

Regulation of Pharmacy Ownership: Review Paper and Position Statement

Response to changes in pharmacy ownership controls in the Ministry of Health's proposed Therapeutic Products Regulatory Regime

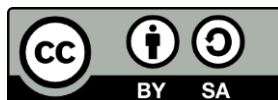
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PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

THE PROFESSIONAL VOICE OF PHARMACY

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Executive Summary and Pharmaceutical Society Position

The Government has announced it intends to repeal the Medicines Act 1981 and replace it with a new regime regulating therapeutic products. A key feature of the proposed new regime is the removal of provisions restricting majority ownership and effective control of pharmacies to pharmacists. The Ministry of Health supports placing conditions around pharmacy licencing rather than ownership as a means of regulation. 'Supervisory pharmacist' and 'responsible pharmacist' roles are proposed to advise on and implement professional standards of practice, regardless of ownership.

This paper sets out the position of the Pharmaceutical Society of New Zealand (the Society) on the Government's proposed regulatory changes and presents international evidence to support our view. We strongly oppose the removal of pharmacy ownership restrictions on the grounds that it will reduce access to pharmaceuticals and pharmacy services for New Zealanders, undermine patient safety, and lessen the capability to innovate to deliver quality integrated patient-centred services. We recommend that restrictions to pharmacy ownership remain in place and that changes to the regulatory regime for therapeutic products be focussed on reducing the burden of regulatory compliance placed on pharmacists. This will enable community pharmacies to operate more efficiently and to innovate to achieve the vision set out in the Government's Pharmacy Action Plan and NZ Health Strategy.

Objectives of the proposed changes

Based on Ministry of Health documents, we understand that the removal of pharmacy ownership restrictions is intended to improve access, increase efficiency and promote innovation without compromising patient safety. The rationale for this change appears to be primarily around the perceived benefits of increased competition.

A number of specific benefits are anticipated by the Ministry:

- **Improved access:** Competition is expected to result in an increase in overall numbers of pharmacies as well as longer opening hours.
- **Increased patient choice:** Competition for customers is expected to drive a wider range of products and services offered within pharmacies, increasing patient choice
- **Increased affordability:** Competition is expected to drive economies of scale through mergers and the growth of corporate pharmacy chains. Because these chains will have enhanced buying power and lower distribution costs, this is expected to result in lower prices for consumers and more affordable medicines.
- **Greater efficiency:** The current regime, and particularly the majority ownership rule, is onerous to manage for pharmacies and regulators alike. Removal of ownership restrictions is expected to directly reduce compliance costs for pharmacies and reduce the administrative burden for Government.
- **Increased innovation:** Increased competition is expected to drive innovation to deliver better pharmacy services and more integrated, patient-centred care.
- **No impact on safety:** The proposed change is expected to be neutral with respect to the safety of

pharmacy services. The Ministry notes there appears to be no link between ownership and quality of service and no evidence that deregulation of ownership is associated with a reduction in patient safety. While there is a potential risk that commercial incentives will lead to the sale of unnecessary or inappropriate medicines, the Ministry argues this risk can be mitigated by rules and professional ethics.

Removal of ownership restrictions will not achieve the objectives sought

The Society has reviewed the material released by the Ministry of Health, along with evidence on the experience of deregulation of pharmacy ownership internationally. We believe that deregulation will not deliver on the Ministry's stated objectives – while there may be some efficiency gains and some pockets of improved access, overall the proposed change fails to improve access, risks harming patient safety, and does not support innovation and patient-centred care.

Reduced access to pharmaceuticals and pharmacy services in rural and lower socio-economic areas

International experience is that the removal of ownership restrictions is associated with an increase in pharmacy numbers, with most of this increase seen in urban areas. This is likely to represent an increase in access for some communities. Note, however, that new pharmacies are predominantly established in locations based on retail sales volumes and profit, rather than locations based on meeting any particular access or health needs of the community, so the degree of improvement in access for those that most need the service is less clear.

By contrast, based on international experience the number of pharmacies in rural and smaller population areas is expected to reduce. There is also evidence of a reduction in the number of pharmacies serving lower socioeconomic communities. In New Zealand, this will worsen urban-rural inequities in the provision of health care, reduce access for people with social, economic, demographic or geographic barriers, and reduce access for children, older people and Māori living in these areas.

The Ministry of Health acknowledges the risk that rural pharmacies may close, but believes this can be mitigated through alternative arrangements such as the internet, depots and remote dispensing. The Society has serious concerns about this approach. Reforms in the regulation of therapeutic products should support Government's policies of enabling and enhancing the role of pharmacists in providing health care to all New Zealanders. This is particularly relevant to those populations with the greatest health needs, including those with low incomes, low health literacy, geographical barriers to accessing health services, Māori, Pacific Islanders and other priority populations.

Reduced competition and patient choice

Internationally, deregulation of pharmacy ownership has been associated with the acquisition of pharmacy businesses by retail giants. Rather than increased competition, the result has been market dominance by one or more retail chains. Smaller operators have found it harder to compete with the economies of scale possible in the large corporates and have disproportionately exited the market. This has been compounded by vertical integration between wholesalers and

pharmacies. The result has been oligopoly and reduced competition.

In a competitive market one might expect the range of products and services offered by pharmacies to expand, however there is evidence that the reverse will occur. Chain pharmacies in other countries, and in particular pharmacies associated with supermarket brands, have come under pressure to offer only high-turnover or more profitable medicines, and in some cases have been reluctant to provide 'less socially acceptable' health care services. This restricts patient choice and reduces the ability of pharmacies to meet the health needs of the community.

These developments stand in stark contrast to the vision set out in the Pharmacy Action Plan, which aims to position the community pharmacy at the heart of their communities, offering a much wider service than medicine supply. The capacity to provide these extended services in New Zealand is likely to be threatened if international trends in corporatisation and homogeneity of products and services are seen here.

No improvement in affordability

International experience suggests that deregulation of ownership has no effect on the sale price of pharmaceuticals. The oligopoly nature of the industry in the countries we looked at means that any financial savings gained through economies of scale or corporate buying power are not usually passed on to the consumer. In New Zealand, the price of prescription pharmaceuticals is effectively determined by PHARMAC and the terms of the Community Pharmacy Services Agreement (CPSA), making any price competition between pharmacies very unlikely.

Risks to patient safety

Competitive markets drive efficiencies, and in the pharmacy sector this is likely to lead to smaller pharmacies, lower staff numbers and higher numbers of sole-pharmacist operators. Reduced staffing, in combination with extended opening hours, is likely to result in significantly increased workloads for pharmacists.

This poses a danger to patients, both through increased risk of error by overstretched pharmacists who cannot check their work with colleagues, and the reduced time pharmacists have to provide support and advice around medicine dosage and adherence.

Exacerbating this risk is the inherent tension between commercial and professional objectives in pharmacy. Where the pharmacist is also the pharmacy owner this tension can be well managed. However if ownership is deregulated, we expect to see greater professional-corporate conflict in the workplace, with an inability for the supervisory pharmacist to effectively uphold professional and ethical standards of practice in the face of corporate pressure to achieve sales targets.

Reduced capability to innovate to deliver integrated patient-centred services

The NZ Health Strategy, Pharmacy Action Plan, Implementing Medicines NZ strategy and PSNZ-NZMA Integrated Health Care Framework for Pharmacists and Doctors all aim to enhance the role of pharmacists working to the top of their scope of practice and emphasise the importance of innovation to deliver integrated, patient-centred services. We believe that deregulation of ownership will undermine that capability, for the following reasons:

- Corporate management policies are likely to reduce the professional autonomy of pharmacists, reduce opportunities for pharmacists to work at the top of their scope of practice, and impair the perception of pharmacists as health care professionals.
- An increased focus on sales targets at the expense of meeting health needs is likely to exacerbate professional conflict between pharmacists and doctors, making the delivery of integrated care more challenging.
- Reduced staffing levels and increased workload on pharmacists is likely to reduce their capacity to try new things and individualise services to the local context or individual patient.

Position of the Pharmaceutical Society of New Zealand

The Society strongly opposes the removal of pharmacy ownership restrictions in New Zealand. We believe this change will reduce equitable access to pharmaceuticals and pharmacy services for New Zealanders, compromise quality and safety of patient care, and lessen the capability to innovate to deliver integrated patient-centred services.

Recommendations

The Society recommends that restrictions to pharmacy ownership remain in place, and cautiously support appropriate models for mixed ownership with medical practitioners. We recommend that changes to the regulatory regime for therapeutic products be instead focussed on reducing the burden of regulatory compliance placed on pharmacists. This will enable community pharmacies to operate more efficiently and, in doing so, free up capacity to innovate new and cost-effective pharmacy services.

In particular, we recommend:

- **An enhanced and appropriately resourced pharmacy licensing authority.** This body should be given the

authority, powers and capability to ensure licensing effectively supports safe, responsible, high-quality and equitable pharmacy health care services. These powers could include the power to decline or withdraw licences to achieve the objectives of regulation, and the discretion to evaluate local health care needs and the location of existing services when considering applications for pharmacy licences.

