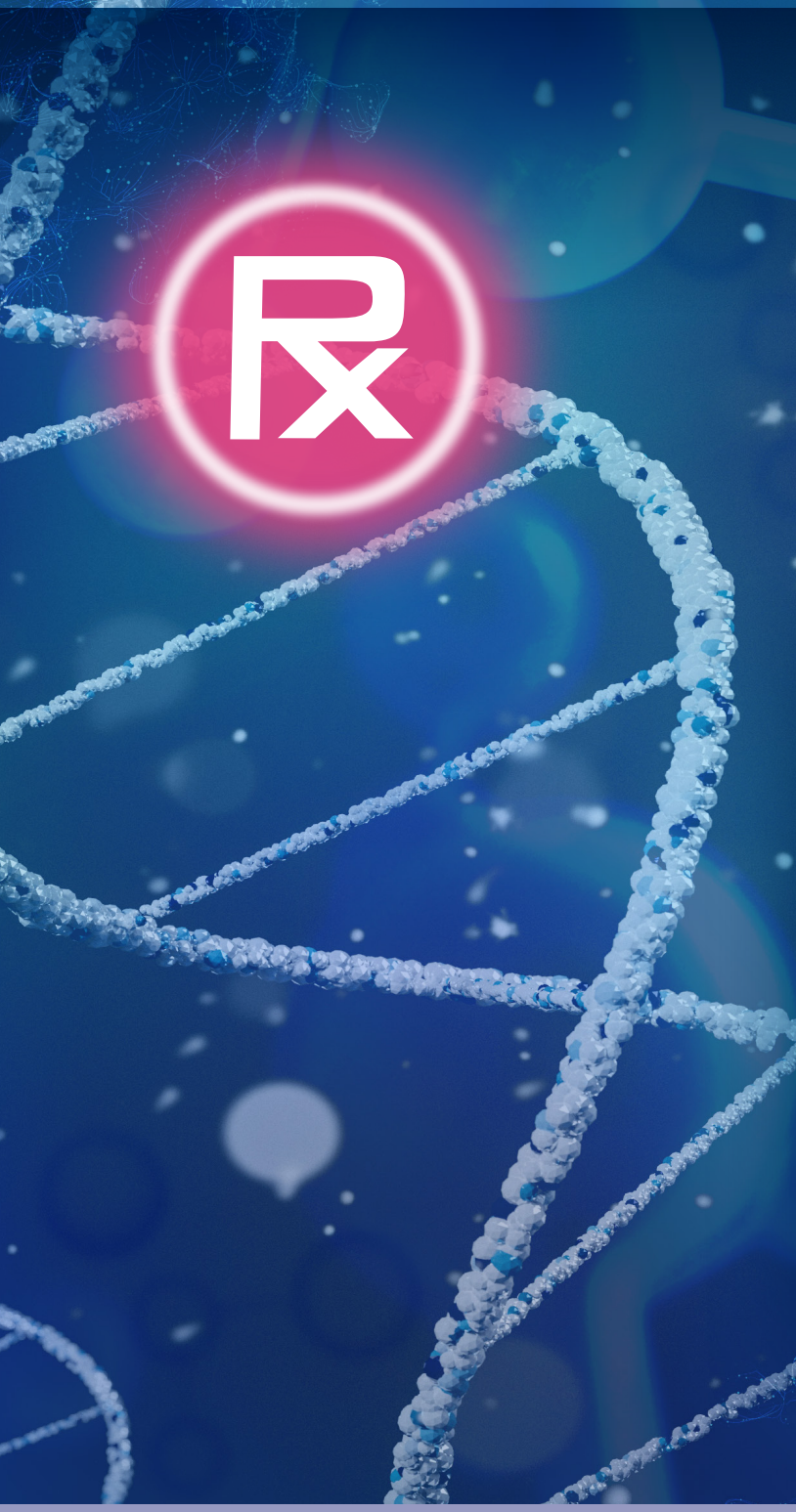

The Pharmaceutical Society of Hong Kong
The Practising Pharmacists Association of Hong Kong
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From Dispensers to Clinical Providers—Charting the Course for Pharmacy 2.0

The release of Volume 33, Issue 1 of the Hong Kong Pharmaceutical Journal (HKPJ) marks a watershed moment for our profession. As we stand at the threshold of 2026, the traditional image of the pharmacist—as a custodian of "medication logistics"—is rapidly being eclipsed by a vision of the pharmacist as an indispensable clinical provider and primary care leader. This issue serves as both a manifesto and a roadmap for this transformation, blending global trends and strategic blueprints for service expansion with insights from local and international leadership.

Global Trends: The Clinical Pivot of Community Pharmacy

One article in this issue examines the global expansion of community pharmacy services (p. 7). Internationally, pharmacists are repositioning from traditional dispensing roles toward patient-centered clinical delivery. In jurisdictions such as Australia, the United Kingdom and Canada, pharmacists have successfully integrated vaccination services and independent prescribing into their standard scope of practice. Central to this global shift is the implementation of structured medication management programs, such as Home Medicines Reviews (HMR) and MedsCheck. These services, often supported by government remuneration frameworks, ensure that life-saving cognitive interventions are financially sustainable and accessible, proving the pharmacist's role as an irreplaceable pillar in public health.

The Australian Inspiration: Systemic and Clinical Strategies for Hong Kong

Drawing on these international successes, we delve specifically into how systemic and clinical strategies inspired by the Australian model can elevate the pharmacist's role in Hong Kong (p. 25). The path forward for our local profession is anchored in "system-level enablers." In Australia, the success of clinical pharmacy is not accidental; it is the result of a deliberate integration of pharmacists into the primary care infrastructure. This includes the development of robust quality care programs and formal accreditation standards that ensure service consistency.

For Hong Kong to bridge the gap, we must move beyond pilot projects and advocate for permanent systemic changes. This includes expanded eHRSS functionality to allow two-way clinical communication between doctors and pharmacists and the formalization of clinical service integration within the District Health Centre (DHC) framework. Simultaneously, we must enhance our professional readiness, ensuring that every pharmacist possesses the advanced clinical reasoning skills required to manage complex multimorbidity in a modern primary healthcare system.

Strengthening Community Capacity: The Jockey Club PHARM+ Network

A practical and highly promising embodiment of this evolution is highlighted in our report on the Jockey Club PHARM+ Community Medication Service Network (p. 30). This initiative, funded by the Hong Kong Jockey Club Charities Trust and led by the University of Hong Kong (HKU), represents a sophisticated effort to build the clinical capacity of our community pharmacies.

The recent roundtable meeting focused on developing smoking cessation services underscores the potential of community pharmacies to lead high-impact public health initiatives. By engaging a diverse array of stakeholders—including non-governmental organizations and academia—the PHARM+ project is standardizing service quality and fostering a collaborative environment for knowledge exchange. This network serves as a vital proof-of-concept for capacity building; it demonstrates that through structured evaluation of service effectiveness and rigorous professional training, community pharmacies can transition into high-functioning clinical service hubs. These hubs are capable of delivering consistent, high-quality interventions that address chronic disease risk factors at the grassroots level.

A National Voice: An Interview with Mr. Zhao Ning

Our professional transformation also requires a robust and unified organizational structure. In an exclusive interview, Mr. Zhao Ning emphasizes the necessity of a "national voice" and a unified pharmacist network to advocate for our interests (p. 12). Mr. Zhao points out that in many advanced healthcare systems, the influence of the pharmacy profession is proportional to its organizational unity. A fragmented profession struggles to negotiate with policymakers or secure the necessary legislative changes to expand the scope of practice.

His insights remind us that individual clinical excellence, while vital, must be paired with collective policy advocacy. By building a unified network, we can ensure that pharmacists are recognized as key stakeholders in the healthcare ecosystem—expert providers whose input is essential to the design of health services—rather than mere suppliers of medicinal products.

Advancing Clinical Practice: Management of Resistant Hypertension

On the clinical front, this issue addresses the management of resistant hypertension within our "Drugs & Therapeutics" section (p. 15). We provide a detailed review of aprocitentan, a newly FDA-approved endothelin receptor antagonist, and reaffirm the established role of spironolactone in the treatment pathway. As medication regimens become increasingly complex, pharmacists must master these pharmacological nuances—such as the clinical value demonstrated in the PATHWAY-2 trial—to fulfill their roles as clinical consultants and provide precise guidance to patients.

Conclusion: Embracing Our Clinical Future

The evidence presented in this issue makes one thing clear: the future of pharmacy lies in our ability to translate expert drug knowledge into direct clinical outcomes. As we navigate this transition, we must remain proactive in redefining our boundaries. The shift from "dispensing" to "providing" is not merely a change in title, but a commitment to clinical accountability and patient advocacy.

With the burden of chronic disease rising in our society, the clinical expertise of the pharmacist has never been more vital. By embracing innovation, advocating for systemic reform and maintaining an unwavering focus on evidence-based practice, we will ensure that the pharmacy profession remains at the heart of a resilient and patient-centered healthcare system.

May P S Lam
Editor-in-Chief
April 2026

Prepared by Candice Leung & Anne Ng

Osimertinib Plus Chemotherapy for EGFR-mutated Advanced Non-Small-Cell Lung Cancer

Date: January 1,2026

EGFR-mutated advanced non-small-cell lung cancer (NSCLC) has traditionally been treated with EGFR tyrosine kinase inhibition, but disease progression and central nervous system involvement remain major clinical challenges that limit long-term disease control.

The FLAURA2 study was an international, phase 3, randomized trial that enrolled 557 patients with untreated, EGFR exon 19 deletion or L858R-mutated locally advanced or metastatic NSCLC. Participants were assigned to osimertinib plus platinum-pemetrexed chemotherapy or osimertinib alone, with the final analysis showing a median overall survival of 47.5 months versus 37.6 months, respectively. This corresponded to a hazard ratio for death of 0.77 (95% confidence interval [CI] 0.61–0.96; P=0.02).

Apart from the survival benefit, the study observed improved disease control, including prolonged progression-free survival, and the benefit was observed across clinically relevant subgroups, including patients with and without baseline brain metastases. However, this combined regimen also increased treatment burden, with grade 3 or higher adverse events reported in 70% of patients receiving osimertinib plus chemotherapy (leading to 12% of discontinuation) versus 34% with osimertinib alone (7% of discontinuation).

In conclusion, the study reinforced osimertinib as a backbone EGFR-targeted agent while establishing platinum-pemetrexed as an effective intensification strategy in selected first-line patients.

Source: www.nejm.org

A Placebo-Controlled Trial of the Oral PCSK9 Inhibitor Enlicitide

Date: February 4, 2026

A recent phase 3 trial evaluated whether enlicitide, an oral PCSK9 inhibitor, could provide potent LDL cholesterol lowering in adults at elevated cardiovascular risk. The study was designed to test a convenient oral alternative to injectable PCSK9-targeted therapy in patients who still had residual LDL-C burden despite receiving standard lipid-lowering treatment.

The CORALreef Lipids trial enrolled 2,909 adults, with a mean age of 63 years and 39.3% women. Participants were randomized 2:1 to enlicitide 20 mg once daily or placebo for 52 weeks, with the primary endpoint defined as the percent change in LDL-C from baseline to week 24.

Enlicitide produced a mean LDL-C reduction of 57.1% at 24 weeks, compared with a 3.0% increase in the placebo group, corresponding to an adjusted between-group difference of -55.8 percentage points (95% confidence interval [CI] -60.9 to -50.7; P<0.001). The LDL-lowering effect was sustained through week 52, and key secondary lipid outcomes also favoured enlicitide compared to placebo, including reductions in non-HDL cholesterol, apolipoprotein B, and lipoprotein(a). A large proportion of treated patients achieved clinically meaningful LDL-C goals, with 70.3% reaching both at least a 50% LDL-C reduction and an LDL-C level below 70 mg/dL. Safety outcomes were broadly similar between groups, and no major new tolerability signal was reported.

These results suggest that oral PCSK9 inhibition with enlicitide may become a valuable option for intensive lipid lowering, especially for patients with atherosclerotic cardiovascular disease or high residual cardiovascular risk who would benefit from a non-injectable therapy for better adherence.

Source: www.nejm.org

Ileocaecal Resection Versus Infliximab for Ileal Crohn's Disease: Retrospective 10-year Follow-Up of the LIR!C Trial

Date: February 18, 2026

As a chronic inflammatory bowel disease, Crohn's disease can be difficult to control when it is localized to the ileocaecal region and does not respond to conventional treatment. In this setting, long-term comparative data from the LIR!C trial suggest that ileocaecal resection (ICR) may offer a durable alternative to infliximab (IFX), particularly when the goal is sustained remission without ongoing therapy.

In this study, a retrospective 10-year follow-up of the LIR!C trial evaluated ileocaecal resection versus infliximab in adults with non-structuring, immunomodulator-refractory ileocaecal Crohn's disease. The analysis included 129 of 143 original participants, with follow-up data available for 66 patients in the resection group and 63 in the infliximab group; the median age at randomisation was 28 years and the median follow-up was 11 years.

The primary long-term endpoint was 10-year therapy-free remission, defined as clinical remission without Crohn's disease-related therapy after resection or discontinuation of infliximab. Therapy-free remission was significantly higher with ICR than with IFX, at 35.8% versus 13.2%, respectively, with an absolute difference of 22.6 percentage points (95% confidence interval [CI] 7.8–36.8; p=0.0038–0.004). For overall 10-year clinical remission, the two strategies were broadly comparable: 36.5% in the ICR group versus 28.4% in the IFX group. The hazard ratio for clinical remission was 0.79 (95% confidence interval [CI] 0.52–1.20; p=0.27), indicating no statistically significant difference in the overall time-to-remission analysis.

Moreover, an exploratory age-stratified analysis suggested that younger patients exhibited greater benefit from surgery. The estimated 10-year clinical remission rate in a 20-year-old was 54% with ileocaecal resection versus 24% with infliximab, while for a 30-year-old it was 38% versus 28%, respectively.

Overall, the study supports ileocaecal resection as an effective early treatment option for selected patients with ileal Crohn's disease, particularly when the goal is remission without ongoing Crohn's disease therapy.

