Innovation and Professional Realignments

Doctor and pharmacist — *back to the apothecary!*

Siaw-Teng Liaw and Gregory Peterson

**Abstract**

The Australian National Medicines Policy embodies four tenets: availability, quality, safety and efficacy of medicines; timely access to affordable medicines; quality use of medicines (QUM); and a responsible and viable medicines industry. The promotion of QUM requires a multidisciplinary approach, including contributions from government, the pharmaceutical industry, health professionals, consumers and academia. However, there are significant tensions and unintended effects associated with the multidisciplinary approach, especially with the relationships between prescribers and dispensers of medicines.

The general practitioner and the pharmacist share a common ancestor — the apothecary. The separation of dispensing from prescribing, which began in medieval Europe and 19th century England, reframed and confined the patient–doctor relationship to one of diagnosis, prescription and non-drug management. The role of pharmacists was limited to dispensing, though the present trend is for their responsibilities to be widened. Historical antecedents, the contribution of an increasing number of actors to the costs of health care, universal health insurance and an evolving regulatory framework, are among the factors influencing doctor–pharmacist relations.

The prescribing and dispensing of medicines must be guided by an ethical clinical governance structure encompassing health professionals, regulators, the pharmaceutical industry and consumers. There must be close monitoring of safety and effectiveness, and promotion of quality use of medicines and improved patient outcomes. Ongoing training and professional development, within and across professional boundaries, is essential to support harmonious and cost-effective interprofessional practice. The approach must be “apothecarial” with complementary roles and responsibilities for the prescriber and dispenser within the patient–clinician therapeutic relationship, and not adversarial.

*The Australian* health care environment faces a number of challenges related to the increase in chronic illness, an ageing society, feminisation of the health workforce, increasing specialisation, escalating costs of health care, rising patient expectations, the worried well, and the attenuation of the traditional relationship between increasingly mobile working families and their family doctors. Australian health care is traditionally episodic, based on separate encounters with a number of independent providers. This fragmented care, along with poor communication and inconsistencies in health practice within a complex environment and knowledge base, also makes it difficult for the patient to understand and manage their illness and care.

The Chronic Care Model in the United States and the Expert Patient Program in the United Kingdom place the partnership between the patient and clinician/practice as a central component of successful care of chronic illness. The vision is one of “activated” and engaged patients in full control of the management of their own illness. This underpins the importance of patient-centred care and highlights the centrality of the clinician–patient therapeutic relationship.

This paper focuses on the relationship between two key players in the quality use of medicines: the general practitioner and the pharmacist. The

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general practitioner and the pharmacist share a common ancestor — the apothecary — who diagnosed, prescribed and dispensed a medicine. The apothecary's medicine embodied medical knowledge and underpinned the patient's expectation of a medicine as the "product" of patient–doctor interaction. The skill of the diagnostician was embedded in the prescription, and payment was for the medicine, the tangible output of the encounter. With dispensing separated from diagnosis and prescribing, the doctor's direct link to the symbolic value of the prescribed medicine is diminished. The doctor is also no longer a purveyor of medicines.

The doctor–pharmacist relationship will also be examined in the context of an increasingly complex economy, with more actors contributing to the direct costs of health care, universal health insurance, pharmaceutical benefits, an evolving regulatory framework, the National Medicines Policy, and a complex interplay of intrinsic and extrinsic factors that influence the doctor–pharmacist relationship. Some ways forward will also be discussed.

The Australian National Medicines Policy
The Australian National Medicines Policy (NMP) incorporates four tenets: (1) availability, quality, safety and efficacy; (2) timely access to affordable medicines; (3) quality use of medicines (QUM); and (4) a responsible and viable medicines industry. The NMP encompasses a mix of educational, managerial and regulatory strategies to promote QUM, emphasising links among government, industry, consumers, prescribers and dispensers of medicines. In its early stages, the development and implementation of the NMP was coordinated by the now dormant Australian Pharmaceutical Advisory Council (APAC), which included representation from all major professional and consumer groups.