- **A more pragmatic approach to the administrative processes for dispensing and supply of medicines.** Currently, very specific rules and processes govern matters such as the permitted quantities, timeframes, and record-keeping requirements around dispensing, and the mechanisms by which pharmacists can supply

medicines to other registered health professionals. More flexibility around these processes would reduce the bureaucratic overhead for pharmacists.

- **Streamlining of regulatory functions among agencies.** PHARMAC, DHBs and Medsafe are each mandated with a specific role in the management and funding of the pharmaceutical supply chain. From the pharmacy perspective, the process can often operate as three silos, with inconsistencies and gaps that create additional work for frontline pharmacists. For example,

PHARMAC funding of medicines that do not have Medsafe registration approval requires extra engagement by the pharmacist with prescribers and patients. Addressing these sorts of issues will support community pharmacies to operate more efficiently.

A more comprehensive comment and presentation of recommendations will be possible when the exposure draft of the new Therapeutic Products Bill is released.

Pharmacy Ownership Regulation: Review of International Experience

About the Pharmaceutical Society of New Zealand (PSNZ)

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 3,500 pharmacists from all sectors of pharmacy practice. We provide pharmacists with professional support and representation, training for continuing professional development, and assistance to enable them to deliver to

all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines.

The Pharmacy Profession in New Zealand

Pharmacists in New Zealand are health professionals recognised under the Health Practitioners Competence Assurance Act 2003, and are registered with the Pharmacy Council of New Zealand to practice the profession of pharmacy.

Registration authorises the full extent of permissions granted to pharmacists under the Medicines Act 1981, Medicines Regulations 1984 and other related laws, such as the Misuse of Drugs Act 1975 and Misuse of Drugs Regulations 1977. Registration as a pharmacist also demands compliance with a number of professional obligations, including the Codes, Statements, and Guidelines issued by the Pharmacy Council, including the Code of Ethics, Pharmacist Advertising Guidelines and others. These documents set additional professional standards for practising pharmacists to take responsibility for the management and utilisation of medicines and optimise medicines related health outcomes. A full understanding of the legal and ethical factors related to medicines and their supply is a fundamental requirement of competence, registration and practice as a pharmacist.

Due to the extent of professional and regulatory controls around medicines and pharmacy practice, the “anomaly” of pharmacy ownership restrictions compared to other licensing arrangements is understandable and necessary.

New Zealand Pharmacist Workforce

New Zealand has more than 3500 practising pharmacists working in a number of practice areas including community pharmacy, hospital pharmacy, general practice and Primary Health Organisations (PHOs), academia and research, District Health Boards (DHBs), government agencies and the pharmaceutical industry. Around 75% of the practising pharmacists work in the (approx.) 900 community pharmacies, which over 1.3 million members of the public visit each month.¹ Approximately 13% of the pharmacist workforce practice in hospitals and 2% in clinical roles in general practices, PHOs and DHBs.³

Pharmacists practice and provide care across the whole of New Zealand. Current Pharmacy Council pharmacist workforce data does not distinguish the location of practice other than local Regional Council areas. However, on this basis, 62% of the pharmacist workforce is based in the regions of Auckland, Canterbury, and Wellington, the areas of high population density.³

Government Support for the Role of Pharmacists

The Ministry of Business, Innovation and Employment's (MBIE) 'Occupation Outlook Report on Pharmacists' notes the need for pharmacists is expected to increase due to the increasing demand for health care services from New Zealand's aging population, and “a particular need for

*pharmacists in rural and provincial regions in New Zealand”.*⁴

The Ministry of Health's 'Implementing Medicines New Zealand 2015-2020' document for delivering on the objectives of the Medicines New Zealand Strategy, highlights how “*pharmacists are in a position that makes them accessible to people seeking health care or advice*”.⁵

The strategy to describe and support enhancing the role of pharmacists is more comprehensively described in the Ministry's Pharmacy Action Plan 2016-2020.¹ Implementing the range of recommendations in the Action Plan to better utilise the role of pharmacists, is stated to have a large impact on the health outcomes of all New Zealanders. In the Pharmacy Action Plan, the government and Ministry of Health describe pharmacy as “*much more than the traditional model of supplying medicines*”:

*Pharmacists are an integral part of most people's experience of healthcare, both in the community and in hospitals. However, the current system does not make the best use of pharmacists' unique skills [...] they also have the skills to help people use medicines safely and effectively and to reduce medicine-related harm.*¹

In addition, the government noted that “*the community pharmacist is often the part of the health system that people have the most regular contact with, and the easiest access to.*”¹

The Pharmacy Action Plan also notes a number of challenges being faced by the New Zealand health system, including:¹

- Our ageing population and the growing burden of long-term conditions;
- Our ageing and unevenly distributed workforce;
- Access and equity to improve health outcomes for Māori, Pacific, and other priority populations;
- Health Literacy – the capacity to find, interpret and use information and health services effectively;
- Information and technology;
- Fiscal sustainability.

A principal feature of the government policies and strategies for enhancing the role of pharmacists, is through a more integrated model of care and collaboration between health professionals. The recently reviewed New Zealand Health Strategy includes the strategic themes of being people-powered, care closer to home, and operating as 'one team'.⁶

Integrated and Person-Centred Practice

The Society strongly supports a more integrated and collaborative model of pharmacist-provided care and services. The 'Vision 2020 Partnership for Care: Pharmacists and Doctors working together' joint statement by the Society in partnership with the New Zealand Medical Association (NZMA), formalised the desire for the professions of pharmacy and medicine to work together in an integrated and collaborative health practice environment. The joint statement identifies:

A desired future state of collaboration and partnership that is based on strong and supported clinical relationships, optimised for the benefit of the patient and the health system. It outlines the major goals and enablers that will shape and guide the actions that both professions need to take to reach that vision.⁷

The recently released Integrated Health Care Framework for Pharmacists and Doctors, co-developed by the Society and NZMA⁸, provides the structure for identifying and managing all necessary factors in developing new innovations or models of care so that these are person-centred, integrated, support collaborative practice, and can be successfully implemented to meet the desired outcomes. The Society strongly supports the Principles of Integrated Pharmacist-Doctor Care described in the Framework:

All care must be patient-centred: recognising the uniqueness of an individual's disease, life commitments, leisure activities and personal illness experience due to culture, beliefs and previous experiences

Recognise the Influencers of both health care integration and the implementation of services

Acknowledge the different skill sets that each profession brings to the care of every patient (including other members of the MDT)

Acknowledge the sustainability requirements of each profession

Doctors and pharmacists will work together in collaboratively developed models for shared patient care including prescribing

Doctors and pharmacists will work with innovative funding mechanisms that support the collaborative models of care

Pharmacy Practice and Service / Health Care Provision

The proposed changes to the pharmacy ownership restrictions focus on the integrity of the supply chain, managing risks to public health and upholding professional standards, and the Ministry states that restricting ownership is not required to meet these. Much of the commentary and arguments supporting the removal of restrictions on pharmacy ownership focus predominantly on the economics and commercial aspects of the supply of medicines and not the diversity of care pharmacists deliver through the practice of pharmacy as part of the primary health team. However, as stated in the Pharmacy Action Plan, pharmacy is "*much more than the traditional role of supplying medicines*".¹

The World Health Organisation (WHO) has noted⁹ that community pharmacists are the health professionals most accessible to the public and have a vital role in:

- The provision of health care;
- Monitoring the use of medicines;
- Small-scale preparation of medicines;
- Responding to and managing symptoms of minor ailments;
- Advising other health professionals and the public on medicines;
- Health promotion;
- Domiciliary services including residential care services, medication reviews in homes and more.

In addition to the core dispensing role, New Zealand pharmacists provide extensive and varied health interventions for their local communities through:

- Access to a health care professional without cost or appointment required;
- Provision of personalised information, advice, and counselling;
- A triage point for people who are not sure if their health concern requires their doctor's assessment, or whether it is sufficiently "minor" to be managed without medical involvement;
- Provision of medicines without a prescription, either under the direct supervision of the pharmacist, or after the required assessment by the pharmacist themselves¹⁰;
- Referral or 'sign-posting' to other services or healthcare providers;
- Health promotion and lifestyle advice for the maintenance of good health;
- Patient information to support the safe and effective utilisation of all medicines to optimise benefits of treatment, such as through administration techniques and dosing advice;
- Provision of dosing and adherence support e.g. reminder charts, medication cards and dose administration aids such as blister packs.

Some pharmacies also offer additional services which vary according to local service availability and local population need, including:

- Medicines management services:
- Long Term Conditions – optimal supply and use for the management of chronic conditions e.g. diabetes, cardiovascular disease, respiratory diseases and dementia;
- Medicine Use Reviews supporting understanding and adherence of medicines;
- Medicines Therapy Assessment addressing clinical concerns relating to safety and efficacy of medicines;
- Community Pharmacy Anticoagulation Management Service (Warfarin monitoring);
- Needle Exchange programme;
- Opioid substitution treatment (e.g. Methadone dispensing);
- Immunisations e.g. influenza, meningococcal, diphtheria, tetanus and pertussis (Tdap), varicella zoster;
- Smoking cessation services;
- Screening and prevention of rheumatic fever;

- Paediatric gastroenteritis assessment and rehydration;
- Accredited pharmacist-supply of specific medicines such as trimethoprim for uncomplicated urinary tract infections, sildenafil for erectile dysfunction, emergency hormonal contraception.