Source: www.thelancet.com

Finerenone Demonstrates Clinical Benefits in Albuminuria for Patients with Type 1 Diabetes and Chronic Kidney Disease

Date: March 5, 2026

Despite advancement in diabetes care over the past years, renin-angiotensin system inhibitors remains as the mainstay treatment approach for patients with chronic kidney disease (CKD) derived from type 1 diabetes. Finerenone, a nonsteroidal mineralocorticoid receptor antagonist, was previously proven to delay CKD progression in patients with type 2 diabetes and CKD. Yet, its clinical efficacy and safety amongst patient groups with type 1 diabetes and CKD remain unknown.

The FINE-ONE trial was a phase 3, international, prospective, double-blind and randomized study which compared the use of finerenone with placebo in adults with type 1 diabetes and CKD. A total of 242 eligible participants were randomly assigned in 1:1 ratio to receive oral daily finerenone (n=120) or matching placebo (n=122) for 6 months. The initial dosing of finerenone in the treatment group was done based on participant's eGFR at screening: (1) 20 mg per day if eGFR ≥ 60 ml/min/1.73m2 or (2) 10 mg per day if eGFR is between 25 to less than 60 ml/min/1.73m2. Participants receiving 10 mg per day as initial dose may further titrate dose to 20 mg per day from month 1 onwards, depending on subsequent serum potassium and eGFR levels. The primary efficacy outcome was the relative change in urinary albumin-to-creatinine ratio from baseline over 6 months.

At month 6, the geometric mean percentage change in urinary albumin-to-creatinine ratio was -34% (least-squares geometric mean ratio to baseline=0.66, 95% confidence interval [CI], 0.60-0.73) in the finerenone group and -12% (least-squares geometric mean ratio to baseline=0.88, 95% confidence interval [CI], 0.79-0.98) in the placebo group respectively. The urinary albumin-to-creatinine ratio using finerenone had decreased by 25% more than matching placebo (least-squares geometric mean ratio=0.75, 95% confidence interval [CI], 0.65-0.87, P<0.001). Safety outcomes were similar in both groups with comparable incidence of adverse events.

In conclusion, finerenone demonstrates statistically meaningful decrease in urinary albumin-to-creatinine ratio than placebo over 6 months in adult patients with type 1 diabetes and CKD.

Source: www.nejm.org

Apixaban Demonstrates Lower Bleeding Risk than Rivaroxaban among Patients with Acute Venous Thromboembolism

Date: March 12, 2026

Patients with acute venous thromboembolism (VTE) usually requires anticoagulation therapy for a minimum of 3 months in order to prevent recurrent thrombotic events. Given the ease of drug administration and reduced need of monitoring, apixaban and rivaroxaban are the most commonly prescribed direct oral anticoagulants for patients suffering from VTE. However, uncertainty remains regarding the difference in bleeding risk between the two anticoagulants.

The prospective, international, randomized, open-label, blinded end-point COBRRA trial randomized 2700 patients with acute venous thromboembolism in 1:1 ratio to receive either (1) apixaban 10 mg twice daily for 7 days followed by 5 mg twice daily (n=1345) or (2) rivaroxaban 15 mg twice daily for 21 days then 20 mg daily (n=1355) for 3 months. The primary outcome was the incidence of clinically relevant bleeding, a composite of major bleeding or clinically relevant non-major bleeding as defined by the International Society on Thrombosis and Haemostatsis during the 3-month treatment period.

Clinically relevant bleeding occurred in 3.3% of patients in the apixaban group and 7.1% of patients in the rivaroxaban group (relative risk=0.46, 95% confidence interval [CI], 0.33-0.65, P<0.001) during the 3-month trial period based on intention-to-treat analysis. Recurrence of symptomatic VTE was documented in 1.1% and 1.0% of patients in the apixaban and rivaroxaban group respectively (relative risk=1.08, 95% confidence interval [CI], 0.52-2.23). No deaths attributed to recurrent venous thromboembolism was noted in both treatment groups.

To summarize, the risk of clinically relevant bleeding was significantly lower when patients with acute VTE were given apixaban as compared with rivaroxaban as primary treatment.

Source: www.nejm.org

Atezolizumab-FOLFOX Therapy Prolongs Disease-free Survival in Patients with Stage III Mismatch Repair Deficient Colon Cancer

Date: March 26, 2026

Colorectal cancer is the third commonest cancer in Hong Kong and local data reveals approximately 15% of localized colon cancers demonstrates mismatch repair deficiency (dMMR), which poses intrinsic resistance against standard fluoropyrimidine therapy. Thus, immunotherapy targeting dMMR colorectal cancer is rapidly developing to improve survival outcomes. Atezolizumab, an anti-programmed death ligand 1 antibody, prevents the downregulation of anti-tumour T cells and hence enhancing the immune system to work against the malignant tumour.

In this phase 3, international ATOMIC trial, a total of 712 eligible patients with resected stage III dMMR colon cancer were randomly assigned in 1:1 ratio to receive either (1) atezolizumab (IV 840 mg every 2 weeks) plus modified FOLFOX6 (mFOLFOX6) for 12 cycles followed by atezolizumab monotherapy for 13 cycles (n=355) or (2) modified FOLFOX6 therapy for 12 cycles per standard of care (n=357). The mFOLFOX6 regimen in both groups consisted of fluorouracil, oxaliplatin and leucovorin with the same dose per square meter. The key primary end point was disease-free survival, defined as the time from randomization to disease recurrence or death from any cause.

As of the data-cutoff date (February 4, 2025), the 3-year disease-free survival was 86.3% (95% confidence interval [CI], 81.8-89.8) in the atezolizumab-mFOLFOX6 group and 76.2% (95% confidence interval [CI], 70.9-80.6) in the mFOLFOX6 group, with a stratified hazard ratio for disease recurrence or death of 0.50 (95% confidence interval [CI], 0.35-0.73, P<0.001). Yet, the 5-year overall survival between the two groups did not show statistically significant difference (89.7% in atezolizumab-mFOLFOX6 group vs 87.9% in mFOLFOX6 group, stratified hazard ratio=0.90, 95% confidence interval [CI], 0.55-1.47). Incidence of grade 3 or above adverse events was also more prevalent in atezolizumab-mFOLFOX6 group (84.1%) than mFOLFOX6 group (71.9%).

To conclude, the addition of atezolizumab to mFOLFOX6 regimen as immunotherapy significantly improved disease-free survival among patients with stage III dMMR colon cancer.

Source: www.nejm.org

Review on the Global Expansion of Community Pharmacy Services

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ABSTRACT

This review examines the global expansion of community pharmacy services, focusing on emerging trends that reposition pharmacists from traditional dispensing roles towards patient-centred clinical service delivery. Drawing on international policy developments and evidence, the review highlights the measurable benefits of these services in improving access to healthcare, reducing system costs, and optimising patient outcomes.

The review serves as a basis for evaluating adoption prospects in Hong Kong, emphasising the pressing need to enhance primary healthcare capacity in response to demographic changes and rising chronic disease burdens. It concludes that these expanded services offer a proven, scalable pathway to strengthen health system efficiency, continuity of care, and population health outcomes in the evolving primary care landscape.

Keywords: *Community pharmacy, community pharmacist, primary healthcare, vaccination,medication management, prescribing*

INTRODUCTION

The global expansion of community pharmacy services marks a transformative era in healthcare, with pharmacists increasingly recognised as pivotal providers of clinical care beyond traditional dispensing roles. This evolution is particularly urgent for regions grappling with rapidly ageing populations, such as Hong Kong. According to the Hong Kong population projection report, Hong Kong faces a rapidly ageing population, projected to reach 34% by 2046 [(1)]. There is an increased need for the management of elderly health, from disease prevention to the management of chronic conditions. One solution is to divert these services into primary healthcare, which encourages citizens to receive preventive and chronic disease management from the healthcare team in the community [(2)]. Community pharmacists are essential partners in primary healthcare, delivering accessible, efficient, and patient-centred care in addition to the traditional role of dispensing services.

This review examines three emerging pharmacy services that are transforming community pharmacy practice globally: **vaccination services**, **medication management services**, and **pharmacist prescribing**. Each service represents a critical expansion of the pharmacist's role from traditional dispensing to comprehensive clinical care delivery within primary healthcare settings. These developments reflect a global recognition that pharmacists, as highly accessible healthcare professionals, can significantly contribute to improving health outcomes, enhancing healthcare accessibility, and optimising health system efficiency. The lessons drawn from global experience offer vital perspectives for adopting similar innovations in Hong Kong, where pharmacists can play a strategic role in meeting evolving health system needs.

Vaccination Services

Pharmacist-led vaccination services have gained significant attention worldwide, reflecting a broader shift toward accessible, community-based preventive care. As trusted healthcare providers embedded within communities, pharmacists are uniquely positioned to enhance immunisation coverage, reduce disease burden, and support public health goals [3]. The models involving pharmacists in providing vaccination services have evolved from policy advocacy to practical implementation across diverse healthcare systems in many overseas countries, and Hong Kong is now exploring its potential as part of expanded pharmacy services.

According to the data reported by the International Pharmaceutical Federation (FIP) in 2024 [4], pharmacists in 44 countries are authorised to administer vaccines, which has dramatically increased from 13 countries in 2016 [5]. In countries such as the United States, the United Kingdom, Canada, and Australia, pharmacists routinely provide immunisations for influenza, pneumococcal disease, HPV, COVID-19, and travel-related illnesses. Pharmacist-led vaccination services in these countries are funded through a combination of public reimbursement, private insurance, and out-of-pocket payments, with each country adopting a slightly different model. Nevertheless, the services are well-supported and sustained by country-wide initiatives that provide remuneration for pharmacy-based vaccination services, covering vaccine costs and service fees.

The integration of vaccination into pharmacy practice has demonstrated measurable benefits, including increased vaccine uptake, reduced healthcare costs, and improved access in underserved areas [3]. Furthermore, as highlighted by the FIP's 2025 report focusing on funding models, the economic and societal impact of pharmacy-based vaccination [3], the key enablers for the successful implementation of such a programme included legislative support, standardised training, reimbursement mechanisms, and public awareness campaigns. Countries that have adopted these frameworks report higher vaccination rates and greater patient satisfaction.

The global development of pharmacist-led vaccination sets an essential example for Hong Kong to consider in evaluating our own services locally. As highlighted by the 2023 review published in the Hong Kong Pharmaceutical Journal on 'Review of Pharmacy-Based Vaccination in Hong Kong' [6], some of the significant barriers to the implementation of pharmacy-based vaccination in Hong Kong observed from this publication included access to vaccine, expectation of pharmacists' roles and the difficulties for community pharmacies to fulfil infrastructure-related requirements. Furthermore, other crucial considerations should consist of clear guidelines on the criteria for community pharmacies or other primary healthcare settings, as well as a standard operating procedure within the site to ensure the safe administration of the vaccination service to patients. Finally, public engagement and education on the potential expanded roles of pharmacists should be emphasised, and an effective collaborative model for integrating pharmacist-led vaccination services with existing healthcare infrastructure should be explored to facilitate continuity of care.

Medication Management Services

The scope of community pharmacy practice in primary healthcare has evolved significantly internationally, with the provision of structured, clinical medication management services representing one of the major developments. Medication management services are known by different names in different parts of the world, but essentially involve the systematic assessment of a patient's medications by a pharmacist. Key examples include Medication Therapy Management (MTM) and the Comprehensive Medication Review (CMR) in the United States [7], the New Medicine Service (NMS) and Discharge Medicines Service (DMS) in the United Kingdom [8], the Home Medicines Review (HMR) in Australia [8], and programmes such as MedsCheck in Canada [10]. The core aim of all these services is to optimise therapeutic outcomes through improved adherence, identification of adverse drug events, and resolution of medication-related problems [11]. This widespread adoption under various nomenclatures signals a global recognition of the pharmacist's value in managing medication regimens.

Structured medication review is a well-established component of modern healthcare systems, with services tailored to regional funding and policy frameworks. Internationally, these programmes vary in scope and delivery but share a common goal: optimising medication use and improving patient outcomes.

In the United States, Medication Therapy Management (MTM) and Comprehensive Medication Reviews (CMRs) are mandated for at-risk beneficiaries under Medicare Part D [12].

The United Kingdom's National Health Service funds targeted services such as the New Medicine Service (NMS), which supports adherence during the initiation of new treatments, and the Discharge Medicines Service (DMS), which promotes medication safety following hospital discharge [8]. Canada's MedsCheck and Australia's Home Medicines Review (HMR) similarly offer publicly funded, pharmacist-led reviews through provincial or national frameworks [9,10].

These international models demonstrate that structured medication review is a recognised and funded element of care, often operating synergistically with other pharmacist-led services. The scope of these services typically encompasses two main types: comprehensive reviews of a patient's entire medication regimen and targeted interventions addressing specific issues [7,13]. This holistic approach—focusing on the patient's complete medication profile rather than a single disease state—complements disease-specific management and preventive services, contributing to a more integrated and effective healthcare system.

Crucially, the sustainability of medication review services is secured through formal reimbursement structures. Unlike traditional dispensing, these cognitive services are funded by governments and insurance systems that recognise their value in improving health outcomes and reducing overall healthcare costs [11,14]. Primary funding models include government-funded systems (e.g., UK, Australia, Canada) and insurance-mandated models (e.g., US Medicare) [8–10,12]. The cost is typically not borne directly by the patient, as the service is valued for its system-wide impact on preventing costly hospitalisations and complications [11,14].

The global evidence presents a clear and compelling case for the value of structured medication review. A recent systematic review and meta-analysis consolidates this evidence, demonstrating that these services produce significant positive outcomes across clinical, economic, and humanistic domains by reducing overall healthcare costs and enhancing patient satisfaction and quality of life [14].