Equity and access to affordable medicines
Medicare Australia subsidises medicines and health services through the Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Scheme (MBS). In addition, there is a cap on individual or household annual out-of-pocket expenditure on medicines and health services after which subsidies for PBS and MBS services are extended further or made available for free. The Repatriation PBS (RPBS) provides veterans with subsidised medicines. Medicines included in the PBS may be prescribed in three categories: (1) unrestricted, (2) restricted to specific conditions, or (3) requiring an authority to prescribe. An authority to prescribe entails a telephone call with a trained clerical person — a cost containment approach resented by many doctors. The recently introduced streamlined authority codes scheme allows doctors to prescribe a list of (cheaper) drugs, using a drug group number available online, bypassing the telephone approval process. Some drugs, such as isotretinoin (Roaccutane), are prescribed only by specialists.

When patents expire, medicines prices fall as cheaper generic brands become available, making more cost-effective care possible. However, there are many vexed issues for policymakers, regulators and professionals in this area, including the sometimes significant delay between patent expiry and the availability of a generic, market distortions through authorised or "pseudo-generic" brands, and the difficulties (addressed through recent PBS changes) of generating cost benefits for consumers and the government from the availability of cheap generics. Strategies to foster the use of generic medicines include differential subsidies to promote them over proprietary drugs and allowing pharmacists to substitute generic drugs for proprietary brands, legalised in Australia in 1994. However, while there are now government incentives for Australian pharmacists to dispense generic brands, there are no similar incentives for doctors to prescribe them.

The "down-scheduling" of many previously prescription-only medications in Australia means pharmacists are "prescribing" an increasing range of medications (eg, non-steroidal anti-inflammatory drugs, histamine H2-receptor antagonists, emergency contraception). The "pharmacist only"
scheduled medicines, also available in many other countries, represent another strategy to improve access.

**Safety and quality in the use of medicines**

For a drug to be legally available to individuals in Australia, it must be approved by the Therapeutic Goods Administration (TGA). Listing on the PBS requires a recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC) and final approval by the Commonwealth Minister for Health or, if high costs can be anticipated, by the full Cabinet. In addition, the National Strategy for Quality Use of Medicines has a number of QUM strategies in place. The National Prescribing Service (NPS) was formed to provide independent advice to government and independent information to health professionals and consumers. In January 2008, the QUM map (www.qum-map.net.au) listed 1429 projects to promote QUM in Australia. These range across disciplines; hospitals and general practice; regulatory, managerial and educational strategies; and all attributes of QUM, which include efficacy, effectiveness, equity, safety, appropriateness and costs.

Safety is an increasing priority. An estimated 16% of hospitalised patients suffer an adverse event, with 50% of these events being preventable. Admissions in Western Australian public hospitals due to adverse drug events (ADEs) in people aged 60 years or over showed a five-fold increase in the age-standardised rate of ADE-related hospital stays between 1981 and 2002, with more than a doubling in the rate between 1991 and 2002. The largest increases occurred in those aged over 80 years — a worrying finding given the ageing Australian population. About 10.4% of the 17.5 million people who make 95 million visits to their general practitioner annually will experience an ADE; about one million being moderate or severe and 138,000 requiring hospitalisation.

**A multidisciplinary approach to safety and quality in the use of medicines**

The National Strategy for Quality Use of Medicines is multidisciplinary in nature, recognising that doctors, pharmacists, nurses and consumers all play roles in ensuring QUM. This gives rise to many challenges as teams must work across service boundaries and differing organisational, financial, professional and disciplinary requirements and priorities. In the management of chronic disease, the experience is as yet suboptimal with the recognition that multidisciplinary teams need to work more effectively. Collaboration between general practitioners and other health services often falls short of expectations.

In this context, there are significant tensions and unintended effects associated with the multidisciplinary approach to QUM and especially with the relationship between prescribers and dispensers. This paper examines the practical philosophy of the apothecary, its evolution into the separate roles of the pharmacist and the general practitioner, and the implications of this divide. Historical antecedents, an evolving regulatory framework, health insurance and pharmaceutical benefits, and a complex interplay of intrinsic and extrinsic factors will be explored in relation to the doctor–pharmacist relationship.

**Methods**

The literature was surveyed from the perspective of multidisciplinary and interprofessional care, general practice, pharmacy practice, primary health care, and quality use of medicines. A narrative review was conducted and the findings reported below.