The New Zealand National Pharmacist Services Framework, published by the Society in 2014, presents the profession's definitions and descriptions for a wide range of existing and potential professional pharmacist services, including many described above.¹¹

A pharmacist may recommend and sell a medicine or device when they provide some of these services. However, they may decide that no treatment is appropriate or required, and therefore provide the consultation without any remuneration for their time and expertise. This illustrates how professionalism takes priority over profits and sales targets.

The practice of pharmacy in New Zealand has evolved under the existing pharmacy licensing regulations that restrict majority ownership to a pharmacist. The pharmacist, as the owner of a pharmacy, brings their knowledge and understanding of the full range of regulatory, ethical and

professional obligations and standards of practice to that pharmacy's provision of health care and services. The financial accountability as a pharmacy owner is balanced against the professional and ethical accountability as a registered health professional. However, this balance of accountability can cause conflict due to commercial pressures to achieve sales targets when working under non-pharmacist ownership structures.

As is being increasingly recognised by the government and the wider health sector, pharmacists provide an important contribution to the health care of New Zealanders that is much more than just medicines supply. Therefore, removing pharmacy ownership restrictions has the potential to adversely impact on many levels, including:

- The effective implementation of government strategies to greater utilise the role of pharmacists in improving the health of all New Zealanders;
- Provision of equitable access to the wide-ranging and diverse services and care for the public by pharmacists;
- Creating conflict between the professionalism of the practice of pharmacy and commercialism.

Reason for Review and Position Statement

Following the cessation of the Australia New Zealand Therapeutic Products Agency (ANZTPA) project, the New Zealand Government announced an intention to repeal and replace the Medicines Act 1981 and Regulations. The proposed new regulatory regime is intended to comprehensively regulate all therapeutic products while being flexible, enabling and future proof.¹²

At present, the Medicines Act and Regulations control the manufacture, sale, and supply of medicines. This includes the licensing and operation of pharmacies which have unique functions specific to pharmacists and pharmacy practice. The Ministry of Health (The Ministry) have stated that the proposed new regulatory regime intends to remove the restrictions on the ownership of pharmacies.¹²

In the Pharmacy Action Plan 2016-2020¹, the Ministry states that *"a robust regulatory regime is vital for delivering high-quality integrated health services that are safe and effective"*. The Society supports the government's intent for the new regulatory regime to drive progress towards

achieving the New Zealand Health Strategy vision for *"all New Zealanders to live well, get well and stay well."*⁶

The Society intends to comprehensively examine the potential impact that the repeal of the Medicines Act 1981, and the proposed new Therapeutic Products legislation, will have on the future of the profession of pharmacy in New Zealand. While the Society has a strong interest in all aspects of the proposed regulatory regime, this document focuses specifically on the proposed removal of restrictions on pharmacy ownership and outlines the Society's position which has been informed by a comprehensive review of international and local published literature regarding the regulation and the deregulation of pharmacy overseas.

Overview of Current Regulation

Regulation of Pharmacy Ownership

The ownership and licensing of community pharmacies in New Zealand is currently regulated by the Medicines Act 1981 (particularly sections 5A-B, 42A-C, 55A-G and 114A-B) and the Medicines Regulations 1984. The provisions set out:

- The meaning of 'holding an interest' in a pharmacy;
- The requirement for every pharmacy to be under the supervision of a pharmacist;
- Security of pharmacies;
- Restrictions on prescribers holding an interest in pharmacies;
- The licensing and conditions of pharmacy licences and required criteria for pharmacy operators, including:
 - Restriction on companies operating pharmacies;
 - Restrictions on individuals operating or holding a majority interest in pharmacies;
 - Restrictions limiting the number of pharmacies companies or pharmacists may operate or hold a majority in.

Pharmacy licences are issued by the Licensing Authority at the Ministry of Health under the Act. Currently, no pharmacy may be open to the public unless it is licensed and under the immediate supervision and control of a pharmacist, and the licence authorises the establishment of a pharmacy at a specific site and for the licence holder to provide pharmacy practice at that site.

New Zealand does not place any restrictions on the distribution of pharmacies, as occurs in some countries such as Australia and Spain. In New Zealand pharmacy numbers and the location of each community pharmacy is determined by the pharmacist owner.¹³ The legislation specifies:

- 51% of ownership to be held by a registered pharmacist (must have effective control);
- A pharmacy licence may be granted to a company, however, the majority of the share capital must be owned by an individual pharmacist or pharmacists;^{14,15}
- No person or pharmacist may operate or hold a majority interest in more than 5 pharmacies;
- Restriction of prescribers from taking any interest in pharmacies, unless an exception is granted by the regulator.

Further to the licensing of a pharmacy, government funding for pharmacy services is administered by the Community Pharmacy Services Agreement (CPSA), the funding contract between the local District Health Board (DHB) and the individual pharmacy.¹⁶

Regulation of Medicines: “Not ordinary items of commerce”

The supply of medicines from a health professional is considered a fundamental healthcare service. Locally and

internationally, medicines and therapeutic products are recognised as not being ordinary items of commerce, and as such they are highly regulated in their status, controls, and supply.

Direct to consumer advertising of medicines is permitted in New Zealand, however such adverts are required to comply with the associated legislation and regulations, and meet the Advertising Standards Authority (ASA) Therapeutic Products Advertising Code.¹⁷ In addition to the regulatory controls that permit direct-to-consumer advertising of medicines, any promotional activity conducted either by or on behalf of pharmacists require compliance with further professional restrictions described in the Pharmacy Council of New Zealand and Pharmaceutical Society's Advertising Guidelines¹⁸, including that:

Promotional methods must not encourage the public to equate medicines with ordinary articles of commerce. The emphasis or focus of the advertisement must be on the benefits of the product or service rather than its price.¹⁷

This statement clearly highlights how in pharmacies, professional practice and the therapeutic appropriateness of medicines overrides the commercial activity of 'selling' medicines. Where free economic markets encourage competitive pricing, pharmacies are not able to advertise based on comparative pricing or on cost savings. This is considered unethical practice as the focus on the provision of medicines by a pharmacist is intended to be on the potential therapeutic benefit of a treatment, not the cost.

Internationally, the European Court has noted that the nature and therapeutic effects of medicinal products distinguishes them substantially from other goods.¹⁹ If medicinal products are consumed unnecessarily or incorrectly they may cause serious harm to health and can also lead to a waste of financial resources and increased healthcare costs.¹⁹

Regulation of Pharmaceutical Prices

In addition to these strict controls around the “product” pharmacists supply, the dispensing of medicines pursuant to a prescription is unique to the pharmacy profession. However, pharmacists have no control of the pricing of that “product” when it is government funded. The pharmaceutical schedule price is negotiated and set by PHARMAC, themselves being exempted from the Commerce Act; while the margin and fee for dispensing are fixed by the terms of the CPSA. A nominal prescription co-payment that the patient pays is set by the Ministry of Health, and contributes to the cost of that medicine to the pharmacy; it does not contribute to a profit margin for the pharmaceutical. This further illustrates the extraordinary regulatory aspects of medicines where a retailer (the pharmacist) has no control over the cost and “sale price” of a product that only they are permitted to supply by law.

Proposed Therapeutic Products Regulatory Regime

The Ministry's overarching objective for the new regulatory regime is to ensure the safe supply and effective use of therapeutic products and to enhance accessibility that enables the development of innovative ways of providing pharmacy services.¹²

The Ministry have suggested that the current restrictions on pharmacy ownership are not necessary to achieve the safety objectives of the regulatory scheme.¹² The primary method of ensuring this is through licensing requirements, including that pharmacy businesses are under the supervision of qualified pharmacists, specifically supervisory pharmacists, who have control over and professional knowledge of the work being done. However, the Ministry state that it does not require a registered pharmacist to be a shareholder of the business, or for the business to be restricted to a specified location, citing the examples of mobile pharmacists or centralised dispensing hubs.¹²

Under the proposed changes, the Ministry state new pharmacy licences may be:

- Open to any "fit and proper person";
- The restriction on the number of pharmacies that can be owned by one person will be removed;
- Some restriction on prescribers owning pharmacies will remain;
- Pharmacy licences will no longer be restricted to a physical location.

The Ministry believe that competition in economic markets can help keep costs lower and develop better services to compete for business, therefore the proposed regulatory changes will enable a more dynamic pharmacy industry focussing on high-quality professional services and business innovation.¹²

Government Considerations and Expectations in Removing Restrictions on Pharmacy Ownership

The government has released a series of documents related to the Therapeutic Products Bill (The Bill) that describe context and proposals for the new regime, and decisions made by Cabinet.¹² In addition, a further collection of documents have been released under the Official Information Act²⁰ that relate to advice, briefings, discussion documents and correspondence regarding the proposed changes to the licensing of pharmacies. The Society has reviewed these documents and summarised the Ministry's expectations through the removal of restrictions on pharmacy ownership below.