While some jurisdictions offer these services as a private, out-of-pocket option, this model could potentially create significant access barriers and fail to capture the public health benefit of widespread medication optimisation. The international trend is decisively towards funded models that recognise the system-wide value and cost savings. Hong Kong, as a world-class city facing the dual challenges of an ageing population and increasing polypharmacy, has seen many pharmacists independently incorporating medication review services into their own practices. However, the absence of a coordinated and structured programme presents a great opportunity — transitioning from a reliance on direct patient payment to a publicly or insurer-funded medication review model could strategically enhance the efficiency, equity, and overall quality of the healthcare system.

Pharmacist Prescribing

According to the 2025 FIP report, a growing global trend is emerging, allowing pharmacists to prescribe, ranging from collaborative practices with prescribers to full independent prescribing [15].

The extent of prescribing rights can be categorised as dependent or collaborative prescribing, where the prescribing is driven by a protocol, or as collaborative practices with prescribers, such as repeated prescription prescribing. On the other hand, pharmacist independent prescribing (PIP) refers to a situation where pharmacists have full autonomy in initiating, continuing, adjusting, and discontinuing drugs, using their own clinical judgement[15,16].

The table below summarises the countries/jurisdictions and the type of prescribing services offered. Although the list is not exhaustive and may be incomplete, it clearly illustrates the global trend in pharmacist-prescribing services.

Countries and / or jurisdictions	Prescribing Services by Community Pharmacists
Canada [17]	Practice varies between jurisdictions, range from conditions-based prescribing (e.g. for minor ailments, smoking cessation, urgent medicines) to full rights on prescription only medicine with additional prescribing authorisation, except controlled drugs
United States [15]	Practice varies between jurisdictions, range from collaborative prescribing agreement on certain conditions/ drugs for contraception, HIV pre/post exposure and smoking cessation
United Kingdom [18,19]	Independent prescriber within their clinical competence

Wales and Scotland [15,18]	Conditions based (e.g. travel medicines, UTI, shingles etc) Provision of urgent medicine under protocol
Switzerland and Denmark [15]	Renewal of prescription for certain chronic conditions Prescribing medicine from a pre-defined list for acute conditions such as allergic rhinitis, UTI or respiratory conditions
Australia [20–22]	Practice varies between jurisdictions. Some states (e.g. Queensland) had established permanent service already on conditions-based prescribing (e.g. UTI, acne, contraceptive pills), while other states had some permanent practice implemented, while piloting other conditions
Singapore [23]	Collaborative prescribing within approved drug formulary

In all the overseas models reviewed, additional postgraduate training is required to become a pharmacist prescriber as this is generally not covered in the undergraduate curriculum. This includes courses that cover general principles in prescribing and, more specifically, the enhancement of knowledge in the clinical area of prescribing to ensure competency level is met [16]. Most countries would require some years of clinical experience as a prerequisite for these postgraduate courses [16,19]. From 2026, graduates from the UK will have full independent prescribing rights at registration, as prescribing training is now embedded into the curriculum [24]. It will be important to observe the extended scope of services this critical mass of prescribing pharmacists can create, potentially transforming the role of community pharmacies as an essential primary care access point.

Regarding the benefits of pharmacist prescribing, a scoping review conducted in 2015 on Canadian pharmacists [25] and a systematic review [26] examining global publications both agree that pharmacist prescribing can enhance patient access to healthcare services and improve patient outcomes.

However, establishing pharmacist prescribing takes time and careful planning, often involving piloting to evaluate the best approach before becoming a usual practice. For example, the state of Queensland in Australia has piloted several condition-based protocols before accepting them as standard practice [20]. Apart from the need for piloting new services, substantial government input is required for implementation, as seen in the overseas experience, whether it involves legislative changes that allow for prescribing rights or a funding model that supports its sustainability. It is worth noting that some countries adopted the user-pay model, and not all prescriptions are subsidised by the government. For example, most programme piloting in Australia employs a consumer-pay model [16,22], in addition to some jurisdictions in the United States that utilise an insurer-pay model [15].

CONCLUSION – HONG KONG PERSPECTIVES

The three services reviewed—vaccination services, medication management services, and pharmacist prescribing—represent significant opportunities to transform community pharmacy practice in Hong Kong from a primarily product-focused model to a patient-centred clinical service model. Global evidence consistently demonstrates that these expanded pharmacy services enhance healthcare accessibility, improve patient outcomes, reduce system costs, and optimise the utilisation of highly trained pharmacy professionals. The timing is particularly opportune in Hong Kong with the expansion of primary healthcare services and the electronic health record platform allowing the availability of transparent information between different healthcare providers. As we navigate the challenges of an ageing society and seek to build a sustainable, equitable, and efficient healthcare system, the expanded scope of community pharmacy services offers a proven pathway to strengthen primary healthcare while ensuring that the public has timely access to high-quality pharmaceutical care.

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A National Voice, A Unified Pharmacist Network
An Interview with Mr. Zhao Ning

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ABSTRACT

Mr. Zhao Ning currently serves as the Deputy Chief Pharmacist at Peking University First Hospital, but his influence extends far beyond the hospital walls. He is the founder of the China Pharmaceutical Affairs Network (CPAN, "藥事網"), a nationwide alliance of over 6,000 hospital pharmacists dedicated to advancing pharmacy practice and medication safety. Simultaneously, Mr. Zhao is a prominent voice in public health education, hosting the "Healthy China" show on China Central Television (CCTV) where he dispels common medication misconceptions for the general public. In this interview, he shares his unique strategy for uniting a profession and promoting the role of pharmacists through public education.

Keywords: *Public Health Education, Pharmacist Advocacy, Professional Network, Profession Advancement*

INTERVIEW WITH MR. ZHAO NING

Q: Your role as a pharmacist on national television is unique. Could you tell us about your work on China Central Television (CCTV) and the motivation behind it?

Mr. Zhao: In China, media platforms have a significant role in shaping public perception. It is essential to make good use of television exposure to promote the role of pharmacists. I am currently the host of the medical show "Healthy China" on CCTV, as well as a medical guest on other shows on CCTV. On the show, I invite various medical experts to share credible health information and debunk common myths.

As the national broadcaster, CCTV provides an unparalleled platform to showcase the pharmacist's expertise and professionalism to a vast audience. To date, our content has accumulated more than **five billion views** and trended on major social platforms like TikTok and Weibo, which has greatly enhanced the public image of pharmacists. This has also directly translated into increased demand for paid hospital pharmacist consultations.

Looking ahead, I have developed a "five-year plan" aiming to create a regular rotation of pharmacists on CCTV. This initiative will provide greater opportunities for talented pharmacists to showcase their expertise and solidify our profession's influence.

Q: In addition to your media work, you founded the China Pharmacist Association Network (CPAN, "藥事網"). What motivated you to establish CPAN?

Mr. Zhao: The journey began in 2013, a time when the value of pharmacists was not widely recognized in China. Most physicians and patients were unfamiliar with our expertise, so the utilisation of pharmacist consultations was low.

An opportunity arose when a prominent newspaper, China Pharmaceutical News, invited me to write a blog on drug information. The overwhelmingly positive reader feedback

highlighted a clear public appetite for pharmacist-led education. This success inspired me to connect with fellow hospital pharmacists to form a professional team. Our founding principle was simple: by uniting pharmacists in patient education, we could collectively elevate the public's perception of our profession.

Q: How does CPAN connect pharmacists across China and create a trusted community?

Mr. Zhao: To ensure a trusted, professional environment, membership is verified through a real-name system where pharmacists must confirm their identity, often using their official hospital credentials. This allowed us to build a secure network that has grown to over 6,000 hospital pharmacists.

Within this community, members share views on new policies, seek advice on clinical challenges, and discuss relevant news, from government regulations to medical incidents and recruitment advertisements. Our members actively engage in discussion, fostering a lively and interactive community.

We also have specialty subgroups for clinical pharmacists, Chinese medicine pharmacists, and PIVAS (Pharmacy Intravenous Admixture Services) pharmacists to exchange specific insights. Through this strong network, pharmacists can find credible collaborators for new projects, driving the advancement of pharmacy services and research nationwide.

Q: How do you leverage the CPAN to contribute to patient education?

Mr. Zhao: We believe that our professionalism is best demonstrated through the delivery of high-quality patient education. One of the most common approaches is writing articles on drug-related information. Making use of the reputation of CPAN, we collaborate with several state media outlets and have been granted permission to publish our articles in their newspapers.

Crucially, CPAN acts as a facilitator, not a gatekeeper. We connect our members with media outlets, which then independently select well-written articles for publication. This transparent, merit-based approach ensures every member has an equal opportunity.

This has a powerful secondary benefit: career advancement. In many Chinese hospitals, contributions to public education are now a key metric for promotion, so pharmacists who actively educate the public are more likely to be recognized in their careers.

Q: Online medication purchasing is now common. How has this influenced CPAN's services?

Mr. Zhao: This trend created a natural evolution for our services. After reading our articles, patients often have more questions, so many of our members now offer paid online consultations through platforms like the JD Internet Hospital (京東互聯網醫院). They provide paid services such as polypharmacy management and medication counseling.

Crucially, these consultations do not require a physician referral, establishing an autonomous and direct pharmacist-patient relationship. Patients can then order necessary non-prescription medications for home delivery. This integrated model—from education to consultation to delivery—builds lasting patient trust and solidifies the pharmacist's value in the digital age.

CONCLUSION

Mr. Zhao Ning's career demonstrates a powerful dual-pronged strategy: harnessing the reach of national media to build public trust while simultaneously creating a robust, collaborative digital network to empower pharmacists from within. His efforts have not only provided a unified voice for thousands of practitioners but have also charted a clear path for the future advancement of the pharmacy profession in China.

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For your patients with early symptomatic Alzheimer's disease (AD) and confirmed AD pathology[1]

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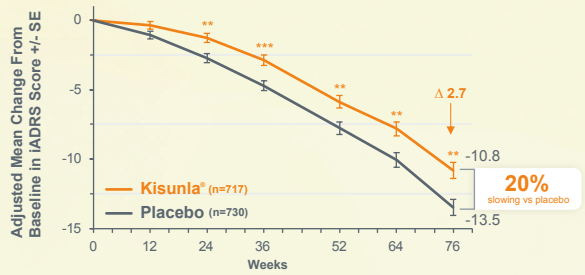
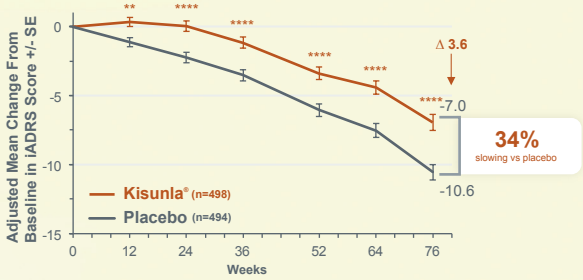
iADRS CHANGE FROM BASELINE THROUGH 76 WEEKS

Overall indicated population[1,2†]



Low-medium tau indicated population[1,3†]



TRAILBLAZER-ALZ 2 trial design

In this study, 1736 patients were randomized 1:1 to receive 700 mg of Kisunla® every 4 weeks for the first 3 doses, and then 1400 mg every 4 weeks via intravenous infusion (N=860) or placebo (N = 876) for a total of up to 72 weeks. The primary efficacy endpoint was change in the integrated Alzheimer's Disease Scale (iADRS) score from baseline to 76 weeks. Amyloid clearance* was assessed with amyloid PET scans at 24, 52, and 76 weeks, discontinuation, or study completion (76 weeks). ARIA-monitoring MRIs were performed before infusions 1, 2, 3, 4, and 7.[1,4]

*Cleared defined as when patients reach amyloid levels considered negative for amyloid pathology. <24.1 Centiloids equaled a negative amyloid PET scan. If the amyloid plaque level was <11 Centiloids on a single PET scan or 11 to <25 Centiloids on 2 consecutive PET scans, the patient was eligible to be switched to placebo.[1]

Key Kisunla® Takeaways[1-8]

As measured compared to placebo TRAILBLAZER-ALZ 2 at 76 weeks:[1-3,5-7]

- **Significant slowing of cognitive and functional decline in the indicated population**
- **38% reduced risk of progressing to the next stage of disease and of 48% reduced risk of progressing to moderate dementia in the indicated population**

- **Potential to stop dosing upon removal of amyloid plaques to minimal levels[1†]**
- **Once-monthly 30-minute infusion[1]**

As measured in the gradual-titration arm compared to original dosing in TRAILBLAZER-ALZ 6:

- **Reduced frequency of ARIA-E[8]**

Kisunla®, like other amyloid-targeting therapies, can cause ARIA, which is usually asymptomatic, though rarely serious and life-threatening events can occur. ARIA can be fatal.[1,4]

In TRAILBLAZER-ALZ 2, the most frequently reported adverse reactions in the indicated population were ARIA-E, ARIA-H, and headache.[1]

[†]In the Phase 3 clinical trial, dosing was continued or stopped in response to observed effects on amyloid-PET imaging.[4]

ARIA=Amyloid-related imaging abnormalities; iADRS=integrated Alzheimer's Disease Rating Scale; IV=intravenous; LS=least squares; MCI=mild cognitive impairment; MRI=magnetic resonance imaging; PET=positron emission tomography; Q4W=every 4 weeks.

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Use of Aprocitentan and Spironolactone in Resistant Hypertension Management

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ABSTRACT

Aprocitentan was approved by the United States Food and Drug Administration (U.S. FDA) in March 2024 as the first oral agent of a new drug class to treat resistant hypertension. The endothelin receptor antagonist, which is not registered in Hong Kong, is indicated as an add-on therapy in the treatment of hypertension in combination with other antihypertensive agents. Spironolactone, on the other hand, has a much longer history since its FDA approval in 1960 and currently has the role of treating resistant hypertension with other antihypertensive agents of different mechanisms of action. Both spironolactone and aprocitentan were found to be efficacious in reducing blood pressure and their safety profiles were characterised in medical literature. However, there is a lack of head-to-head comparison between the two antihypertensives. This article reviews the two old and new antihypertensive agents in terms of their distinctive mechanisms of action, approved indications, as well as their efficacy and safety profiles with evidence from the results of major clinical trials.