**Findings**

**Historical antecedents**

The general practitioner and the pharmacist share a common ancestor — the apothecary. The antecedents of apothecaries can be found in ancient Egypt, Mesopotamia and Sumeria. The first recorded apothecary shops, which prepared “...a wide range of medicines including classical, Persian and Indian drugs and chemicals”, appeared c. 850 AD. Persian scholars introduced many medical and medicinal concepts into Europe. The
Edict of Palermo, issued in 1231, stated that medicine and pharmacy were separate professions requiring distinct skills, for example, compounding medicines versus diagnosis. It stipulated government control over many aspects of market entry, contracting and payment: physicians and apothecaries were not to enter into business relationships, and the number of apothecaries, their locations and prices were subject to government oversight. The financial motivation appeared to be the association of medicines with the commercially vital spice trade. It also helped that apothecaries had a relatively high social rank that allowed their profession to stake an independent claim on the role of dispensing.

This government-decreed separation spread across medieval continental Europe, regulated by central and local government authorities as well as professional guilds. Apothecaries were not distinguished from dealers in eastern herbs and spices (“spicers”), and overlapping functions continued into the 18th century. Apothecaries were in guilds alongside surgeons and barbers or had their own guilds. Disputes over professional boundaries with physicians were common. Five hundred years after the Edict of Palermo, the 1777 Royal Declaration in France established professional pharmacy in France and prohibited competing organisations, such as religious hospitals and societies, from selling drugs.

In 1617, King James I of England signed a charter establishing the Society of Apothecaries as a corporate body, with the caveat that the English apothecary “understood that he was not permitted to charge for his consultation, and was quite prepared to rely on the sale of drugs and medicines for his profit”. While the Apothecaries’ Charter did not specifically prevent apothecaries from examining and treating patients, “it was accepted” that apothecaries could only charge for drugs. This institution shaped the legal rules defining professional boundaries. The Society of Apothecaries won (on appeal to the House of Lords) a case brought against a member for providing medical advice to a patient because “their Lordships accepted the argument that it was contrary to custom and against the public interest to prevent the apothecaries from giving advice and treatment” to the poor and middle classes. The House of Lords’ decision took into consideration adherence to custom and the “public interest”. The argument that the poor should also have access to medical services thus enabled the apothecaries of England and Wales to integrate prescribing and dispensing. The Apothecaries Act (1815) recognised the role of the Society of Apothecaries to license apothecaries in the field of medicine — forerunners of the general practitioner.

The Edict of Palermo, which separated dispensing from prescribing, was a pragmatic strategy by a medieval European state to regulate the manufacture and sale of drugs. By the 18th century, this was common practice in Europe. In the UK, however, this separation was only consolidated through the welfare state and third-party payments arising from the 1911 National Insurance Bill and subsequent insurance scheme. Pharmacists were given the legal authority over dispensing in England. Doctors could still dispense for uninsured dependents, in rural areas with no pharmacy and in after-hours/emergency situations. Although the rural exception continues to today, the separation of prescribing and dispensing spread to cover almost all the population in conjunction with universal coverage under the UK National Health Service after World War II. Similarly, in Australia universal health insurance and pharmaceutical benefits have consolidated the separation of prescribing and dispensing. However, recent initiatives to promote an expanded role for pharmacists — pharmacist prescribing and involvement in health promotion and prevention — appear to reflect a growing recognition of the value (and cost-effectiveness) of the apothecary model. Does this mark a return of the apothecary or apothecarial practice by the pharmacist and doctor?

**Back to the apothecary?**

**Pharmacist prescribing**

In England, pharmacist supplementary prescribing and independent prescribing were introduced in 2003 and 2006, respectively, to improve access
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to medicines and better utilise the skills of health care professionals. To be eligible, pharmacists must have at least 2 years’ post-registration clinical experience in the UK.25 Pharmacist supplementary prescribing was allowed for a specific non-acute medical condition or health need in accordance with a clinical management plan agreed with a medical/dental practitioner and patient. Supplementary prescribing was extended in 2005 to include podiatrists, physiotherapists, radiographers, and optometrists. Supplementary prescribers must work within their professional competence and must consult and where necessary pass back prescribing responsibility to the medical/dental practitioner. The independent pharmacist–prescriber assumes responsibility for the assessment and consequent clinical management, including prescribing, for both undiagnosed and diagnosed conditions. While increasing, independent pharmacist prescribing in 2006 represented only 0.004% of primary care prescribing.26-28 Cardiovascular medicines were the most frequently prescribed, followed by central nervous system, respiratory, endocrine and gastrointestinal medicines.