Regulatory Policy and Function

The Ministry's high-level objectives for The Bill focus on:

Safety

- Ensuring high-quality care without compromising patient safety;
- Improving health outcomes for people;
- Ensuring accountability is appropriate and transparent;

Access

- Enabling people to obtain therapeutic products in a timely way;
- Supporting patient choice and convenience where possible;

Efficiency

- Practically administering the regulator's roles;
- Enabling innovation in health care;
- Health care providers complying with regulations.

Ministry documents and advice regarding The Bill state that:

Pharmacy license ownership restrictions are an anomaly in New Zealand's licensing system. Licenses do not normally seek to restrict business owners, but rather regulate the risk of an activity via conditions. Conditions on a licence rather than ownership restrictions better manages risks and enables a competitive market.¹²

Costs, Economies of Scale and Market Competition

The Ministry note increasing health expenditure within a constrained funding environment and achieving value for money is imperative.¹ The government believe removing ownership restrictions will create more competition between pharmacies and lower the price of medicines.¹² Ministry advice to the Health Minister has described their expectations that:

Deregulation of pharmacy ownership would lead to further corporatisation of the sector [...] greater economies of scale and more buying power may result in lower distribution costs and therefore lower prices.²⁰

The Ministry suggest such competition can lead to the development of better services to compete for business.²⁰

Compliance with Regulatory Requirements

The Ministry have noted that compliance with ownership restrictions consumes the effort of both pharmacists and the regulators without gains in safety.²⁰ They suggest removing ownership restrictions could "enable pharmacies to structure their businesses in more efficient ways to focus on service, rather than ownership compliance."²⁰

The new regulatory regime proposes to develop a 'Supervisory Pharmacist' role, with the intention of assuring compliance with licence conditions and implementation of professional standards in ownership situations where the owner(s) could be an individual, trust or corporate body holding multiple pharmacy licences¹² and are not required to be a registered pharmacist.

While referring to an 'apparent' onerous compliance with ownership restrictions by pharmacists, the Ministry have also described challenges with the existing ownership requirements:

[The licensing rules] have proved difficult to administer as, in practice, a range of company arrangements have been put in place to get around the restrictions, to the point that there are serious questions about whether the intent of the policy [i.e. for effective control of a pharmacy by pharmacists] is being met and should be retained.²⁰

Safety, Quality, and Innovation of Pharmacy Services

The Ministry have stated that:

In practice there is not necessarily a link between ownership and quality of service provision and there is no evidence of any increase in health and safety concerns or poor service in 'chain' pharmacies. i.e. those with shareholdings by large companies.²⁰

The Ministry's advice to the Health Minister also describes how:

More flexible ownership arrangements could assist in achieving the mutual goal of the pharmacy profession and the Government of helping the sector move toward better, integrated, and consumer centred care. Ownership restrictions may be more likely to hinder rather than enable these developments.²⁰

However, they note that changes in ownership restrictions may create risks to professional practice, including:

Sharp commercial practices such as selling unnecessary or inappropriate medicines or misleading marketing. Those risks are mitigated through advertising rules and the professional ethics of pharmacists, who will still control dispensing and pharmacy practice as a whole.²⁰

Accessibility to Pharmaceuticals

In their advice to the Minister of Health, the Ministry recognise a potential negative impact on pharmacies in smaller towns:

It is possible that some pharmacies in smaller population centres may close if competition from large outlets in neighbouring towns renders them unviable, meaning a reduction in access to pharmaceuticals. Access issues can be mitigated through licensing provisions such as allowing medicine depots and non-pharmacy retail licenses for remote places. There would also be the possibility for smaller pharmacies becoming attached to GP practices, with travelling pharmacists visiting several of these pharmacies in a week.²⁰

The Ministry expect that deregulation of pharmacy ownership “could also lead to a general increase in the accessibility of medicines, related to the establishment of new pharmacies or increased opening hours.”²⁰

Evidence and Experience of Removing Restrictions on Pharmacy Ownership ('Deregulation')

The definition or application of the term 'deregulation' in papers and reports from other countries varies and can refer to more of a 'reduction' of restrictions, through to complete removal of regulatory restrictions. Due to the pre-existing regulatory structure of ownership or of the medicines themselves, and also the distribution and government funding structures, how the specific effects described overseas compare to the proposed regulatory changes in New Zealand may differ. However, the experiences of similar changes overseas are relevant for consideration in respect to the potential adverse or unintended impact of deregulation in New Zealand.

Similarly, any effect on the cost of pharmaceuticals to either the government or consumer, may not be comparable or relevant to New Zealand practice, due to the unique national negotiation of pharmaceutical prices by PHARMAC, and the fixed dispensing fee and margins set by the CPSA. There are also differences in the availability and controls around prescribed medicines and those available over the counter. This is a significant consideration when using international data or experience to describe potential benefits or pitfalls of deregulating ownership in New Zealand.

With those considerations recognised, understanding the Ministry of Health's reasoning for deregulating pharmacy ownership provides the Society with an opportunity to examine evidence around the suggested benefits and objectives. Consideration can then be given to the potential relationship with, and impact on, current government and professional policies and strategies related to medicines, pharmacy services, and the pharmacist workforce.

The Society has comprehensively reviewed an extensive range of local and international published evidence and experience regarding the regulation and controls of pharmacy ownership to enable us to develop our position.

Legal Judgement Recognising Restricting Pharmacy Ownership to Pharmacists: European Union

Almost half of the 28 countries in the European Union (EU) have regulatory controls on pharmacy ownership. The EU's

Court of Justice considered the restrictions around the ownership and operation of pharmacies to pharmacists alone, against the provisions of the European Treaty for freedoms of establishment and movement of capital. The Court judged that existing pharmacy ownership restrictions in some Member States to pharmacists alone, can be justified, and that a Member State may take measures that reduce risks to the reliability and quality of the provision of medicinal products to the public.¹⁹

In its judgement, the Court noted that pharmacists, like other business owners, have an objective of making a profit. However, it is not their sole economic objective, as they also operate from a professional viewpoint. The Court recognised:

[The] private interest connected with the making of a profit is thus tempered by his training, by his professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his investment but also his own professional existence.¹⁹

The judgement also noted a view of risks to the professional independence of pharmacists employed by non-pharmacists, and that legislative rules can protect this independence by preventing a non-pharmacist owner from exerting influence over employee pharmacists. This is given that:

The interest of a non-pharmacist in making a profit would not be tempered in a manner equivalent to that of self-employed pharmacists and that the fact that pharmacists, when employees, work under an operator could make it difficult for them to oppose instructions given by him.¹⁹

Therefore the Court ruled that restrictions on ownership and operation of pharmacies can be justified, and the EU Member States were permitted to restrict pharmacy ownership and operation to pharmacists.²¹

We note that The European Court records an absence of evidence to demonstrate that more relaxed ownership controls are able to ensure the same level of reliability and

quality in the provision of medicinal products to the public.¹⁹ In fact, evidence from many countries suggests relaxed ownership controls and financial competition may create conflict for the pharmacist to prioritise corporate demands above the needs of patients and the requirements of professional pharmacy practice.

European research has found regulation of the establishment of new pharmacies and pharmacy ownership varies between deregulated countries and regulated countries:

- All regulated countries applied statutory provisions, taking demographic (e.g. minimum number of persons to be supplied by the pharmacy) and geographic (e.g. minimum distance to existing pharmacies) criteria into consideration. However, there was freedom of establishment in the deregulated countries with minor exceptions.
- Deregulated countries tended to allow any individual or entity to own a pharmacy (with limitations in some countries, e.g. for prescribers and manufacturers), whereas, in the regulated countries, only pharmacists

Effect on the New Zealand Public

Accessibility to Medications and Pharmacy Services

As stated earlier, the Ministry expects that deregulating pharmacy ownership will increase the accessibility of pharmaceuticals, as increasing the number of pharmacies and increasing market competition will lower prices of therapeutic products and increase the public's access to a pharmacy.

However, the physical supply of a medicine from a pharmacy, either via a prescription or an over the counter purchase, cannot be considered in isolation of the care, advice and clinical and risk assurances provided by the pharmacist themselves, or those working under their direct supervision. Consumer research from 2011 showed that nearly two-thirds of New Zealanders sought medical advice from their pharmacist ahead of visiting their GP.²³ This highlights the significant role pharmacists play in the provision of health care to the community. Therefore, any actions that may impact on the role and practice of the pharmacist, can potentially affect the provision of health care to a community.

Overseas experience describes how removing pharmacy ownership restrictions may result in increased patient access to pharmacy services through the rapid establishment of corporate chains. These generally increased pharmacy numbers and extended opening hours in some areas. However, the reported increase in opening hours achieved an increase from 42 to 53 hours per week on average²⁴, and the increase in the number of pharmacies predominantly occurred in urban areas only.²⁵

The opening hours of New Zealand pharmacies vary around the country and are often dependent on the needs of the community that the pharmacy is serving. A brief internet search indicates that already many are open more than 50 hours a week with a considerable number open 80 hours a week or more, particularly in metropolitan areas and adjacent to extended-hours medical centres.

To encourage the extension of pharmacy opening hours in the UK, new pharmacies which opened for "100 hours" per week were exempt from the licence condition of being "necessary and desirable."²⁶ However, the British Government withdrew this exemption in 2012 as it generated "clustering of additional pharmacies that bring about little improvement in access" and more restrictive

could own a pharmacy (with possibilities for co-ownership in Austria and Spain).