Keywords: *Aprocitentan, Spironolactone, Resistant Hypertension, Endothelin receptor antagonist, Aldosterone antagonist*

INTRODUCTION

Hypertension is a highly prevalent disease and its rate of control is suboptimal globally. It is well known for its association with an increased risk of various cardiovascular and kidney outcomes, and different target organ damages can occur. In Hong Kong, hypertension is a significant public health issue due to its high prevalence. According to data from the Population Health Survey 2020-2022 conducted by the Department of Health, the prevalence of hypertension was 29.5% among the age group 15-84 years, and the prevalence increased with age accounting for 57.4% in those aged 65-84 years, highlighting that there is a higher risk in elderly[1].

Individuals with poorly uncontrolled hypertension despite the use of multiple antihypertensives may lead one to suspect the possibility of resistant hypertension. Currently, resistant hypertension can be defined as blood pressure (BP) above goal despite treatment with three antihypertensive drugs with different mechanisms of action, including a diuretic at maximally tolerated doses; alternately it also refers to the phenomenon in which use of four or more antihypertensives are required for controlling BP at goal[2]. This three-drug regimen commonly includes an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin receptor blocker (ARB), a long-acting calcium channel blocker (CCB), and a thiazide-like diuretic. To confirm the diagnosis of resistant hypertension, pseudo-resistance has to be excluded, and common causes such as inaccurate BP measurement, poor adherence to antihypertensive therapy, and white-coat effect should be evaluated[2, 3].

Resistant hypertension is not uncommon around the world. For example, based on BP goal of 130/80 mm Hg, the prevalence of resistant hypertension is approximately 8.5% to 20% among hypertensive adults in the United States[4]. Common comorbidities such as obesity, chronic kidney diseases, and diabetes were identified as risk factors for resistant

hypertension in multiple cohort studies[5]. In the Hong Kong local population, a cross-sectional descriptive study examining the clinical profile of patients aged 30 years or above reflects that the prevalence of resistant hypertension is around 7.4% in the primary care setting of Hong Kong[6].

Patients with resistant hypertension can have more than 50% higher risk of stroke, myocardial infarction, end-stage renal disease, and cardiovascular death than their hypertensive counterparts without treatment resistance[7, 8]. Therefore, effective BP management is critical to minimize the risk of such complications. Resistant hypertension requires high doses and/or higher number of antihypertensives for BP control, but safety and efficacy of the add-on (non-first-line) drugs is a concern and generates much interest in this research area. Currently, aprocitentan and spironolactone are two drugs that are indicated to treat hypertension in patients who are unresponsive to or whose BP is not adequately controlled on other antihypertensive medications. Comparing these two drugs can also provide insights about their clinical use in hypertensive patients with different comorbidities such as those with hyperkalaemia and renal failure. Therefore, this article aims to provide a discussion about these two add-on drugs in the management of resistant hypertension.

OVERVIEW OF APROCITENTAN

Tryvio (aprocitentan) has been approved by the U.S. FDA on 19 March 2024 and its European counterpart, Jeraygo, has been authorized in European Union by European Medicines Agency (EMA) on 27 June 2024 for combination with other antihypertensives to lower BP in adults who are not adequately controlled on other drugs[9, 10]. Aprocitentan is approved to be taken 12.5mg orally once daily[11]. In Hong Kong, aprocitentan is not yet registered and listed in Hospital Authority Drug Formulary.

Pharmacology

Aprocitentan is an active metabolite of macitentan, a drug used for treating pulmonary artery hypertension. Aprocitentan functions as a dual endothelin receptor antagonist (ERA) that blocks endothelin-1 (ET-1) binding to both ETA and ETB receptor subtypes, with an inhibitory potency ratio of 1:16 [12]. ET-1 has caught the attention of researchers as its expression is enhanced in endothelium in patients with severe hypertension. ET-1, as one of the most potent vasoconstrictors in human body, is a 21-amino acid peptide mainly produced by endothelial cells, and it exerts harmful effects in the pathogenesis of hypertension including vasoconstriction, fibrosis, cellular proliferation, and inflammation through ETA and ETB receptors found on vascular endothelial and smooth muscle cells. Notably, in hypertension, ET-1 contributes to endothelial dysfunction, vascular hypertrophy, remodeling, sympathetic activation, and elevated aldosterone production[13]. Aprocitentan achieves its antihypertensive effect by inhibiting ET-1 signaling in these pathophysiological processes.

Aprocitentan is a highly protein-bound drug (>99%) and is eliminated in both urine and feces[14]. As the drug's main elimination pathways are independent of CYP enzymes, there is low potential for interactions with drugs that inhibit or induce CYP enzymes. Indeed, no significant interaction with commonly used drugs have been reported as of today. The drug's long elimination half-life of about 41 hours enables it to be administered on an once-daily basis[11]. Aprocitentan can be taken without regard to food, and no clinically significant differences in its pharmacokinetics were observed following administration of a high-fat, high-calorie meal[11]. A recent double-blind study supported that the pharmacokinetics of aprocitentan is unlikely to be different between Caucasian and Japanese subjects, and suggested that dose adjustment may not be necessary in patients of different ethnicity[15].

Efficacy

PRECISION was a 4-year, multicenter, blinded, randomized, parallel-group, phase 3 trial examining the effect of aprocitentan in patients with sitting systolic blood pressure (SiSBP) ≥ 140 mmHg despite taking three standardized antihypertensive drugs, including a diuretic [16]. This trial consisted of a 4-week placebo run-in period and was followed by three parts. Before the placebo run-in period, all patients were transitioned to standard background antihypertensive therapy (SBAT) consisting of valsartan (ARB) 160 mg, amlodipine (long-acting CCB) 5 or 10 mg, and hydrochlorothiazide (diuretic) 25 mg, which was maintained consistently throughout the whole trial period. After the 4-week placebo run-in period, part 1 started with a total of 730 participants with uncontrolled SiSBP (≥140 mmHg) using the unattended automated office blood pressure measurement (uAOBPM), and they were randomized to receive either aprocitentan 12.5 mg, aprocitentan 25 mg, or placebo once daily in a 1:1:1 ratio during the initial 4-week double-blind treatment phase. In part 2, all participants transitioned

to a 32-week single (patient)-blind phase where they received aprocitentan 25 mg daily. After that, for part 3, participants underwent re-randomization to either continue aprocitentan 25 mg or switch to placebo in a 1:1 ratio for a 12-week double-blind withdrawal period. The study concluded with a 30-day safety follow-up assessment for all enrolled participants. The primary endpoint was the change in mean trough SiSBP from baseline to week 4 (part 1), while the key secondary endpoint assessed the change in mean trough SiSBP from withdrawal baseline from week 36 to week 40 (part 3).

For primary endpoint, the least-squares mean (LSE) changes were -15.3 (0.9) mmHg for the 12.5 mg dose, -15.2 (0.9) mmHg for the 25 mg dose, and -11.5 (0.9) mmHg for placebo. The treatment differences versus placebo were -3.8 (1.3) mmHg (97.5% CI -6.8 to -0.8, p=0.0042) for aprocitentan 12.5 mg and -3.7 (1.3) mmHg (97.5% CI -6.7 to -0.8, p=0.0046) for the 25 mg dose. For the key secondary endpoint, the mean difference of SiSBP with placebo compared to aprocitentan 25 mg after 4 weeks of treatment withdrawal was 5.8 mmHg (95% CI 3.7 to 7.9; p < 0.0001). The between-group differences in SiSBP persisted through week 48.

Safety

Mild-to-moderate fluid retention or edema including peripheral edema and face edema emerged represented the most common adverse event in a dose-dependent manner during the entire study and occurred mainly in part 1. Incidence rates were 9.1% with aprocitentan 12.5 mg, 18.4% with aprocitentan 25 mg, and 2.1% with placebo. In part 2, edema adverse events were reported in 17% of participants, with differential incidence rates based on prior treatment allocation: 23% among placebo-switched subjects, 16% for those transitioning from aprocitentan 12.5 mg, and 12% for patients maintained on aprocitentan 25 mg. Two severe adverse events of pulmonary edema occurred in one participant from the aprocitentan 25 mg arm in part 1 and one participant from part 2, both associated with acute hypertensive crisis that likely precipitated the condition. Overall, seven participants (3%) discontinued aprocitentan due to edema.

During the whole trial, eleven participants required hospitalizations for heart failure. In part 1, two cases occurred in the aprocitentan 25 mg arm: one case involved pulmonary edema that resolved with treatment and with completing parts 2 and 3 in the aprocitentan 25 mg, while the other represented worsening of pre-existing chronic heart failure. Part 2 recorded six events, including one participant previously on aprocitentan 25 mg and five placebo-switched participants. Three of them occurred within 3 weeks of aprocitentan initiation. Part 3 featured three additional hospitalizations, with two occurring in the aprocitentan 25 mg arm and one in the placebo arm.

In addition, a total of 11 treatment-emergent deaths (1.3% of participants) were reported but were not regarded by investigators to be study treatment-related. One death occurred in part 1, nine in part 2, and one in part 3. Causes included COVID-19 (5 participants), procedural colon perforation (1 participant), and cardiovascular deaths (5 participants). Adverse events leading to permanent treatment discontinuation were rare in part 1 but occurred slightly more often with aprocitentan (3% at 12.5 mg, 2% at 25 mg) than with placebo (1%). In part 2, 3.8% of subjects discontinued due to adverse events, with higher rates in those who switched from placebo (5.1%) compared to those continuing 12.5 mg (2.6%) or 25 mg (3.8%).

OVERVIEW OF SPIRONOLACTONE

Spironolactone is a drug with the brand name Aldactone approved by the U.S. FDA on 21 January 1960, and it can be used as an add-on treatment for hypertension unresponsive to other therapies[17,18]. Spironolactone is also available as Qaialdo for use in the European Union, although currently it is mainly prescribed for managing refractory edema associated with diseases (e.g. heart failure, hepatic cirrhosis, nephrotic syndrome, and essential hypertension) and primary aldosteronism, but not resistant hypertension, in the European member states[19]. Other therapeutic uses of spironolactone include moderate to severe acne vulgaris and hirsutism in female gender. In Hong Kong, spironolactone is a registered pharmaceutical product with its date of registration that can be traced back to 1983[20]. It is marketed as oral tablet dosage form in dosage strength of 25 mg, but the drug can also be prepared extemporaneously for oral suspension of different dosage strengths[18]. For treatment of hypertension, the dose is commonly initiated at 25 mg daily and titrated as needed after 2 to 4 weeks based on response and tolerability up to 100 mg daily[2, 18].

Pharmacology

Spironolactone is an aldosterone antagonist that has a steroidal structure and also commonly known as mineralocorticoid receptor antagonist. It acts by competitive binding of aldosterone receptors at the principal cells in the collecting ducts of the kidney. This inhibition leads to two effects: inhibition of epithelial sodium channels (ENaCs) expression and inhibition of sodium-potassium ATPase (Na/K ATPase) expression. The inhibition of ENaC expression will decrease the ENaC concentration at the collecting duct, which leads to a decrease in sodium reabsorption. The inhibition of Na/K ATPase expression also decreases sodium reabsorption and potassium secretion. The above effects increase the excretion of water and lowers the effective circulating volume, which exhibits the diuretic and antihypertensive effect of spironolactone[21]. Of note, mineralocorticoid receptor antagonists are the only diuretics that do not require access to the tubular lumen for inducing diuresis, and it would be best for patients to take the diuretic drug earlier during a day to avoid urination in the late evening[22]. In view of the effect of aldosterone antagonist on serum potassium level, the risk of hyperkalemia can magnify in patients with renal impairment and/or with concurrent use of potassium supplementation, food or drink that are rich in potassium, and drugs such as ACEI, ARB, and direct renin inhibitor. Aldosterone antagonist should be avoided in patients with hyperkalemia[17].

Patients are advised to establish a routine pattern and be consistent to take spironolactone with regards to food on a daily basis, as food can increase the bioavailability of the drug by approximately 95%. Although spironolactone has a short half-live of about 1.4 hours, it is metabolized to multiple active metabolites including canrenone which has a long half-life of about 16.5 hours[23].

Spironolactone, notably, exhibits non-selective binding to progesterone and androgen receptors as well, and has the potential to cause progestational and anti-androgenic effects (collectively known as endocrine effects) including gynecomastia, impotence, and menstrual irregularities. Another aldosterone antagonist, eplerenone (Inspra), has very low affinity for the two sex hormone receptors owning to its 9,11-epoxide group, therefore it can largely avoid the endocrine effects associated with spironolactone. However, eplerenone is less potent and often requires twice-daily dosing for adequate BP lowering effect, and previous randomized controlled trials did not show BP lowering in daily dosage range of 25 to 100 mg when compared with placebo, suggesting higher dosages are required for effective BP management[24, 25, 26]. Eplerenone, but not spironolactone, is also subject to CYP3A4-mediated drug interactions.

Efficacy

The role of spironolactone in treatment of resistant hypertension was first described by Ramsay et al. in medical literature back in 1980[27]. In recent years, a number of randomized clinical trials aimed to validate and determine the efficacy of spironolactone in resistant hypertension, and many found that spironolactone was more effective than placebo or other antihypertensive drugs[28, 29]. Among all clinical trials, PATHWAY-2 offered the most compelling data about the efficacy of spironolactone.

PATHWAY-2 was a 12-month double-blinded, placebo-controlled, crossover phase 4 clinical trial with a sample size of 314 patients which compared the efficacy of spironolactone, doxazosin, and bisoprolol in treatment of resistant hypertension in the U.K[30]. Only patients aged 18 to 79 years with seated clinic systolic blood pressure (SBP) above 140 mmHg or home SBP above 130 mmHg despite on treatment for at least three months of maximally tolerated dose of an ACEI or an ARB, a CCB, and a diuretic were eligible for this trial. Patients rotated, in a randomized manner, through 12 weeks of once daily treatment with each of spironolactone, bisoprolol, doxazosin, and placebo, in addition to their baseline BP medications.