The implementation of the UK supplementary and independent prescribing programs included training and a physician-supervised practicum to ensure public safety and probity, and a capacity to distinguish between professional and commercial responsibilities.29 The English Department of Health attempts to address potential conflicts of interest surrounding prescribing and dispensing responsibilities by requiring that, where a pharmacist both prescribes and dispenses a medicine, a “second check” must be carried out by a suitably competent person.25

In the US and Canada, pharmacists are able to legally prescribe a range of medicines.29,30 In the USA, protocol-based prescribing by pharmacists by 2001 had been successfully legislated in at least 25 states.29 The limited international experiences to date (UK, US, and Canada) suggest that pharmacists are capable of prescribing a range of drug therapies safely and effectively, including oral contraceptives, analgesics, antihypertensives and warfarin.29-35

Expanded roles for pharmacists

The pharmacy profession is currently exploring expanded roles in primary care. These include prevention and aspects of chronic disease management36 with medication reviews in individuals’ homes or residential aged care facilities37,38 and the development of formularies and reviewing repeat prescriptions.39 These are changes which give rise to new models of interprofessional care in the hospital and community.39 Pharmacists can improve prescribing practices, reduce health-care utilisation and medication costs, and contribute to clinical improvements in many chronic medical conditions, such as cardiovascular disease, diabetes, and psychiatric illness.41-43 Studies show that pharmacist involvement in therapeutic monitoring improved adherence to medicines and costs in asthma44 and outcomes of lipid-lowering drug therapy.45,46 Pharmacists accompanying physicians to visit patients with complex medical conditions reduced costs and simplified medicines regimes without reducing quality of care.47 Pharmacists employed in primary care practices controlled prescribing costs sufficiently to offset their employment costs.48

Experience to date indicates that while doctors were content for pharmacists to provide information regarding medicines or do simple health checks, they were less happy for them to be involved in prescribing decisions49-51 or to write sickness certificates for mild illnesses.52-53

The available evidence for an expanded role of pharmacists in prescribing and medication management draws mainly on descriptive and small-scale studies.54 More high-quality and larger scale studies are needed for a comprehensive assessment of the effectiveness of an extended role of pharmacists as independent health professionals or as participants in the multidisciplinary team.55-57

Tension areas between doctors and pharmacists

The changing role of pharmacists, and the possibility that their responsibilities could be extended further, is associated with an underlying tension between doctors and pharmacists. The issues
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revolve around professional authority and practice, remuneration and patient care.

There is a widespread perception that doctors and pharmacists prescribe and dispense to increase income or other benefits, and that their behaviour is influenced by links with drug manufacturers. While separation of dispensing removes direct financial incentives from doctors’ prescribing decisions, financial incentives may influence pharmacists’ dispensing; for example, whether to propose generic substitution and their choice of generic brand. However, patients are not necessarily able or willing to pay out of pocket for medicines, and professional norms and reputational mechanisms provide constraints on inappropriate behaviour. There are no studies directly comparing the cost-effectiveness of doctor and pharmacist dispensing, but a review of the strategies by East Asian countries to achieve separation concluded that neither physician nor pharmacist dispensing was intrinsically more cost-effective than the other.

In Australia, the mix of multidisciplinary strategies to promote QUM within a cost-effectiveness model highlights these tension areas. This is particularly evident in relation to the promotion of an increasing and broader role for pharmacists in prescribing, and in the prevention and management of chronic disease in a growing elderly population. The complex network of relationships within the QUM strategy, with actors pursuing different agendas, will influence, positively and negatively, the professional and personal relationships in predictable as well as unanticipated ways.

Patient self-treatment

The self-management activities of the patient and consumer, especially self-medication, are a significant factor. Self-treatment, defined as diagnosing a health problem, choosing medication or treatment and administering this without professional assistance, is of course common. Patients will seek medical expertise to obtain a medicine or, if knowledge of the medicine and its proper use is available directly, self-medicate. Self-medication is prevalent in Australia, where there is significant consumer spending on complementary and over-the-counter medicines.