- Pharmacy chains were allowed in the deregulated countries, whereas multiple ownership was, except for a limited number of branch pharmacies, not permitted in the regulated countries.¹⁹
- Reregulation of the pharmacy sector in some countries was done on an ideological basis with an initial belief that the market and increased competition could solve many of the perceived problems in the pharmacy sector, and lead to better efficiency, defined as lower costs and better quality.²²

As already recognised by the Ministry, extensive evidence from many countries informs us that through deregulating pharmacy ownership in New Zealand, the overall number of pharmacies will probably increase through the establishment of corporate chains.⁹ In particular, the number of urban pharmacies will likely increase¹⁰ significantly, however, the number of pharmacies in rural communities will likely decrease.¹¹

regulations were reintroduced with a new market entry test based on pharmaceutical needs assessments.²⁷

The government anticipates ownership deregulation will create more choice for the patient, better access to medicines through extended opening hours and cheaper 'over-the-counter' medicines through corporate bulk buying power in urban locations. However, deregulation can lead to inequitable access to quality pharmacy services in other locations.²¹

European experience shows that in many cases, new pharmacies were established close to existing pharmacies with high sales volume.²⁸ The location of new pharmacies was therefore predominantly based on retail sales and profit, as opposed to meeting any particular access and health needs of the community. Subsequent economic pressures then lead to the closure of many independently owned and operated pharmacies, particularly in rural locations, which reduces equitable access to pharmacy services.^{21,29}

The Swedish Government removed restrictions on state ownership of pharmacies in 1971, aiming to introduce private ownership into the pharmacy sector.²² Then in 2009, they removed restrictions on the location and ownership of pharmacies that were referred to as a 'reregulation'.²² A review of the Swedish experience notes:

It is not self-evident that increased numbers of pharmacies automatically leads to better availability of medicines for the patient... the medicine supply in smaller pharmacies [if the size of pharmacies reduces] will most probably be more limited; especially... less frequently sold medicines that might also not be kept in stock for profit reasons...hence decreasing availability to these medicines²²

The review also notes how the Swedish Government documents do not discuss the possible consequences of the reform in relation to advice and improving the use and adherence to medicines.²²

Overseas experience is showing that deregulation favours the larger pharmacy chains and the concentration of pharmacies in affluent areas at the expense of areas of economic deprivation. The differences in service provision

between corporate pharmacy owners and pharmacist owner-operators may further increase the inequalities in access, meaning that:

Those most in need of health care i.e. those who are socioeconomically disadvantaged, are those who are least likely to be able to access it.³⁰

The experience of deregulation in England has seen “the demise of the high-street and the rise of out-of-town shopping.” The authors of one report states:

It is also worthy of note that independent pharmacies tend to be located in the heart of communities, whereas supermarkets are more often found in out-of-town retail developments which are difficult to access without a car.³⁰

Independent pharmacies are often more accessible for people without private transport, typically those people with lower incomes.⁷ Deregulation of pharmacy ownership

and location of pharmacies in economically profitable urban areas has the potential to reinforce inequities in access to pharmacy-based services. Socio-economically disadvantaged people without access to a car are unable to visit supermarket pharmacies without considerable difficulty and/or expense. This means the sustainability of the independent community pharmacy is important for the health care of the communities they serve.

The increase in the number of pharmacies after deregulation may improve the physical/geographical access to medicines for some people, particularly in urban areas, however, access to medicines is only one part of equitable health care and without the health literacy, advice and support that a pharmacist provides, access alone is a risk to patient safety. Therefore, any regulatory changes that risk the viability of small independent community pharmacies, particularly in rural or socio-economically disadvantaged areas, will have a detrimental impact on equitable access for all New Zealanders.

Effect on Community Pharmacy

Currently, in New Zealand, the majority (55%) of the community pharmacies are owned by independent pharmacist business owners.³¹ Any changes to the regulations affecting independent community pharmacy ownership could have a significant potential for considerably changing the future of pharmacy in New Zealand.

As recognised in an opinion by the European Court Advocate General:

A pharmacist who owns his own pharmacy is financially independent, which ensures his freedom to engage in his profession. Such a pharmacist has full control of his tools and can, therefore, pursue his profession with the independence which characterises the liberal professions. He is both the head of a business in touch with economic realities, which are linked to the management of his pharmacy and a health professional who is concerned to balance his economic requirements with public health considerations, a fact which distinguishes him from a mere investor.³²

Corporatization: Large Retail Chains and Supermarkets

Overseas experience shows that corporate ownership in New Zealand will likely lead to monopolies of pharmacies and wholesalers, which reduces competition:¹²

- In the United States, 'CVS' and 'Walgreens' monopolise half of the retail pharmacy business in major cities. The US Federal Trade Commission expressing concerns a Walgreens merger with a further pharmacy group could reduce competition, adversely affecting consumers.³³
- In Canada, 'Shoppers Drug Mart' has been purchased by the grocery giant Loblaw, and the Rexall chain has been purchased by American giant McKesson.
- In the United Kingdom (UK), retail pharmacy chain 'Boots' has about a quarter of the pharmacy market share³⁴, and corporate chains and supermarkets combined have over half of the pharmacy market share.³⁵

These monopolies of pharmacy ownership by retail giants lead to a restriction in consumer choice and a reduction in competition, the opposite of the government's intentions

by deregulating pharmacy ownership in New Zealand. Prices of over-the-counter (OTC) medicines have not been found to decrease after a deregulation of ownership.²¹

In New Zealand, the current pharmacy ownership and licensing regulations have permitted pharmacies to operate within some supermarkets. One supermarket is reported as intending to open more pharmacies in supermarkets “with an outside partner in order to get around fairly outdated restrictions on the number of pharmacies one pharmacist can own.”³⁶ Legally, the supermarket and the pharmacy have to be separate companies, which is why the partnership with a pharmacist is necessary for the provision of the pharmacy licence in these circumstances.

While the ownership restrictions and licensing requirements have technically been met in order to grant a pharmacy licence, the supermarket location presents a professional and ethical conflict, whereby the professional and ethical attributes of practicing as a health professional clashes with a commercially focused business that sells products that are damaging to health including cigarettes, alcohol and soft drinks. In this situation, there is no background professional or ethical philosophy as with a provider of health care, it is a profit-focussed commercial enterprise.

Two years after the CVS pharmacy chain in the United States stopped selling tobacco products, executives of Walgreens Boots Alliance at their January 2017 annual shareholder meeting were defending their decision to continue selling cigarettes.³⁷ Walgreens Boots Alliance have recently settled allegations of breaches of federal anti-kickback statutes by inducing staff to recruit ineligible patients into their 'Prescription Savings Club'.³⁸

The Warehouse chain opened pharmacies in several of its stores across New Zealand around five years ago, however, all but one closed at the beginning of 2012. The company state that “the pharmacy experiment was a success, but the company decided to end it because it was not part of its core business.”³⁹

In 2016 Countdown pharmacies began offering a \$2 discount on the usual \$5 co-payment charge for prescriptions in the majority of its stores. After the \$3 co-payment was rolled out in all 14 Countdown in-store pharmacies, it was reported that “business was booming”.³¹

In North Dakota in the United States, pharmacy ownership has remained restricted to pharmacists since regulations were established 1963, which were designed to keep pharmacy "local and responsive to local patients". Pharmacy supermarket chains have repeatedly challenged the North Dakota law, even going to the U.S. Supreme Court 1974.⁴⁰ In a 2010 public ballot to change or retain pharmacy ownership regulation, a spokeswoman for North Dakotans for Affordable Health Care (NDAH), an organisation largely funded by Walgreens, stated that "NDAH will be focusing on cost; Pharmacists will be focusing on cost, access, and quality of care."⁴⁰ The executive vice president of the North Dakota Pharmacists Association stated that:

The reality is that [discounted] \$4 prescriptions are a marketing ploy, one designed to get customers into the store and buying non-prescription products while they wait. Fewer than 1% of all prescriptions are covered by the \$4 programs.⁴⁰

The significance of the potential changes in regulations relating to pharmacy ownership, to the supermarket and corporate chains (and the size of the potential profits) can be gauged by the amount of money corporate giants have been willing to invest to secure their stake in the pharmacy market. With Walmart spending \$9.3 million to aid efforts to eliminate the North Dakota ownership restrictions.⁴¹ However, they proved unsuccessful.

Corporate pharmacies possess the financial power, by virtue of their large turnovers³⁰ to compete aggressively with smaller or independent pharmacies. As illustrated by a recent Auckland High Court injunction to prevent a corporate entity associated with a medical practice from opening a new pharmacy in the same centre where a longstanding pharmacy already existed.⁴²

Where the retailing aspects of community pharmacies have been noted and criticised by some, the Society argues that pharmacies deliver a vast range of health care and advice that are not recognised in current funding mechanisms, and the retailing of health products allows pharmacists to perform these unfunded services.