In PATHWAY-2, the average home SBP recorded in the morning and evening on 4 consecutive days before study visits served as the primary endpoint. Among the 314 patients, 219 (68.9%) of them achieved a home SBP of less than 135 mmHg, and 58% patients had their BP controlled, which resolved the resistant hypertension condition. The average reduction in home SBP by spironolactone was superior to placebo (8.7 mm Hg; $p< 0.0001$), superior to doxazosin (4.03 mm Hg; $p< 0.0001$), and superior to bisoprolol (4.48 mm Hg; $p< 0.0001$). The trial results supported that spironolactone was more effective than an alpha-1 blocker and beta-1 blocker as an add-on drug for the treatment of resistant hypertension.

ASPIRANT was another a prospective, double-blind, placebo-controlled, parallel-group trial addressing the concern about the drug that should be used in lowering BP in resistant hypertension[31]. Patients with office SBP ¬140 mm Hg or diastolic BP (DBP) ¬90 mm Hg despite treatment with at least 3 antihypertensive drugs, including a diuretic, were enrolled. A total of 117 patients were assigned using simple randomization method to receive either spironolactone or a placebo as an add-on drug to their antihypertensive regimen.

The primary endpoints in ASPIRANT were difference between fall of average daytime SBP and DBP between spironolactone and placebo groups after 8 weeks of treatment. Results showed that spironolactone led to an average decrease of 9.3 mm Hg in daytime SBP while the placebo resulted in an average decrease in 3.9 mmHg (between-group difference: 5.4 mm Hg; p = 0.024). However, spironolactone (- 4.2 mm Hg) did not significantly influence daytime DBP mm Hg compared to the placebo (-3.2 mm Hg) with a p-value of 0.358. In summary, the trial showed that spironolactone was an effective drug for lowering SBP in resistant hypertension patients using an average of 4.5 antihypertensive drugs after 8 weeks of treatment.

Safety

The safety results in PATHWAY-2 and ASPIRANT trials were illustrated below[30, 31].

Spironolactone patients had the occurrence of similar adverse events such as fatigue, diarrhea, and exertional dyspnea in both trials. In PATHWAY-2 trial, 58 (19%) of the spironolactone participants experienced adverse events including diarrhea, fatigue, dizziness, and exertional dyspnea; whereas 67 (23%) of the doxazosin participants and 68 (23%) of the bisoprolol participants had experienced adverse events during the trial. These results showed that spironolactone patients had the lowest percentage of adverse events among patients of the three drugs. In ASPIRANT trial, 24 adverse events occurred in the spironolactone group (n = 55) while 26 occurred in the placebo group (n = 55), and the adverse events that were probably and possibly related to the study medication in the spironolactone group included diarrhea, fatigue, vertigo, and exertional dyspnea.

On the other hand, there were varying patterns of serious adverse events with only rare occurrence in both trials. In PATHWAY-2 trial, 7 (2%) spironolactone patients experienced serious adverse event such as atrial fibrillation, hypertension, neoplasm recurrence, skin graft, skin ulcer, transitional cell carcinoma, and type 2 diabetes mellitus. For other comparison groups, 5 (2%) doxazosin patients, 8 (3%) bisoprolol patients, and 5 (2%) placebo patients experienced serious adverse events, and the difference was not statistically significant among the four groups (p = 0.82). In ASPIRANT trial, only 2 serious adverse events occurred among 55 spironolactone patients: one patient with acute gastroenteritis and symptomatic hypotension, and one patient with diarrhea and dyspepsia.

Discontinuation of treatment due to intolerability of adverse events was also rare in both PATHWAY-2 and ASPIRANT trials. In PATHWAY-2 trial, there were only 4 (1%) withdrawals for adverse events in both the spironolactone group and bisoprolol group, and the withdrawals percentage was the same for the placebo group (1%). Doxazosin group had the highest number of withdrawals (9; 3%). Further analysis, however, showed that there was no statistically significant difference in the withdrawals for adverse events among the four groups (p = 0.28). In ASPIRANT trial, discontinuation of study medication due to adverse events occurred in 2 (3.6%) patients using spironolactone and in 1 (1.8%) patient using the placebo (p = 0.618).

In addition to the abovementioned adverse events, in PATHWAY-2 trial 6 out of 285 patients (2.1%) exposed to spironolactone developed hyperkalemia with serum potassium greater than 6.0 mmol/L, but discontinuation due to hyperkalemia as well as renal impairment and gynecomastia were not increased with spironolactone comparing with other antihypertensives and placebo. In ASPIRANT trial, there was an increase in serum potassium in the spironolactone group (0.3 mmol/L) while no change in the placebo group (0 mmol/L) and this between-group difference was statistical significant (p < 0.001); similarly, there was an increase in serum creatinine in the spironolactone group (7 μmol/L) while no change in the placebo group (0 μmol/L) and this between-group difference was also statistical significant (p < 0.001). No patient was excluded in ASPIRANT trial because of severe hyperkalemia or progression of renal impairment.

DISCUSSION

Both aprocitentan and spironolactone were proven to be well-tolerated and effective in the treatment of resistant hypertension. PRECISION and PATHWAY-2 trials showed the efficacy of aprocitentan and spironolactone, respectively, in reducing BP. However, as neither study concurrently evaluated both drugs in the same trial, a direct comparison of their efficacy cannot be made. To compare the efficacy of two drugs, a head-to-head randomized controlled trial would be necessary to show their comparative efficacy. Overall, both drugs resulted in a very low discontinuation rate due to adverse effects. For the adverse effect profile of the two drugs, dose-dependent fluid retention and anemia were the major adverse side effects observed in aprocitentan treatment while hyperkalemia and fatigue are the major adverse effects associated with spironolactone treatment. The summary of PRECISION and PATHWAY-2 trials are presented in Table 1 and 2.

Table 1: Dual endothelin antagonist aprocitentan for resistant hypertension (PRECISION): a multicentre, blinded, randomised, parallel-group, phase 3 trial[16]

Journal	Lancet
Publication Year	2022
Study Year	June 2018 to April 2022
Locations	Europe, North America, Asia, and Australia
Settings	Hospitals and research centres
Settings	730 were randomized • 704 completed Part 1 • 613 completed Part 2 • 577 completed Part 3
Baseline patient characteristics	More than half were between age of 18 to 65 years, more than half were men, more than half were recruited in Europe, majority (>80 %) were White, and majority (>60%) used at least 4 antihypertensives at screening
Interventions / Comparison groups	Part 1: Aprocitentan 12.5 mg vs. Aprocitentan 25 mg vs. Placebo Part 2: Aprocitentan 25 mg Part 3: Aprocitentan 25 mg vs. placebo
Outcome(s) / endpoint(s)	Changes in mean trough sitting office SBP from baseline to week 4 (part 1) and from withdrawal baseline (week 36) to week 40 (part 3) Changes at week 4 and week 40 in mean trough sitting office DBP and in 24-hour SBP and DBP measured by ambulatory BP monitoring
Efficacy data	The least square mean change in office SBP at 4 weeks: • Aprocitentan 12.5 mg: -15.3 mm Hg • Aprocitentan 25 mg: -15.2 mm Hg • Placebo: -11.5 mm Hg Office DBP also decreased with both aprocitentan doses compared with placebo: • Aprocitentan 12.5 mg: -3.9 mm Hg • Aprocitentan 25 mg: -4.5 mm Hg Office SBP after 4 weeks of withdrawal increased with placebo compared with aprocitentan (5.8 mm Hg) Office DBP after 4 weeks increased with placebo compared with aprocitentan (5.2 mm Hg) The results from ambulatory BP monitoring confirmed those derived from office measurements
Safety data	Most frequent adverse event was mild-to-moderate edema or fluid retention: • Aprocitentan 12.5 mg: 9% patients • Aprocitentan 25 mg: 18% patients • Placebo: 2% patients Edema or fluid retention also led to discontinuation in 7 patients treated with aprocitentan No signs of hepatotoxicity were observed Hemoglobin levels decreased with both aprocitentan doses: • Aprocitentan 12.5 mg: -8.0 g/L • Aprocitentan 25 mg: -8.5 g/L • Placebo: -0.4 g/L

Table 2: Spironolactone versus placebo, bisoprolol, and doxazosin to determine the optimal treatment for drug-resistant hypertension (PATHWAY-2): a randomised, double-blind, crossover trial[30]	
Journal	Lancet
Publication Year	2015
Study Year	May 2009 to July 2014
Locations	United Kingdom
Settings	Primary and secondary care sites
Number of patients	335 were randomly assigned and 21 were excluded due to no follow-up for any drug; 230 patients completed all treatment cycles
Baseline patient characteristics	Mean age of 61.4 years, 69% were male gender, mean home SBP of 147.6 mm Hg and mean DBP of 90.0 mm Hg, serum potassium level of 4.1 mmol/L, and eGFR of 91.1 mL/min
Interventions / Comparison groups	Spironolactone group vs. doxazosin group vs. bisoprolol group vs. placebo group
Outcome(s) / endpoint(s)	1. Difference in the home SBP change from baseline between spironolactone and placebo 2. Difference in home SBP change from baseline between spironolactone and the average of the other two active drugs (doxazosin and bisoprolol) 3. Difference in home SBP change from baseline between spironolactone and each of the other two active drugs (doxazosin and bisoprolol)
Efficacy data	Mean difference in home SBP change from baseline (all p-values < 0.0001): • Spironolactone vs placebo: 8.7 mm Hg • Spironolactone vs mean bisoprolol and doxazosin: -4.26 mm Hg • Spironolactone vs doxazosin: -4.03 mm Hg • Spironolactone vs bisoprolol: -4.48 mmHg
Safety data	Participants with serious adverse events: • Spironolactone (7; 2%) vs. doxazosin (5; 2%) vs. bisoprolol (8; 3%) vs. placebo (5; 2%) (p = 0.82) Participants with any adverse events: • Spironolactone (58; 19%) vs. doxazosin (67; 23%) vs. bisoprolol (68; 23%) vs. placebo (42; 15%) (p = 0.036) Participants with withdrawal for adverse events: • Spironolactone (4; 1%) vs. doxazosin (9; 3%) vs. bisoprolol (4; 1%) vs. placebo (3; 1%) (p = 0.28) Discontinuations due to renal impairment, hyperkalaemia, and gynaecomastia were not increased with spironolactone relative to other active drugs and placebo

Due to the risk of hyperkalemia, renal dose adjustment is required in spironolactone and it should not be used in patients with an elevated baseline potassium level, while renal dosing adjustment is not required in the treatment of aprocitentan. While aprocitentan provides a promising therapeutic option for resistant hypertension, it has a significantly higher cost than spironolactone. Its availability to patients is also a concern in other countries. For example, currently in the U.S., Tryvio is only available to patients through a specialty pharmacy. Aprocitentan also carries the boxed warnings about fetal harm based on animal data and therefore should be avoided in pregnancy[11]. Unlike spironolactone which had a long history of usage and clinical data, aprocitentan is a very novel drug newly approved for use in the U.S. and European Union last year, and its current place in therapy for resistant hypertension is yet to be defined clearly in different treatment guidelines. The latest 2025 American hypertension guideline is the first major clinical guideline that clearly defined the role of aprocitentan in the treatment algorithm for resistant hypertension[2]. Table 3 summarizes the pharmacological treatment recommendations for resistant hypertension with a focus on the use of spironolactone and aprocitentan in different clinical guidelines.

Table 3: Pharmacological treatment recommendations for resistant hypertension in international clinical guidelines		
	Spironolactone	**Aprocitentan**
2025 AHA/ACC guideline for hypertension[2]	Addition of a MRA for uncontrolled BP cases with an eGFR of ≥ 45 mL/min/1.73 m2, despite use with the first-line antihypertensives (combination of ACEI/ARB, CCB, thiazide-like diuretics)	For uncontrolled BP cases who cannot tolerate or have contraindications to MRA, the addition of one of the following drugs is reasonable: amiloride, beta-blocker, alpha-blocker, central sympatholytic, dual endothelin receptor antagonists, or direct vasodilators
2024 ESC guideline for hypertension[3]	In uncontrolled BP cases despite use of first-line antihypertensives, the addition of spironolactone should be considered. If BP is not controlled with a 3-drug combination and in whom spironolactone is not effective or tolerated, the following should be considered: • Use of eplerenone instead of spironolactone • Addition of a beta-blocker if not already indicated • Addition of a centrally-acting drug, an alpha-blocker, hydralazine, or a potassium-sparing diuretic	New medication that awaits supportive evidence from cardiovascular outcomes trials prior to guideline endorsement
2023 ESH guideline for hypertension[32]	For uncontrolled BP cases with eGFR ≥ 30 mL/min/1.73 m2 despite use of ACEI/ARB, CCB, and thiazide diuretic, the following should be considered: • Addition of spironolactone (preferred) or other MRA • Addition of beta-blocker or alpha-1 blocker • Addition of centrally acting drug	May also be used depending on approval and availability
2023 updated NICE guideline for hypertension[33]	Use of further diuretic therapy with low-dose spironolactone should be considered for cases who have a blood potassium level of 4.5 mmol/L or less Use of an alpha-blocker or beta-blocker should be considered for cases who have a blood potassium level of more than 4.5 mmol/L	*Not mentioned*

CONCLUSION

At present, few studies examining the long-term adverse effects of aprocitentan had been conducted, and more follow-up research has to be conducted to investigate its long-term safety profile and evaluate the possibility of registration of aprocitentan in Hong Kong.

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Questions for Pharmacy Continuing Education Program

2 CE Units

Use of Aprocitentan and Spironolactone in Resistant Hypertension Management

1. ***Which of the following option(s) best describes the definition of resistant hypertension?***
   - *I. Blood pressure above goal despite treatment with any two antihypertensive drugs.*
   - *II. Blood pressure above goal despite treatment with three antihypertensive drugs with different mechanisms of action, including a diuretic, at maximally tolerated doses.*
   - *III. Blood Pressure is controlled only when four or more antihypertensive drugs are used.*

   a. I only
   b. II only
   c. I & III
   d. II & III

2. ***Which of the following statements about resistant hypertension is correct?***
   a. Resistant hypertension is very rare around the world.
   b. Chronic kidney disease, obesity, and diabetes are the risk factors for resistant hypertension.
   c. Spironolactone is the only add-on drug for treating resistant hypertension.
   d. There is no local data on the prevalence of resistant hypertension in Hong Kong.