Rising medicines costs for consumers as a consequence of higher PBS copayments (Sweeny in this issue, page 215) risk increasing the potential for unsupervised patient self-treatment, leading to inappropriate use of medicines. A particular risk is not recognising serious illnesses, with serious or even fatal consequences. It is important to enhance self-care skills, encourage use of safer alternatives, discourage indiscriminate use of potent medicines like antibiotics and encourage the seeking of assistance with more serious diseases. An interprofessional question is whether the pharmacist or non-medical prescriber is sufficiently prepared or motivated to promote QUM by the self-mediator.

Issues with expanded roles for pharmacists

Major reservations about prescribing by pharmacists and other health professionals include the lack of access to complete medical records, and accountability and compromised patient safety from not separating prescribing from dispensing. There are frequent misunderstandings or discrepancies between the patient’s actual intake of drugs and the medication profile recorded by the patient’s doctor. Non-medical prescribing can cause medication misadventure, especially if communication among care providers is poor. Information exchanged is often lacking in relevant content and timeliness. Integrated care and interprofessional teams are desirable, but teams need to work together effectively and agree on responsibility for communication and continuity of care.

Drug-related problems in aged care, where pharmacist prescribing is being advocated, are multifactorial and complex. Issues include lack of prescribing knowledge, presence of multiple comorbidities, altered physiological states and, most frequently, simple misunderstandings in communication, leading patients to “fall through the cracks” in an increasingly complicated health care system. About one-third of elderly patients receive prescribed drugs from two or more doctors. It is therefore not surprising that
the principal cause of preventable drug-related admissions to hospital is communication failures between patients and health care professionals, as well as among health care professionals.69 This fragmented approach to multiple medication and disease management places vulnerable elderly patients at increased risk of adverse drug events.70 Alterations in physiology, use of several pharmacies, multiple prescribers, and other factors place the elderly population at risk of developing adverse drug reactions and clinically significant drug–drug interactions.71

Having multiple prescribers (eg, specialist, general practitioner, nurse and pharmacist) can cause confusion and lead to duplication of therapy,72,73 and other forms of medication misadventure. Excellent communication is required to ensure that all prescribers are aware of the total therapeutic management of the patient. A central coordinating and oversight role by the general practitioner appears to be important.73 A large Canadian study demonstrated that the greater the number of clinicians prescribing medications for an elderly patient, the greater the risk that the patient will receive a potentially inappropriate drug combination.74 A systematic literature review concluded that the number of prescribers, and the number of dispensing pharmacies, is important in determining the prevalence of clinically relevant drug–drug interactions.75 An Australian study also found that having multiple prescribers increased patients’ key medication-related risk factors and was associated with poor health outcomes.76

Non-medical prescribing can lead to too many specialist health professionals, each prescribing medicines, without the oversight of a general practitioner.77 General practitioners typically have a comprehensive and holistic approach to health and illness, which differentiates them from specialists.78 When technical or specialised disease-orientated care bypasses the GP, it is very likely that important elements of care may be neglected.73

Concerns have also been raised about the public’s perceptions of a broadening role of pharmacists and other health care professionals.79 Traditionally, the general practitioner has been the gatekeeper to the health care system, with control over access to most services, including drug therapy for chronic diseases. A weakening of this role would in some circumstances eliminate the need for a general practitioner visit, at least after the initial diagnosis and receipt of the first prescription. Because a visit to a general practitioner and the ensuing receipt of a prescription potentially reinforces the patient’s understanding of the need for therapy, shifting the prescribing of medications for chronic diseases to other health care professionals may negatively affect the patient’s perception of the need for and effectiveness of medication.79 This has significant implications for the safety and quality of care.

Some ways forward

The evidence on the cost-effectiveness and QUM implications of expanding pharmacist roles in prescribing, chronic disease management and prevention is still sparse. However, the potential in terms of safety, quality and interprofessional workforce capacity is great despite the areas of tension described. It is therefore important to build the evidence base for this interprofessional clinical area.

Safety and quality: data and monitoring

The successful implementation and governance of the NMP require data collection and monitoring systems, linking drug utilisation, health services and clinical information, to enable cost-effective and appropriate prescribing of medicines, including those used off-label and outside PBS-approved indications (“leakage”). It is important to have consensus definitions and nationally agreed benchmarks for QUM, interprofessional practice and associated health outcomes.