Pharmaceutical Wholesalers: Vertical, Horizontal and Forward Integration

As outlined below, European experience has also demonstrated how deregulation of pharmacy ownership leads to vertical integration between pharmacies and wholesalers, and horizontal integration between multiple pharmacies. The small number of wholesalers creates anti-competitive monopolies of trade and controlled pricing rather than the free market competition anticipated as a result of deregulation.

Horizontal integration aligns multiple pharmacies with a small number of wholesalers, and this small number of distributors were seen to gain market dominance which limits market competition.²¹ Vertical integration increases the difficulty in setting up new independent pharmacies, as the same discounts and benefits from the wholesalers are not available to independent pharmacies.²⁸ Under deregulation, it is also considered even more difficult to set up a new wholesaler, as existing pharmacy groups obtain benefits from the wholesaler to which they belong, and so are unlikely to support to a new wholesaler outside of their alliance.²¹

Within a few years of the deregulation of pharmacy ownership, "two pharmacy groups in Iceland and three pharmacy groups in Norway controlled 85 and 97% of the markets, respectively."²⁸ In Norway, vertical integration between pharmacies and wholesalers was allowed, but this decision went against recommendations from the

committee that had investigated the pros and cons of different competitive policies.²¹ The Norwegian Competition Authority expressed concern about the oligopolistic structure (where a small number of sellers exert control over the market of a commodity) which developed after the deregulation and recommended regulating essential infrastructure to ensure fair competitive conditions.²⁰

In Norway, lower purchase prices for medicines were expected through the vertically integrated wholesalers and pharmacy chains. However, as there was no price competition, the pharmacy retail price did not decrease.²⁴ The vertically integrated pharmacies were also observed to align their product range to the supply of the owners, and less frequently requested medicines were less available in pharmacies,²⁴ further restricting patient choice. The deregulation of the market appeared to increase the availability of pharmacy services, due to more pharmacies and longer opening hours. However, there were indications of a deterioration in the quality of the pharmacy services.⁵⁶

To prevent oligopolies from developing, some European countries have reregulated pharmacy ownership²⁸ with restrictions to separate distributors and pharmacies, and restricting the involvement of prescribers, manufacturers and wholesale companies from being shareholders in community pharmacies.²⁵ Following the liberalisation of Hungarian pharmacy regulations in 2006, regulatory restrictions on ownership were re-established in 2011, and by January 2014 institutional investors in existing pharmacies were obliged to appoint local pharmacists as directors of the pharmacy and sell at least 25% of their shares to the director or other private pharmacists. Investors will be obliged to sell at least 51% of their pharmacy shares to pharmacists by 2017.²⁵

Franchises

Franchise pharmacies are generally part of a regional or national brand, with the franchisee having some form of revenue sharing with a head office. However, there may be some autonomy in local marketing, buying, merchandising, and professional services.⁴³ Buying a pharmacy franchise may enable an individual pharmacist-owner to operate as part of a larger group to competitively purchase and market goods under the parent banner.

As an ownership option in New Zealand, franchising has the potential to be a valuable strategy in the healthcare sector for clients, society and organisations¹³ as it may offer the efficiencies of corporate business while the pharmacist still retains professional autonomy. Currently, 45% of community pharmacies are affiliated to or part-owned by the Green Cross Health[®] (trading as Unichem[®] or Life[®] pharmacies).³¹ Franchises are increasingly used in the healthcare sector with the aim of enhancing quality and accessibility for patients, improving the efficiency and competitiveness of organisations and/or providing professionals with a supportive working environment.⁴⁴

Flexible Ownership and Integration of Care

The community pharmacist is an integral part of the primary health care team and internationally, the trend has been for community pharmacy to incorporate with primary care to deliver integrated services to meet the needs of the local population.¹⁶

Evidence from the UK demonstrates that the inclusion of a pharmacist as part of an integrated care model of health and social care professionals could help prevent avoidable hospital admission.⁴⁵ The results of the integration of pharmacy services in the UK included a reduced use of hospital beds, low rates of emergency hospital admissions for those aged over 65 years old and minimally delayed transfers of care. Use of residential and nursing homes has

fallen, and at the same time there has been an increase in the use of home care services.⁴⁶

The Pharmacy Action Plan identifies a broad range of pharmacy services that pharmacists can deliver aligned with the New Zealand Health Strategy, and as part of a more integrated health care team. In the UK, 'The Future of Community Pharmacy in England' report notes:

Under the new [NHS] policy, pharmacy will take on additional responsibilities as a key player in a more integrated healthcare system that aims to make every contact count.³⁵

Community pharmacies need to be supported by legislation, and protected from the corporate influences and pressures of commercialism, to implement pharmacy services as funding, staffing resources, and access will be adversely affected by the removal of the current restrictions on pharmacy ownership. Under the proposed changes to the Therapeutics Regulatory Regime, new flexible ownership arrangements for pharmacies could be an opportunity to facilitate integrated consumer centred care and assist in shared working environments through arrangements with medical practitioners.

Regulatory mechanisms that permit appropriate co-ownership of pharmacies with doctors could provide an opportunity to strengthen the professional relationship and support the development of integrated services. However, doctors are unlikely to be willing to work in partnership with individuals who they believe have a focus on generating profit, which may possibly be detrimental to their patients.³⁰

Independent Pharmacies - Opportunities and Diversification

In 2015, NHS England's Deputy Chief Pharmaceutical Officer Bruce Warner implied there were too many pharmacies in the country. This was an echo of the statement made by Chief Pharmaceutical Officer Keith Ridge in 2014. A UK pharmacy journal invited some pharmacy owners to comment on whether Mr Warner's comments were founded:

One pharmacy owner suggested that the right number of pharmacies depends on what the government wants to get out of the community pharmacy sector. This, he argues, is the debate worth having.

If you want distribution of medicines, then you might as well have Amazon [operating] a drone and then you would only need one [pharmacy].⁴⁷

Effect on Professional Pharmacy Practice, Quality of Care and Patient Safety

In the Therapeutic Products regulatory regime documents, The Ministry of Health states that:

The current restrictions on pharmacy ownership are not necessary to achieve the safety objectives of the regulatory scheme.¹²

However, the international experience does show that the removal of restrictions on pharmacy ownership, and the subsequent increase in workplace pressures related to corporate ownership, can adversely affect the safety and quality of care for patients as well as the breadth of services delivered by pharmacies.

As previously mentioned, deregulating pharmacy ownership can lead to an increased number of new

The question of "Have we too many pharmacies?" is also being considered in New Zealand. However, because pharmacists are paid a standard dispensing fee for each prescription in New Zealand, the number of actual pharmacies is less relevant than their distribution and delivery of services.²¹ However, mergers or consolidation of closely located pharmacies, as seen in the UK and Australia, can bring many benefits to the economy by making it possible for the one pharmacy to be more efficient and innovative. In other locations, mergers or pharmacy closures may harm competition by giving the merged businesses market power, which could result in higher prices and reduced choice or quality for consumers.

If two or more small/independent closely located pharmacies merged, the resulting business would not only save on operating costs (efficiencies of scale and increased purchasing power), but it may enable more diverse pharmacy services to be offered. Merging community pharmacies may be an opportunity for a new sustainable model of care and enable independent pharmacies to "unlock their full potential"¹ and deliver clinical pharmacy services which would "shift patients' perceptions of pharmacists from dispensers to providers of healthcare services and trusted clinical advice."³⁵

"Alternative Supply": Internet, Depots, Remote Dispensing

The Ministry documents note the ability of internet trading, Medicine Depots and remote dispensing as alternatives for supply in the absence of a pharmacy. However, New Zealand needs robust regulations that will protect the public and the profession from the risks of medicines supply without the supervision and advice of a registered pharmacist.

The Society recently opposed a PHARMAC proposal for the direct supply of a new treatment for Hepatitis C to patients that bypassed the person's community pharmacist which would fragment care and reduce access to advice and information. Understanding the challenges with the supply and distribution of a high-cost medicine, we were pleased that an alternative mechanism was found which meant patients could receive counselling and advice from their local pharmacist.

The Society considers any supply of a medication to a patient without a pharmacist involvement or oversight does not support the Government aim of an "integrated healthcare system that aims to make every contact count"²³ but will put patient safety at greater risk.

pharmacies and extended opening hours in some areas. This creates a shortage of pharmacists and pharmacy staff, which increases individual workload, and can limit or delay the introduction of novel, extended and patient-centred services at community pharmacies.²¹ Therefore the impact of deregulating ownership on the availability of pharmacists and technicians, and the potential capacity to implement the enhanced pharmacy services desired by government strategies needs to be considered.