3. ***Which statement is correct for aprocitentan?***
   a. High-fat meals greatly reduce its absorption.
   b. It is administered once daily due to its long half life.
   c. Dose adjustment is required in different ethnic groups.
   d. It must be taken on an empty stomach to avoid toxicity.

4. ***Which of the following is NOT an effect due to the pharmacology of spironolactone?***
   a. It increases the secretion of potassium.
   b. It increases the excretion of water.
   c. It decreases sodium reabsorption.
   d. It increases the risk of hyperkalemia.

5. ***Compared with other add-on agents, which is NOT a key statistical finding that supports the use of spironolactone for resistant hypertension?***
   a. Spironolactone produced a significantly greater reduction in home systolic blood pressure than placebo.
   b. Spironolactone produced a significantly greater reduction in home systolic blood pressure than both doxazosin and bisoprolol.
   c. Spironolactone significantly reduced both diastolic blood pressure and systolic blood pressure.
   d. Spironolactone showed no association with hyperkalemia and renal impairment.

6. ***Based on PATHWAY-2 and ASPIRANT, which clinical strategy best applies the trials' safety and efficacy findings to routine care for resistant hypertension?***
   a. Start low-dose spironolactone in every patient with resistant hypertension, irrespective of their serum potassium or creatinine levels.
   b. Avoid spironolactone entirely in resistant hypertension because of hyperkalemia risk.
   c. Use spironolactone only after all other antihypertensives have failed and dialysis is imminent.
   d. Start spironolactone at a moderate dose in suitable patients, check potassium and creatinine within a few weeks and titrate while monitoring.

7. ***Which of the following regions has aprocitentan been approved in?***
   (I) United States
   (II) European Union
   (III) Hong Kong
   a. I and II
   b. II and III
   c. I and III
   d. I, II and III

8. ***Which of the following statements is true about the PATHWAY-2 trial?***
   (I) The trial took place in Japan.
   (II) Spironolactone was found to be more effective as an add-on drug for the treatment of resistant hypertension than both an alpha-1 blocker and a beta-1 blocker.
   (III) It was a phase 4 clinical trial.
   a. I only
   b. II only
   c. I & II
   d. II & III

9. ***In a patient with resistant hypertension, when is spironolactone generally considered an appropriate fourth-line agent regarding baseline serum potassium and kidney function?***
   a. Potassium ≤ 3.5 mmol/L with eGFR > 20 mL/min/1.73 m^2
   b. Potassium ≤ 4.5 mmol/L with eGFR > 45 mL/min/1.73 m^2
   c. Potassium 4.5−5.0 mmol/L with eGFR > 45 mL/min/1.73 m^2
   d. Potassium ≤ 5.5 mmol/L with eGFR > 30 mL/min/1.73 m^2

10. ***Which of the following is correct about the PATHWAY-2, ASPIRANT, and PRECISION trials?***
    a. All were parallel-group trials.
    b. PATHWAY-2 was a crossover trial; ASPIRANT and PRECISION were parallel-group trials.
    c. No placebo arms were used in any of the trials.
    d. All trials had a 12-month duration.

Answers will be released in the next issue of HKPJ.

CE Questions Answer for HKPJ Vol 323(D&T)

Microbial Allies: Exploring the World of Probiotics

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

Advancing the Pharmacist's Role in Hong Kong Through System and Clinical Strategies Inspired by Australia

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ABSTRACT

Hong Kong's healthcare system is facing mounting challenges, including an ageing population, rising chronic disease prevalence, and the need for more accessible primary care. Community pharmacists, with their accessibility and expertise in medicines, are well-positioned to assume a bigger role in meeting these needs. Drawing on insights from the *Primary Care Pharmacy Fellowship Scheme* under Jockey Club PHARM+ Community Medication Service Network Project funded by The Hong Kong Jockey Club Charities Trust, which provided first-hand exposure to advanced pharmacy practice models in Australia, this article explores how Australian pharmacists deliver a broad range of clinical services beyond dispensing. These services are supported by structured funding, accreditation, regulatory enhancement, and digital health integration.

By integrating lessons from Australia with reflections on Hong Kong's local context, the article suggests a dual approach: system-level enhancement to create an enabling environment, and professional readiness to ensure pharmacists are equipped with the skills, collaboration networks, and public engagement strategies to succeed in expanded roles. The discussion aims to inspire reflection and dialogue among pharmacists, healthcare providers and various stakeholders on the future of primary care pharmacy model in Hong Kong.

Keywords: *Pharmacies, Primary Health Care, Pharmaceutical Services, Interprofessional Relations, Accreditation, Health Care Delivery*

INTRODUCTION

In recent years, Hong Kong's healthcare system has been under increasing pressure due to demographic and epidemiological changes. Rising demand from an ageing population, the growing burden of chronic diseases, and the need for more accessible primary care[(1)] have prompted policymakers and service providers to explore new models of service delivery. Community pharmacists, with their accessibility, medication expertise, and trusted status, are well-positioned to contribute more directly to community healthcare needs.

The Primary Care Pharmacy Fellowship Scheme under Jockey Club PHARM+ Community Medication Service Network Project funded by The Hong Kong Jockey Club Charities Trust offered a valuable opportunity to examine how another developed health system – Australia – has integrated community pharmacists into broader primary healthcare functions. During the three-week fellowship in Sydney and Wagga Wagga, the Hong Kong delegation observed a wide range of pharmacy practice models, including high-volume urban pharmacies, rural health programs, specialist compounding services, and aged care services.

Two key lessons emerged from the experience:

1. Expanded scope of practice: enabling pharmacists to provide a wider range of clinical services beyond dispensing.
2. System-level enablers: the policies, funding, accreditation, and digital infrastructure that make such services sustainable and consistent.

This article integrates these perspectives to stimulate professional discussion on how Hong Kong can strengthen its pharmacy profession through both personal professional growth and systemic enhancement.

EXPANDED ROLES IN AUSTRALIA

In Australia, community pharmacists are recognised as integral contributors to primary healthcare beyond the supply of medicines. During the fellowship, the delegation shadowed credentialed pharmacist conducting medication review at residential aged care facilities and participated in Home Medicines Review (HMR) workshops. These services involve comprehensive assessments of patients' medicines, identification of potential risks or interactions, and communication of recommendations to the patient's general practitioner. To strengthen patient-centred care, the on-site credentialed pharmacists work closely with nursing and medical staff in aged care facilities to improve medication safety and optimise therapy.

Pharmacists in New South Wales are authorised to provide a wide range of vaccinations, from influenza and COVID-19 under the National Immunisation Program to privately funded travel and shingles vaccines[2]. In some pharmacies, pharmacists administer thousands of vaccinations each year, improving convenience and coverage.

Figure 1: Designated vaccination room equipped for pharmacist-administered immunisations in a community pharmacy in Sydney.

The scope of practice also encompasses the management of certain minor ailments under structured protocols, such as uncomplicated urinary tract infections, common skin conditions, and continuation of oral contraceptives[3]. Pharmacists in Wagga Wagga contribute to public health initiatives like "Living Well Your Way," offering screening for potential chronic obstructive pulmonary disease (COPD) and heart failure, and referring patients to medical care for further assessment and potential diagnosis when appropriate[4].

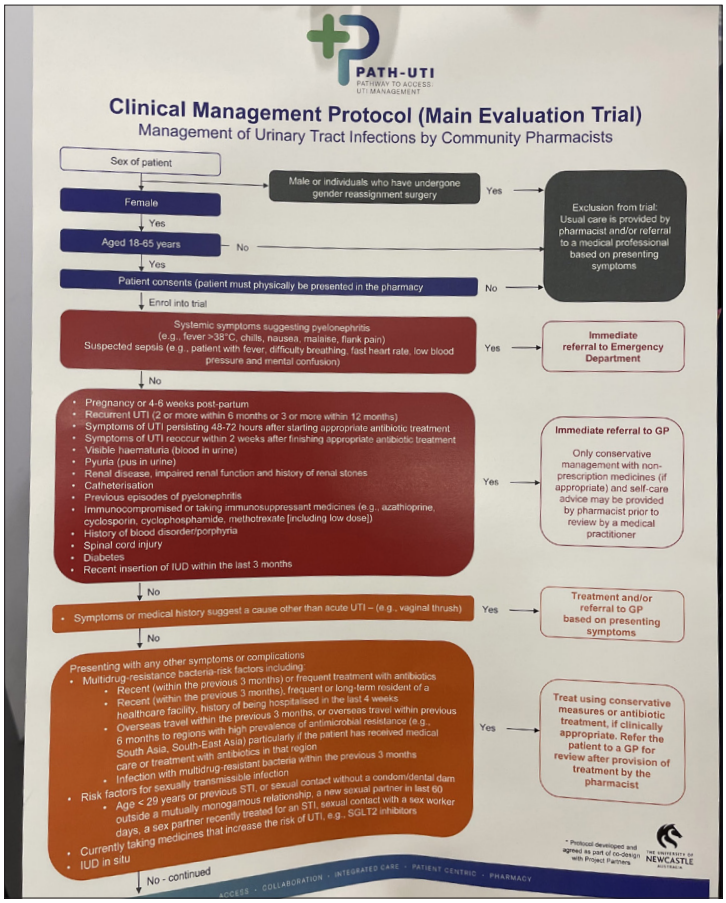

Figure 2: Standardised clinical management protocol for urinary tract infection managed by community pharmacists in New South Wales, Australia

The delegation also observed specialised services such as compounding personalised medicines, sleep apnoea diagnostics, and opioid dependence therapy. These examples illustrate the diverse ways pharmacists can address community healthcare needs in collaboration with other healthcare providers when targeted training, authorisation, and support are in place.

Figure 3: Compounding lab in an Australian community pharmacy for personalised medicine preparation.

The Skills Behind the Services

The fellowship experience highlighted that expanded services require more than regulatory permission. Pharmacists consistently demonstrated advanced communication skills, including effective patient interviewing and counselling, as well as strong interprofessional

collaboration with doctors, nurses, and allied health professionals. They applied evidence-based clinical decision-making to assess conditions and make appropriate recommendations.

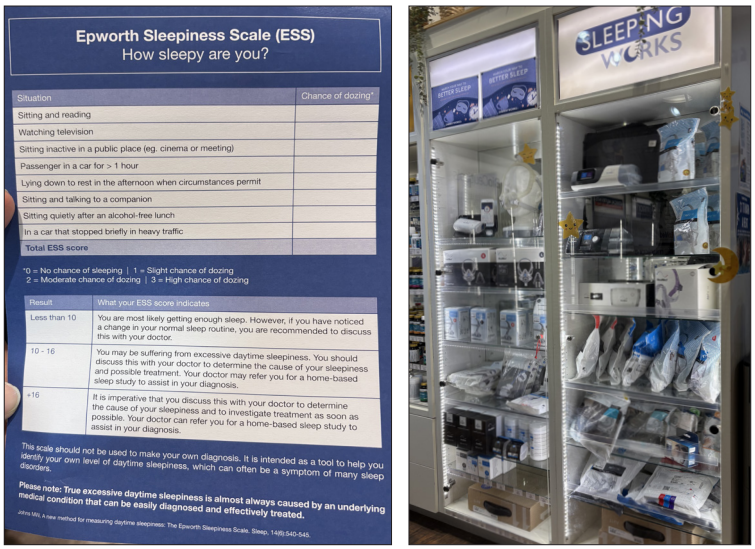

Figure 4: Sleep apnoea diagnostic services at a community pharmacy in collaboration with a respiratory and sleep specialist

Also, digital health literacy is increasingly important, enabling pharmacists to navigate shared health records, electronic prescribing systems, and integrated medication management platforms. Quality assurance was embedded in daily practice, through adherence to protocols, detailed documentation, and participation in accreditation programs.

In Australia, these competencies are developed through structured training, continuing professional development, and formal credentialing processes[5]. These ensure that pharmacists undertaking advanced services have the competence and confidence to deliver them safely and effectively.

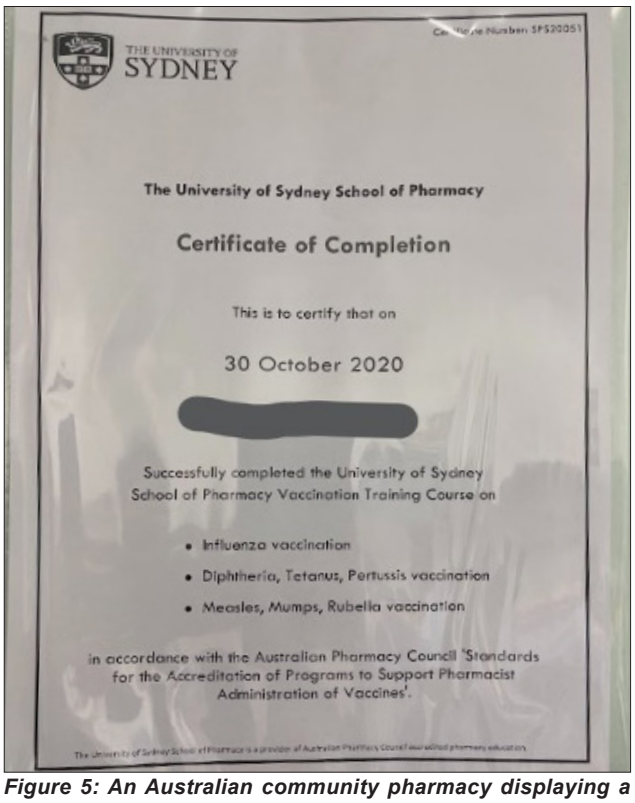

Figure 5: An Australian community pharmacy displaying a certificate of completion specifying the vaccine types that the pharmacist is qualified to administer

Figure 6: Quality Care Pharmacy Program (QCPP) Decal displayed in an Australian pharmacy to signify the accreditation.