The main sources of information about QUM in Australia are (1) Australian Statistics on Medicines (ASM),80 and (2) BEACH (Bettering the Evaluation And Care of Health) reports on general practice activity in Australia.81 The ASM dataset is derived from PBS utilisation (dispensing) data and does not include a large proportion...
of public hospital drug use, drugs costing less than the patient copayment, over-the-counter purchases (except for S3 recordable medicines) or the supply of highly specialised drugs to outpatients through public hospitals under Section 100 of the National Health Act 1953 (Cwlth). The Fourth Community Pharmacy Agreement between the Australian Government and Pharmacy Guild of Australia will provide greater access to complete dispensing data (including less than copayment and safety-net items) from Australian community pharmacies. Finally, information from general practice electronic prescribing packages, which include linked diagnosis data, will enable more comprehensive assessment of the appropriate use of medicines.82

An integrated interprofessional and patient-centred approach
If pharmacists are to assume prescribing rights, there needs to be close collaboration and communication between doctors and pharmacists.40,41,83-85 How do we enhance this interprofessional relationship, communication and practice to achieve appropriate use of medicines? There is still confusion on what constitutes optimal interprofessional health practice, which is not surprising considering the lack of formal teaching of interprofessional collaboration.86 Even in the primary care and family practice setting, where most of the early efforts have concentrated, the resources are marginal at best. Interprofessional tension is still prevalent.

Mutual trust and respect are essential elements of interprofessional relationships.87 If these elements are truly present, then members of the health care team can together determine, on the basis of their shared understanding of each others’ roles and expertise, who will lead the team in a given patient care context. Transparency of decisions, including financial ones, must be a key shared principle. Collaborative practice requires negotiation and a non-competitive, non-hierarchical approach to patient and client care. Until health care workers (including doctors and pharmacists) agree on what collaborative practice entails, true interprofessional collaborative practice will not occur.87 Unless academic settings are developed to provide training for primary health care professionals to work in teams, reform initiatives are unlikely to generate anticipated benefits.86 Collocation, as envisaged in the GP Super Clinics program currently being introduced by the Australian Government, is a promising model to evaluate.

We coined the term “apothecarial” to describe the approach of integrating the complementary roles and responsibilities for the prescriber and dispenser in the patient–clinician therapeutic relationship. An example of the apothecarial approach is the Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics (IMPACT) project, which was designed to provide a demonstration of the feasibility of integrating the pharmacist into primary care office practice in Ontario, Canada. The IMPACT multifaceted practice model includes the embedded pharmacist performing medication reviews for individual patients, providing pharmaceutical information to health care providers, conducting system-level activities to promote QUM and communicating with other providers and pharmacists, and activities to integrate the pharmacist into the practice. The IMPACT program has identified significant drug-related problems, for example not receiving a medicine, not receiving it appropriately or receiving too low a dose, in the participating practices. System-level changes include drug administration plans and chronic disease management protocols, alerts and reminders. All the relevant Family Health Trusts have adopted the IMPACT model for the next round of funding.40

Conclusion
The historical separation of prescribing and dispensing in Europe is explained by professional, regulatory and commercial factors which are still relevant today. Separation does not guarantee cost efficiencies or effectiveness or appropriate use of medicines. The incentives, challenges and conflicts of interest may just take different forms, and the potential for conflict of interest based on financial incentives remains.
A whole-of-government, inter-sectoral and multidisciplinary approach to QUM requires clear and explicit rules to govern the relationships within the multidisciplinary health care team generally, and between doctors and pharmacists specifically. Interprofessional education and practice is essential to train and support an interprofessional workforce to promote quality of care and QUM. More broadly, there must be a regulatory framework that brings the health professions, consumers, the pharmaceutical industry and other actors together in addressing the historical, social, and economic determinants of QUM.

Finally, it is crucial that QUM occurs within the context of rigorous clinical governance frameworks, close monitoring of safety and quality, and ongoing professional and interprofessional training and development. The approach must be “apothecarial”, recognising the complementary roles and responsibilities of prescribers and dispensers — and not adversarial.

Competing interests
The authors declare that they have no competing interests.

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