Recent Canadian research shows that corporate owners are placing greater demands on pharmacists and this can lead to risks to patient care. Pharmacists working in corporate chain pharmacies were more likely to report inadequate staff numbers to provide safe and effective patient care, they were more likely to report pressures to

meet quotas for advanced services and did not have enough time for breaks or for job tasks. The researchers found that:

Pharmacists in workplaces with quotas for immunisations and medication reviews and higher prescription volume were all more likely to report that their work environment was not conducive to safe and effective patient care.⁴⁸

Pharmacists working in independent pharmacies or hospital pharmacies/long-term care settings were also less likely to report a work environment that was not conducive to safe and effective patient care.⁴⁸

The authors compare their findings by drawing on experience from the UK about increasing workloads on pharmacists' well-being, noting *"increased prescription volumes are associated with increased dispensing errors or near misses, thus compromising patient safety."*⁴⁸

Following regulatory reforms in Norway and Iceland, the average pharmacy is smaller in terms of sales and size of the staff.²⁸ In Norway, the deregulation of pharmacy led to increased numbers of pharmacies in some areas, but also resulted in fewer pharmacists per pharmacy *"implying that the available human capital has become more diluted."*²⁸ A survey of pharmacists following the reforms note that *"73% of pharmacists reported a significant increase in workload since the reform, and 40% said that the workload was unacceptable periodically or often."*²⁸

The pressure of increased workload on pharmacists not only has the potential to directly risk patient safety in terms of dispensing errors, but it may also reduce the quality of care provided to patients if pharmacist capacity limits the delivery of extended pharmacy services.

The experience of Norway and Iceland show that in those areas where pharmacy numbers, and hence competition increased, customers benefited from discounts on co-payments. However, it was noted that *"in terms of quality and availability of information and advice from pharmacists, the effects of the new policies are not clear."*²⁸

The 'WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies' (2014) examined the impact of deregulation of pharmacy on medicines accessibility, quality of pharmacy services and costs in nine European countries.²¹ In some countries, deregulation has led to an increased pharmacist workload and this meant less time for counselling and advice and less consumer satisfaction.

The tension between the "business of pharmacy" and the professional responsibilities of a pharmacist as a health care professional in "community" pharmacy practice has frequently been discussed. Deregulation and corporatisation in the UK have led to the discussion of whether the focus on profits compromises working conditions and patient care, and *"highlighted a deterioration in pharmacy staff skills and information services."*¹⁸

Further to these recent discussions in the UK, a controversial pharmacist interview published in a UK newspaper, reports the opinions of an employee pharmacist (and confirmed by many others), that when working for one of the corporate pharmacy chains:

The cuts to staffing that have made him feel unable to serve patients properly, the business targets that he is expected to meet, the pressure to behave like a salesman as much as a medical professional – and he believes managers treat him as a disruptive threat for questioning these practices.⁴⁹

This evidence demonstrates how retaining restrictions on pharmacy ownership and protecting the pharmacy market from corporate chains is essential to sustain the safety and quality of care for patients, as well as the breadth of services delivered by pharmacies. Deregulation will potentially have a detrimental impact on the quality of care pharmacists are able to provide for patients, due to the need to balance increased workload and reduced staffing, the capacity to deliver quality services and achieve financial targets. Therefore, patient safety and support to achieve the optimal use of medicines will be compromised.

Health Professional Autonomy and Ideals vs Corporate Business Objectives

The Ministry have stated that professional standards can be delivered by the "supervisory pharmacist" and "responsible pharmacist" roles that will be responsible for advising owners on and overseeing the implementation of professional practice standards and licence conditions.¹²

However, as overseas experience has demonstrated, this is not effective in practice and may lead to a conflict between professional practice and corporate business targets. Research from Canada found that corporate pharmacy managers reported more conflict than independent managers, and suggested that this may be explained by the corporate pharmacy manager not owning the pharmacy and having professional autonomy:

There is a separation of the professional and higher managerial level. As a result, these pharmacy managers may be more limited in their ability to substantially affect the managerial decisions made at the upper levels of the organisation. The manager in a corporate pharmacy is, therefore, more likely to experience conflict in managing the demands of the professional pharmacy practice, which may not align with the corporate mission/direction.⁴³

The day-to-day provision of pharmacy practice may not be consistent with the employee pharmacy manager's idealised concept of pharmacy practice and this may lead to conflict in the corporate business. Whereas independent pharmacy managers may be more autonomous and better able to align business practice with their own professional ideals of pharmacy practice.

Pharmacists are subject to the professional code of ethics and standards of practice whereas non-pharmacist business owners are not:

Corporate pharmacy managers, as pharmacists / professionals, identify more with professional objectives than with the more business-oriented objectives of their employers. As a result, maintaining a professional orientation may create conflict for corporate managers if the professional objectives and ideals of the profession differ from the principals of the employing organisation.⁴³

A business manager who is expected to deliver a financial profit for the corporate shareholders may not understand the professional obligations of a pharmacist and prioritise commercial interests over professional practice, and the low levels of professional autonomy afforded employee pharmacists, may result in conflict between the health care professional and the manager:

Evidence is emerging of pharmacy companies pressuring pharmacists into conducting significant numbers of MURs, even threatening disciplinary action if employee pharmacists fail to achieve the targeted number of MURs.³⁰

International experience and evidence demonstrates that the proposed responsible pharmacist/superintendent pharmacist roles are not effective in practice, and professional-corporate conflicts remain. Research from Norway and Iceland, following deregulation, reported that "75% of pharmacists reported that the conflict between professional and commercial interests had become greater after the reform."²⁸

Evidence suggests that non-pharmacist corporate owners and their senior management teams are more likely to favour increasing financial revenues and reducing costs through increased prescription volume and maximised process efficiency. As they are not pharmacists, they may be less concerned with achieving pharmacy's professional objectives, and the unfunded and unrecognised patient-focused activities that pharmacists provide are likely to be of low priority. The consequence of this has been pharmacists employed in larger organisations perceive themselves to have less autonomy, due in part to the more bureaucratic and predetermined structures of these organisations.⁵⁰

As Harding and Taylor (1997) state:

*Successful large bureaucratic organisations require rational and routinized procedures for maximising efficiency, and this is reflected in their delivery of rationalised, standardised pharmaceutical services dictated by company policies. Thus the autonomy of pharmacists employed in such organisations to practice discretion in their occupation is precluded.*³⁰

However, research from Canada also notes that:

*Franchise and independent managers have a more personal connection to the financial viability and long-term success of the pharmacy than corporate managers. Along with being the owner or franchisee come the inherent risks and rewards of operating a business.*⁴³

As health care professionals, pharmacists need professional autonomy to enable them to deliver quality pharmacy services appropriate for their local community needs and separate from service targets and financial pressures. The long-term investment of franchise and independent pharmacy owners in their communities is put at risk by the potential proposed deregulation of pharmacy ownership in New Zealand.

Workplace Conditions: Pressure, Stress and Patient Safety

An employer must make sure, as reasonably possible, that health and safety risks in the workplace are identified and managed properly. This includes workplace stress and fatigue:⁵¹

UK pharmacists have reported significantly higher levels of workplace stressors than the general working population

and raised concerns about "work-life balance, the nature of the job, and work relationships being the most influential on health and well-being."⁵² The pharmacists' self-reported error involvement was linked to both "high dispensing volume and being troubled by perceived overload (dispensing errors), and resources and communication (detection of prescribing errors)."⁵²

In Australia, Canada, and the States, workplace stress in community pharmacies that impact on patient safety is a growing concern. The reasons identified for this increase in stress include:

*The changing pattern of pharmacy ownership, with more corporate entities enforcing business-related demands on pharmacists, leading to reduced professional autonomy, provision of expanded scope and enhanced services without relaxation or delegation of traditional roles and insufficient or inefficient use of technicians.*⁵³

In addition, "higher prescription volumes, lack of breaks, workflow interruptions and staffing levels were other issues identified as potentially contributing to dispensing errors."⁵³

In the UK, the growth in corporate ownership of community pharmacies has been associated with:

*"More stressful working environments and greater economic pressures which potentially have consequences not only for the well-being of pharmacists but also for patient safety".*⁵⁴

After deregulation, pharmacists in Iceland and Norway reported "a significant increase in workload and increased conflict between professional and personal interests, which add stress to the working environment."²⁸ Whereas following deregulation in England, the reported decrease in profitability in community pharmacy⁵⁵ led to a reduction in the average size of pharmacies, a reduction in pharmacist pay rates and the number of employees.⁵⁶ Reductions in staffing levels lead to an increase in the workload of staff and which reduced the capacity to provide pharmacy services. Patient safety is also put at risk if sole-charge pharmacists are required to check their own work.

Sabine Vogler noted that several studies in Sweden confirmed what pharmacists verbally reported in the interviews for her research: "an increased workload for pharmacists, a deteriorated environment for counselling and advice as well as less consumer satisfaction."²¹ These concerns were endorsed by further studies from Sweden which "pointed to deficiencies in counselling and identified a negative effect on safety and quality issues after deregulation."²¹

The Society is concerned that the potential changes to the restrictions controlling pharmacy ownership in New Zealand will have a detrimental impact on the ability of pharmacists to practice pharmacy in a safe and professional manner.

Effect on Pharmacy Services

The proposed new Therapeutics Products legislation focus purely on medicines supply and not the professional assessment of health need and provision of health care and advice that a pharmacist provides.

As recognised through the government policies and strategies, a considerable body of evidence supports a wide range of enhanced pharmacist-provided services in

providing economic and health benefits; in addition to the care and advice provided daily to communities. As already indicated, deregulation of pharmacy ownership can result in a reduced capacity to deliver extended pharmacy services.