THE SYSTEM BEHIND THE SERVICES

While individual skills are indispensable, the sustainability of expanded pharmacy services in Australia is closely linked to systemic support. A key example is the Community Pharmacy Agreement (CPA), a formal agreement between the government and the pharmacy sector that provides structured remuneration for dispensing, clinical services, and public health programs[6]. This ensures that services such as HMR, MedsCheck, and immunisations are accessible to patients without cost barriers and financially viable for pharmacies.

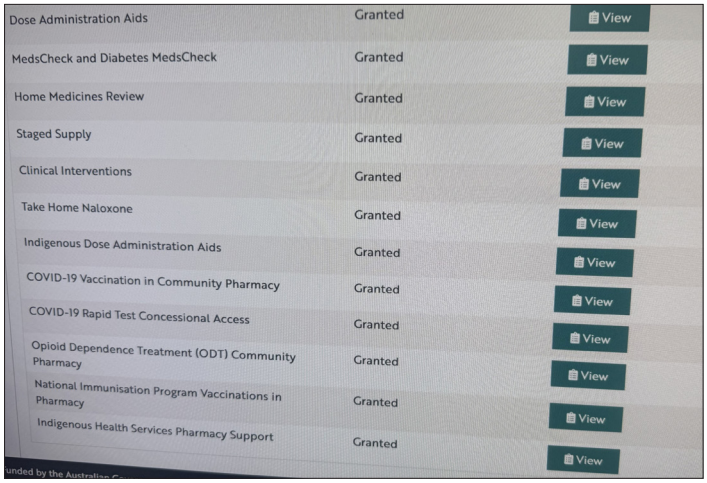

Figure 7: Screenshot of services eligible for remuneration at an Australian community pharmacy

Accreditation through the Quality Care Pharmacy Program (QCPP) ensures national standards for service quality, safety, and operational procedures, and is a requirement for participation in many funded programs[7]. Regulatory enhancement at the state level authorise pharmacists to manage certain conditions under clear protocols, enabling timely access to care while maintaining safety.

Digital health integration further supports this model. The My Health Record system provides a national platform for sharing key health information among healthcare providers, allowing pharmacists to access medication histories, test results, and hospital discharge summaries[8]. Collaborative networks, such as Primary Health Networks (PHNs), also play an important role by commissioning pharmacy-based programs and reinforcing collaboration with general practice and hospitals.

HONG KONG's CURRENT LANDSCAPE: STRENGTHS AND CHALLENGES

Hong Kong has a strong foundation for further development. Pharmacists are highly trained, university-educated, and regulated by the Pharmacy and Poisons Board[9]. Community pharmacies are easily accessible, and there is a growing interest in clinical services, as seen in pilot programs for minor ailments, medication management, and selected preventive services such as interprofessional immunisation program.

However, several challenges remain. The current scope of practice for most community pharmacists is limited to dispensing and providing over-the-counter advice. The Electronic Health Record Sharing System (eHRSS) has limited uptake and is voluntary, restricting pharmacists' access to comprehensive patient information. Furthermore, there is no structured funding or accreditation system for clinical services, leading to variability in service accessibility, quality and sustainability. Public awareness of pharmacists' clinical potential remains low, and intense retail competition can limit investment in service development.

Bridging the Gap with a Dual Approach

The Australian experience underscores that expanding pharmacists' scope requires both systemic enhancement and professional readiness.

On the systemic side, establishing a structured funding mechanism—informed by the approach of Australia's CPA—would allow pharmacy services such as medication reviews, chronic disease screening, and preventive care to be accessible to the public and sustainable for providers. Developing a Hong Kong-specific accreditation program would standardise service quality and build public trust, with accreditation linked to eligibility for funded programs. Regulatory reviews could explore opportunities for trained pharmacists to manage selected conditions and explore collaborative service models. Expanding the scope and functionality of eHRSS, with appropriate safeguards, would improve information sharing and care coordination.

On the professional side, pharmacists can take steps to prepare for expanded roles. Upskilling through continuing education in advanced communication, chronic disease management, interprofessional collaboration, and digital health will be necessary. At the same time, building collaborative networks with local clinics, hospitals, non-governmental organisations, and allied health professionals can strengthen interprofessional trust.

Moreover, participating in small-scale service pilots, such as medication adherence programs or health screening events can demonstrate value and generate local evidence. Engaging the public through community outreach and health promotion activities will also help raise awareness of pharmacists' clinical capabilities.

The success of HMR service in Australia shows how policy and professional readiness converge to deliver impactful pharmacy services. It is funded under the CPA and requires mandatory credentialing[10]. Its success depends on pharmacists' ability to conduct comprehensive clinical assessments and communicate effectively with general practitioners to ensure meaningful medication changes that improve patients' quality of life. The collaborative framework between pharmacists and doctors offers Hong Kong valuable insights into how it can harness the full potential of its primary healthcare workforce.

Opportunities for Hong Kong

Based on what the delegation saw in Australia, there appear to be opportunities for Hong Kong to pilot and evaluate similar models. Potential starting points include government-funded medication review services for elderly patients with multiple chronic conditions, development of an accreditation framework for pharmacies offering clinical services, expansion of pharmacist involvement in preventive care initiatives, and investment in digital infrastructure to facilitate secure and efficient information sharing.

In parallel, interprofessional education and training could prepare the next generation of pharmacists for broader roles, while public engagement campaigns could increase awareness and acceptance of new services. Realising these opportunities in Hong Kong would require careful adaptation to its healthcare structure, regulatory environment, and population needs.

Working Together to Build Trust and Alignment

Expansion of pharmacy services in Hong Kong should be developed in partnership with all healthcare stakeholders. Constructive dialogue with the medical, nursing, and allied health professions is essential to clarify roles, address concerns, and ensure that services complement rather than overlap with existing care.

Funding and accreditation frameworks should be co-designed with input from professional bodies, patient groups, and government agencies to ensure they meet community needs,

maintain safety, and support sustainability. Public communication on the expanded pharmacy services should emphasise the shared goal of improving access, reducing pressure of the healthcare system, and enhancing patient outcomes.

CONCLUSION: A SHARED RESPONSIBILITY FOR THE FUTURE

The fellowship experience demonstrated that when policy and practice evolve together, pharmacists can deliver high-quality, patient-centred care that strengthens the primary healthcare. For Hong Kong, the path forward requires a combination of systemic enhancement in funding, accreditation, regulatory support, and digital integration; and professional capacity building through skills development, collaboration, service innovation, and public engagement.

These reflections are informed by observations during the Primary Care Pharmacy Fellowship Scheme. By working in partnership, policymakers, professional leaders, educators, and frontline pharmacists can explore how best to adapt and implement ideas that can help create a future where patients benefit from safe, accessible, and integrated primary healthcare.

Acknowledgements

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Our heartfelt thanks go to the many individuals and organisations who welcomed us and openly shared their practice models and experiences. Their generosity in sharing knowledge and insights has been invaluable in deepening our understanding of community pharmacy practice and management.

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Jockey Club PHARM+ Community Medication Service Network - Roundtable Meeting on Development of Smoking Cessation Service in Community Pharmacy in Hong Kong

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INTRODUCTION

In support of the strategic development of primary healthcare in Hong Kong, the Hong Kong Jockey Club Charities Trust has initiated and funded Jockey Club PHARM+ Community Medication Service Network Project. In this project, the Department of Pharmacology and Pharmacy, The University of Hong Kong (HKU) is committed in building the capacity of community pharmacies, evaluating service effectiveness and enhancing professional standards to ensure service quality, efficiency and consistency.

HKU regularly convenes roundtable meetings with different stakeholders and creates a collaborative network among providers of community pharmacy services to foster knowledge exchange, collaborative learning and stakeholder engagement. These forums foster knowledge exchange and harmonise clinical practice, as well as strengthening interprofessional collaboration to meet the goals of a more robust primary healthcare system.

Roundtable Meeting on Development of Smoking Cessation Service in Community Pharmacy in Hong Kong (the Roundtable) was successfully held on 11 March 2026 in campus of The University of Hong Kong. This article presents the summary, key insights and consensus made in the Roundtable.

OBJECTIVES OF THE ROUNDTABLE

In light of Hong Kong's ongoing public health challenges related to tobacco use, community pharmacies represent a strategic and accessible platform for delivering effective smoking cessation services. Despite their potential, there is a recognised need to develop standardised service models, enhance pharmacists' training, and foster collaborative efforts with other healthcare providers and policymakers to maximise the impact. This meeting aims to convene a roundtable of pharmacy professionals, public health experts, service providers and other stakeholders to assess the current landscape, identify resource and training requirements, and collaboratively brainstorm a sustainable, people-centred service model. Strengthening the role of community pharmacies and pharmacists in smoking cessation could ultimately contribute to improved public health outcomes across Hong Kong.

Here are the key objectives of the Roundtable:

- To learn about the latest landscape, opportunities and challenges for developing a structured smoking cessation service in community pharmacy
- To explore resource needs in developing smoking cessation service
- To foster collaboration among different stakeholders such as academics, non-governmental organisation (NGO) partners and healthcare providers to build a robust and accessible model for smoking cessation in community pharmacies

ROUNDTABLE HIGHLIGHTS

The Roundtable convened over 30 representatives from a broad spectrum of stakeholders in the pharmacy and primary healthcare sectors. Participants included pharmacists from community pharmacies, NGOs, as well as District Health Centres (DHC) and DHC Express. The meeting also integrated perspectives from academia, smoking cessation service providers, and representatives of other professional bodies.

Three featured presentations offered practical insights into development of smoking cessation service in community pharmacy:

- Smoking Cessation Service in DHC – presented by Ms Dilys Chow, Pharmacist and Allied Health Team Leader of Sha Tin DHC Express
- Transforming Community Pharmacy Practice: Insights from Frontline Smoking Cessation Experience – shared by Mr John Lee, Programme Coordinator of Smoking Cessation Programme, United Christian Nethersole Community Health Service
- Latest Research Insights on Smoking Cessation and Tobacco Control - delivered by Professor Derek Cheung, Assistant Professor, School of Nursing, The University of Hong Kong

Throughout the Roundtable, participants and speakers engaged in a dynamic exchange of insights, offering critical perspectives on defining the professional roles of pharmacists and community pharmacies within the context of smoking cessation services and public health promotion.

Photo 1: Overview of the Roundtable regarding development of smoking cessation in community pharmacy in Hong Kong

EXECUTIVE SUMMARY FROM PRESENTATIONS

Smoking Cessation Service in DHC

Ms. Chow provided an in-depth review of the smoking cessation initiatives with the DHC framework. DHC serves as a primary resource hub for disease prevention and chronic disease management, with smoking cessation identified as one of the key functional priorities.

Since mid-2022, Sha Tin DHC Express has obtained the Listed Sellers of Poisons license, enabling pharmacists to provide free nicotine replacement therapy (NRT) alongside professional counselling. The service follows a structured five-step clinical pathway:

1. Identification: Active engagement and screening via health risk assessments and community outreach
2. Referral: Utilising internal, external, and self-referral mechanisms
3. Assessment and counselling: Applying the 5A/5R/5D frameworks and the Fagerström Tolerance Scale to evaluate nicotine dependence and readiness to quit
4. Follow-up: Continuous monitoring (face-to-face or via phone) for withdrawal symptoms and NRT adherence
5. Clinical referral: Escalating cases requiring medical attention or other interventions such as Chinese Medicine and acupuncture, psychosocial support

Ms Chow highlighted that one of the critical aspects of this clinical role is the management of complex comorbidities. Recognising that smokers often present with concurrent conditions such as hypertension, diabetes mellitus, and mental health disorders, pharmacists perform vital medication reconciliation. They ensure that smoking cessation pharmacotherapy is safely integrated with existing chronic medication regimens, mitigating potential drug-disease or drug-drug interactions while supporting patients through the physiological and psychological challenges of nicotine withdrawal. During the case-sharing session, Ms Chow particularly emphasised that pharmacists play a pivotal role in reinforcing medication adherence and optimising the use of appropriate pharmacological interventions, including nicotine patches, gums, and lozenges.

Beyond individual clinical care, strategic public engagement is crucial to expanding the reach of smoking cessation services within the DHC framework. To this end, Sha Tin DHC Express actively participates in community-wide campaigns such as hosting interactive booths in shopping mall for 'World No Tobacco Day' organised by the Hong Kong Council on Smoking and Health to raise public awareness.

During the 'Quit in June' initiative organised by Department of Health, pharmacists take a proactive lead in providing free counseling and distributing one-week NRT trial packs to both registered DHC members and the general public, effectively fostering a community-wide 'readiness to quit' through a better accessibility of services.

The success of smoking cessation is fundamentally rooted in a collaborative approach and the provision of robust psychosocial support. The DHC smoking cessation service exemplifies a multidisciplinary management approach, integrating social support, pharmacological expertise, and community resources to enhance the public's 'readiness to quit' and improve long-term health outcomes.

Photo 2: Ms Dilys Chow presents on the DHC smoking cessation service model

Transforming Community Pharmacy Practice – Insights from Frontline Smoking Cessation Experience

Mr Lee shared valuable insights from his extensive frontline experience in United Christian Nethersole Community Health Service smoking cessation programme. Established in 2013, this comprehensive 'one-stop' community model serves diverse population, including local residents, ethnic minorities and new immigrants. The programme offers integrated care through clinic-based face-to-face counselling and treatment, alongside an innovative 'Mail-to-Quit' service that facilitates the delivery of NRT to selected participants' homes.

Drawing from years of frontline service, Mr Lee highlighted several critical challenges when delivering smoking cessation services.

A primary obstacle identified was the widespread misuse and misunderstanding of NRT. These misconceptions are frequently identified during the initial client intake, often before the formal cessation programme begins. Despite the accessibility of over-the-counter smoking cessation products in Hong Kong, many service users struggle with complex dosing regimens, leading to poor compliance and suboptimal outcomes. Mr Lee pointed out that clients often get confused with different NRT formulations or dosages. For example:

- Ambiguity in 'as needed' usage of short-acting NRT such as chewing gums: Clients are often unclear on the timing, whether to use it at the first urge or only when they are already at a smoking spot, as well as the maximum daily dosage or duration of use.
- The high-dose fallacy: There is a common misconception among users that starting with the higher, if not the highest dose of NRT patch automatically yields better results. Mr Lee stressed that education on individualised titration based on their nicotine dependence levels rather than a one-size-fits-all high-dose approach is critical.
- Patch efficacy and duration (e.g. every 16 hours, every 24 hours): Users frequently question the comparative efficacy of different patch formulations, such as whether a 25mg/16h patch offers superior outcomes over a 21mg/24h patch.
- Harm reduction versus absolute cessation: Many smokers struggle with the transition, often attempting to smoke less while using NRT rather than achieving total abstinence from the beginning.

The suboptimal usage and poor understanding of smoking cessation medication create a significant psychological barrier to quit, which diminishes their self-efficacy and motivation to continue the cessation journey.

Another challenge discussed was how pre-existing mental health conditions, psychiatric disorders, and other substance use disorders complicate smoking cessation. Mr Lee emphasised a fundamental shift in clinical perspective: smoking is not merely an isolated addiction, but also a life-correlated behavior. In many cases, smoking is the result of underlying life difficulties and psychological distress rather than the root problem itself. For pharmacists looking to develop smoking cessation services, this necessitates a more empathetic, integrated and multidisciplinary approach.

The rising trend of alternative smoking products (ASPs) such as e-cigarettes and heated tobacco presents a new clinical frontier. Mr Lee shared that many service users perceive ASPs as 'safer' alternatives or effective tools for quitting traditional cigarettes, often leading to a prolonged nicotine addiction. While existing smoking cessation services in Hong Kong are primarily designed for conventional tobacco smokers, there is a service gap for ASP users seeking to quit.

Mr Lee offered key strategic recommendations for community pharmacy to develop the unique service model. He emphasised the impact of medical professionalism on addressing the pharmacological complexities of cessation. Community pharmacists should leverage their expertise to provide individualised medication and health education that directly addresses the client's specific needs. Furthermore, there is a critical need to integrate mental health awareness in pharmacy practice. Pharmacists should be prepared to engage with a client's broader mental state and life context, as underlying stressors are often the primary triggers for relapse. By adopting this holistic approach, pharmacists can effectively identify potential clients who require further psychosocial support from other healthcare professionals or social service units, alongside their pharmacological treatment.

Photo 3: Mr John Lee shares his insights of smoking cessation programme

Latest Research Insights on Smoking Cessation and Tobacco Control

Professor Cheung shared critical insights into the latest research and clinical guidelines, emphasising the transformative role of healthcare professionals in tobacco control through brief

interventions and technological integration in primary healthcare. He highlighted that even a less than 30-second intervention from a healthcare professional can significantly motivate quit attempts, making the implementation of Very Brief Advice (VBA) a pragmatic strategy for busy clinical settings.

To standardise this approach for frontline pharmacists, he introduced the AWARD model (Ask, Warn, Advise, Refer, and Do-it-again). Professor Cheung specifically underscored the importance of professional delivery during these potent 30-second encounters: the practitioners make eye contact, speak solemnly and gesticulate to warn the absolute risk of smoking (e.g. 1 in 2 smokers will be killed by tobacco), advise immediate cessation, and refer to professional services with leaflets. Given that community pharmacies are one of the highly accessible primary healthcare facilities, pharmacists are uniquely positioned to integrate these high-impact, brief interventions into their routine patient encounters.

Apart from VBA, Professor Cheung highlighted the importance of active referral models. Unlike conventional methods where smokers are only given information, active referral involves the proactive transfer of a client's contact information to a smoking cessation service provider at the precise moment when their motivation to quit is highest. The sooner a client is referred, the higher the intention of quitting. Utilising the established referral channels like Integrated Smoking Cessation Hotline 1833183, community pharmacy can streamline the referral process with minimal time burden and reduce the attrition rate.

The session also explored the frontiers of digital and artificial intelligence (AI)-driven smoking cessation interventions. Professor Cheung presented robust evidence supporting chat-based instant messaging and generative AI chatbot as effective tools in smoking cessation.

The final theme from the sharing emphasised a strategic shift toward proactive outreach, delivering timely interventions directly to smokers rather than waiting for them to seek professional help. Smoking hotspots, such as the exits of railway stations, shopping malls, and large commercial buildings, present critical opportunities for healthcare professionals or service providers to engage individuals in their natural environments. Professor Cheung highlighted a successful outreach example targeting construction sites during workers' break times. Utilising carbon monoxide analyser as a tangible physiological assessment tool, practitioners can immediately demonstrate the impact of smoking on the body. This proactive engagement not only raises health awareness in hard-to-reach populations but also provides a low-barrier entry point for smokers to receive brief advice and initiate their cessation journey within the primary healthcare network.

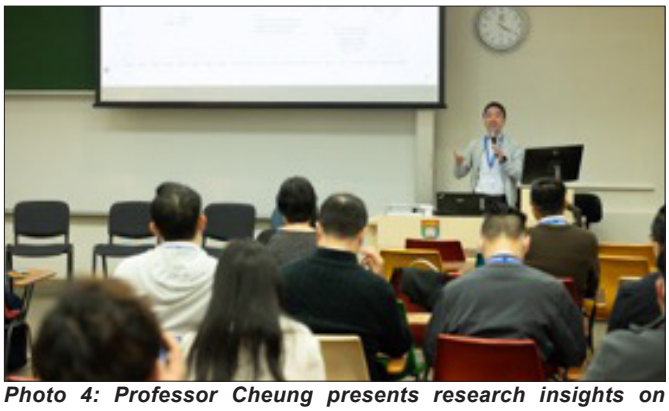

Photo 4: Professor Cheung presents research insights on smoking cessation

KEY INSIGHTS FROM THE DISCUSSION

The interactive panel discussion between speakers and the participants synthesised the challenges and opportunities for integrating smoking cessation into routine pharmacy practice, focusing on three strategic pillars:

- Tailored capacity building: Participants suggested that resources for clinical shadowing or case-based simulations are essential to build the confidence needed for managing complex and co-morbid cases.
- Sustainability: There was a shared recognition that while pharmacists are committed to public health, smoking cessation is an effort-intensive intervention. The discussion explored the necessity of future reimbursement models or financial subsidies to ensure professional and financially viable clinical services.
- Proactive client engagement: Participants discussed strategies for engaging pre-contemplative smokers during routine encounters such as chronic disease medication dispensing, utilising VBA as a low-barrier tool to initiate the conversation without overwhelming the pharmacy's daily workflow.

Photo 5: Panelists discuss the development of smoking cessation in community pharmacy

SUMMARY OF THE ROUNDTABLE OUTCOMES

The Roundtable served as a dynamic platform for knowledge exchange, synthesising evidence-based strategies and common

consensus within pharmacy service providers:

- Collaborative framework: The sharing facilitated a clearer understanding of the active referral pathway, positioning the community pharmacy as a vital access point to the broader primary healthcare network and smoking cessation resources.
- Consensus on brief interventions: There was a strong resonance among participants regarding the feasibility of VBA in a busy community pharmacy setting.

INSIGHTS AND NEXT STEPS

To translate these insights into practice, the following strategic actions were proposed:

- Community pharmacies might establish formal active referral pathways with Integrated Smoking Cessation Hotline 1833183 to strengthen interdisciplinary collaboration. By leveraging the unique accessibility and professional characteristics of community pharmacy, pharmacists can provide a seamless, holistic care that bridges the gap between community encounters and specialised clinical support.
- Community pharmacies are strongly encouraged to participate in the 'Quit in June' campaign. This initiative empowers pharmacists to provide free one-week NRT trial packs following a brief clinical assessment.
- Proactive community engagement is a key approach to maximise the utilisation of smoking cessation resources.
- Recognising that smoking cessation is a clinically effort-intensive service, the Roundtable emphasised the need for ongoing policy advocacy. To ensure the long-term sustainability of smoking cessation services in community pharmacy, it is essential to explore reimbursement models and funding schemes. Despite the resource-intensive nature of this clinical service, the pharmacy profession remains committed to supporting these initiatives for the overarching benefit of public health.

CONCLUSION

The roundtable underscores a pivotal paradigm shift in the provision of smoking cessation services in community pharmacies in Hong Kong. By integrating the systemic framework of local and international guidelines, the clinical insights from frontline service providers, and the latest evidence-based research from academia, this collaborative dialogue has established a comprehensive roadmap for the pharmacy profession.

The successful evolution of smoking cessation services in community pharmacy will hinge on interdisciplinary collaboration. These initiatives will not only enhance population health outcomes but also play a critical role in fostering a tobacco-free culture across the city. By aligning pharmacy practice with the government's vision of a Smoke-free Hong Kong, the profession remains a steadfast partner in the collective effort to safeguard public health and achieve a sustainable tobacco-free future.

SOURCE OF FUNDING

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NEW PRODUCT

Kisunla® Concentrate For Solution For Infusion 350mg/20ml

(Eli Lilly)

edited by Lucilla Leung

Qualitative and Quantitative Composition

Each vial contains 350mg/20ml(17.5mg/ml) donanemab. Donanemab is a recombinant monoclonal humanised antibody produced in Chinese Hamster Ovary(CHO) cells and has a molecular weight of 145kDa.

Indications

KISUNLA is indicated for the treatment of patients with Mild Cognitive Impairment (MCI) due to Alzheimer's disease and Mild Alzheimer's dementia (Early Symptomatic Alzheimer's disease) that are apolipoprotein EƐ4 (ApoEƐ4) heterozygotes or non-carriers.

Beta amyloid evidence consistent with Alzheimer's disease (AD) should be confirmed using a validated test prior to initiating treatment.

ApoE ε4 Genotype

KISUNLA is not indicated in apolipoprotein Eε4 (ApoE ε4) homozygous patients. Patients who are ApoE ε4 homozygotes (approximately 15% of Alzheimer's disease patients) treated with this class of medications, including KISUNLA, have a higher incidence of amyloid-related imaging abnormalities (ARIA) in the brain, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and non-carriers. Testing for ApoE ε4 status is required prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results.

Dose and method of administration

Treatment should be initiated by a physician experienced in the diagnosis and treatment of Alzheimer's disease. KISUNLA should be administered under the supervision of a multidisciplinary team trained in detection, monitoring and management of Amyloid Related Imaging Abnormalities (ARIA) and experienced in detecting and managing infusion related reactions.

The recommended dose of donanemab is 350 mg for the first dose, 700 mg for the second dose, 1050 mg for the third dose (350/700/1050 mg), followed by 1400 mg every 4 week. Treatment should be maintained until amyloid plaques are cleared, as confirmed using a validated method, up to a maximum of 18 months. Treatment should be continued for up to 18 months if monitoring of amyloid plaque clearance with a validated method is not possible. The benefit-risk of treatment should be reassessed at regular intervals on an individual basis and if the patient progresses to moderate Alzheimer's disease.

Monitoring and dosing interruption for amyloid related imaging abnormalities

A recent (within 6 months) baseline brain magnetic resonance imaging (MRI) should be available prior to initiating treatment. An MRI should be performed prior to the second dose (one month), prior to the third dose (two months), prior to the fourth dose (usually three months) and prior to the seventh dose (usually six months). The recommendations for dosing interruptions for patients with amyloid-related imaging abnormalities-oedema/effusions (ARIA-E) and amyloid-related imaging abnormalities haemorrhage/hemosiderin deposition (ARIA-H) are provided in Table 1.

Table 1: Dosing Recommendations for Patients with ARIA-E and ARIA-H

	ARIA-E and ARIA-H Severity on MRI		
Clinical Symptom	**Mild**	**Moderate**	**Severe**
Asymptomatic	Consider suspending dosing	Suspend dosing	Suspend dosing
Symptomatic	Suspend dosing		

Contraindications

Hypersensitivity to donanemab or to any of the excipients listed in the excipients.

Baseline MRI findings of prior intracerebral haemorrhage greater than 1 cm, more than 2 microhaemorrhages, superficial siderosis or vasogenic oedema (ARIA-E), which are suggestive of cerebral amyloid angiopathy (CAA).

Severe white matter disease.

Any finding that could prevent a satisfactory MRI evaluation for safety monitoring.

Interactions

No drug interaction studies have been performed. No pharmacokinetic: drug interactions are expected based on the characteristics of donanemab.

Adverse Effects

Treatment Emergent Adverse Events Occurring in ≥2% of Placebo-Controlled Donanemab-Treated Patients

Gastrointestinal disorders

Nausea

Vomitting

General disorders and administration site conditions

Asthenia

Infections and infestations

Nasopharyngitis

Injury, poisoning and procedural complications

Fall

Infusion related reactions

Skin laceration

Investigations

Weight decreased

Metabolism and nutrition disorders

Dehydration

Musculoskeletal and connective tissue disorders

Arthralgia

Pain in extremity

Neoplasm benign, malignant and unspecified (incl cysts and polyps)

Basal cell carcinoma

Nervous system disorders

Amyloid related imaging abnormality oedema / effusion

Amyloid related imaging abnormality – microhaemorrhages and haemosiderin deposits

Headache

Superficial siderosis of central nervous system

Dizziness

Syncope

Cerebral microhaemorrhage

Psychiatric disorders

Depression

Insomnia

Reproductive system and breast disorders

Benign prostatic hyperplasia

Pharmacological Properties

Pharmacodynamic Properties

Reductions in cerebral amyloid plaques, as measured by amyloid positron emission tomography (PET), were observed among patients receiving donanemab. Donanemab reduced tau pathophysiology, as measured by plasma P-tau217.

Mechanism of action

Donanemab is an immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against an insoluble, pyroglutamate N terminal truncated form of amyloid beta (N3pE Aβ) present only in brain amyloid plaques. Donanemab binds to N3pE Aβ and aids plaque removal through microglial-mediated phagocytosis.

Biomarkers

The percentage of donanemab treated patients with amyloid clearance (that is, less than 24.1 Centiloids or visually negative on an amyloid PET scan) in Study TRAILBLAZER-ALZ2.

Forensic classification

P1S1S3

Hong Kong Pharmaceutical Journal: For Detailed Instructions for Authors

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