Provision of Pharmacy Services

Overseas experience has found that pharmacy service provision varies with the type of pharmacy ownership and is also dependent on the willingness and the capacity of contractors to offer the service, or the appropriateness of the service for the location served by the pharmacy.³⁰

Supermarket pharmacies in the UK were found to be less likely to provide a home delivery service, domiciliary visits, emergency hormonal contraception (EHC), needle-exchange schemes and the supervised administration of medicines management of drug addictions for which supervised administration is required, compared with smaller chains or independent pharmacies.³⁰

Bush and Langley noted that supermarkets, whilst opening extended hours, may not be perceived as "appropriate" locations to provide the less socially acceptable services as they may deter the public from shopping at the store:

*The provision of EHC and services for drug misusers are controversial to certain subsections of the UK population (not to mention pressure groups and the print media) which may deter commercial bodies, reliant as they are on the patronage of the general public, from offering such services.*³⁰

Corporate commercial interests prevailed over the interests of patients when, in response to concerns expressed by some of their customers, Tesco (the UK's largest supermarket group) decided to stop supplying emergency hormonal contraception without a prescription to women younger than 16 years old. It was noted that "companies have a significant responsibility to their shareholders—a responsibility that might not exist with individual professionals."³⁰

These examples demonstrate the potential conflicts that can arise between a commercial environment and the provision of professional services, and adds weight to the criticism that "the commercial interests of pharmacists are inconsistent with the altruistic attitude of the service ideal of professions."⁵⁷

However, differences in levels of provision of screening services such as cholesterol, diabetes, and sexually transmitted infection (STI) testing were provided by the different types of pharmacy outlets:

*Corporate pharmacies possess the financial power, by virtue of their large turnovers, to be able to subsidise provision of these services—which are unlikely to generate significant profits—than small chain and independent pharmacies that appeared less likely to engage in the provision of screening services.*³⁰

In the UK, a larger proportion of supermarket and multiple pharmacies provided the only advanced service, such as medicines use reviews (MURs) than the independents or small chain pharmacies:

*Respondents believed that supermarkets and the major multiple pharmacy chains held an advantageous position in terms of attracting financing for service development despite suggesting that the premises of such pharmacies may not be the most suitable for the provision of such services.*³⁰

Bush and Langley (2009) note some pharmacy services that are valued by patients, are more likely to be provided by the independents or small chain pharmacies:

The delivery of medicines to patients' homes offers no direct, short-term financial return and is

*operated primarily to both benefit patients and, hopefully, retain business in the long term.*³⁰

Taylor and Harding (2003) note that the community pharmacy sector is characterised by a dualistic approach to service delivery where "corporate pharmacies maximise profit through economies of scale and rationalisation, independents pursue profit maximisation primarily by service delivery."⁵⁸ This theory is supported several years later by a "scathing series of articles" in UK's The Guardian newspaper this year, which raised questions about whether the UK pharmacy giant Boots was "putting a drive for profits ahead of safe and appropriate pharmacy care".³⁴ 'How Boots went Rogue' was the headline by Aditya Chakraborty who comments that:

*More than 60% of Boots pharmacists said that commercial incentives or targets have compromised the health, safety or wellbeing of patients and the public, or the professional judgment of staff... half the time or more. That compares to 52% of chemists at other chains.*⁴⁹

The article includes a quote from a corporate employee pharmacist, who states that in their opinion:

*All the company cares about is profit, figures, services. They are not interested in patient safety, appropriate staffing levels, training time for staff, appropriate breaks etc.*⁴⁹

As discussed previously, a potential conflict exists between business and healthcare perspectives within community pharmacies. Community pharmacists are challenged by the "retailer" perception from other healthcare providers, as instead of charging for advice like doctors and lawyers; they earn payment by selling medicines and products.³⁰ After deregulation, greater competition has focussed pharmacy businesses on capturing sales and improving turnover, as opposed to delivering higher quality professional services.

Operational Efficiencies and Service Innovation

Overseas, growing "corporatisation" of the community pharmacy sector following deregulation of pharmacy ownership has seen "multiple pharmacy chains and supermarkets assume a position of predominance in terms of the provision of pharmaceutical services."³⁰

In Europe, pharmacy 'efficiencies' have been achieved as a result of appropriate incentive structures, ownership liberalisation and removal of price restrictions, however, it was noted that equity and access were better achieved through regulations controlling geographic, demographic or needs-based criteria to open new pharmacies.⁵⁹

A review of pharmacy dispensing systems and processes in New Zealand could improve pharmacy operational efficiency, reduce the operating costs of pharmacies and generate savings. However, as a Boots employee pharmacist commented in a survey of UK working conditions, "efficiency has a limit, beyond which patient safety is compromised."⁴⁹

The New Zealand Health Strategy and the Pharmacy Action Plan describe how pharmacists could integrate with primary care. The strategy's 5 key principles⁶, provide a framework for pharmacists to provide a more efficient dispensing/supply service and develop "modern ways to engage with people so that they are supported to manage and improve their own health"¹¹ and provide pharmacy services to optimise patient care and safety. The Pharmacy Action Plan also notes that "these approaches will also help health professionals to reinforce healthy behaviour through opportunistic interactions."¹¹

Further work needs to be done to identify where efficiencies could be made in the medicines supply process. These efficiencies could free up time for the pharmacist to optimise medicines use with patients: explaining how to use medicines safely and effectively and providing extended pharmacy services which improve self-management and reduce costs and demand for other services e.g. general

practice and secondary care. Efficiencies could also be gained through reviewing bureaucratic barriers that currently exist through compliance with Pharmaceutical Schedule Rules, and Pharmacy Licensing audits that focus on unnecessary pedantic nuances of regulatory processes that do not affect patient care or safety.

Effect on Rural/Non-Urban Pharmacies and Communities

Recent publications by New Zealand authors note evidence of rural/urban disparities in rates of disease incidence, access to services and health outcomes, but also challenges and inconsistencies in the definitions applied to what "rural", "rural populations" and "rural health" means in the New Zealand context.^{60,60,61} We note that in discussing access to health services by rural populations, papers rarely incorporate recognition of the pharmacist/pharmacy as a provider of health care.

For the purpose of this document, the term "urban" has been used to describe city/town centre retail locations and include supermarkets and shopping malls, and "rural" to describe smaller residential communities or socio-economically disadvantaged areas, located with a distance to travel to the nearest urban health provider, where the local population may have high health needs with low income and low health literacy demographics.

Access

The international experience demonstrating the effect of removing ownership restrictions on pharmacy numbers in rural areas and those with smaller populations is recognised by the Ministry of Health in their documents and advice.²⁰ The potential impact of the expected loss of pharmacies and pharmacist services on health care provision in these areas is significant, with one in four New Zealanders living in rural areas or small towns and a greater percentage of children, older people and Māori living in these areas. The Ministry of Health website notes:

Ensuring comprehensive, quality services for people living in rural areas is a priority for the Government.⁶²

Norris and others considered the geographical access to community pharmacies in New Zealand in a paper published in 2014. They note:

Lack of geographical access to a pharmacy reduces people's abilities to obtain medicines and the professional advice they may need to use them appropriately.⁶³

The authors discussed how access to pharmacies in rural and remote areas can be problematic in countries with areas of low population density such as New Zealand, Australia, Norway, Finland, and Canada. In order to try to ensure that pharmacies are distributed as widely as possible to meet the spread of population, governments have used various strategies including licensing:

Which means that the government or a licensing authority decides how many pharmacies there should be and where they should be located. As well as providing direct control over pharmacy location.⁶³

In New Zealand, the government has not directly intervened in ensuring access to community pharmacies through influencing pharmacy numbers or their locations.⁶³

As previously mentioned, location is determined primarily by the pharmacist owner in establishing the pharmacy.¹³ Possibly mirroring population shifts over the years, there does appear to have been an urbanisation of pharmacies in New Zealand with a loss of pharmacy numbers in smaller rural towns.⁶³

Patients

People's access to health and disability services in rural areas is affected by socioeconomic deprivation, geographical barriers and distance, transport options, telecommunications, the cost of accessing services and service acceptability.²⁵

In many rural or socio-economically deprived locations across New Zealand, community pharmacies are fundamental providers of health care and advice to the local community. These pharmacist owners are motivated to provide a high quality and effective service, as not only does the financial viability depend upon this, they know their customers and patients well as they live amongst the community they serve. Many of these pharmacies offer a level of personal service that often goes 'way beyond the call of duty' to assist and support, the loss of which would likely be detrimental to the health care of the community if aggressive competition through ownership deregulation forced them to close.⁶⁴

The government and health sector as a whole recognise the significant challenges meeting health needs, and delivering and retaining health services in rural areas. Therefore the potential loss of the health care services and advice from pharmacists presents a significant risk of furthering inequitable access to care for these communities while increasing demands on other providers that do remain.

Closure of rural community pharmacies and community pharmacies in areas of high socio-economic deprivation and high health needs will be a barrier to equitable access to pharmacy services for "all New Zealanders 'to live well, get well and stay well.'⁶⁴

Workforce

The viability of rural community pharmacies will also affect the employment opportunities for pharmacists. Recent New Zealand research has shown that the medical workforce is concentrated in urban areas and is poorly distributed by demography, geography, and discipline to meet patients' needs.

The Honourable Dr Jonathan Coleman stated in the Ministry's Statement of Intent 2015-2019 noted that:

Equitable access to an appropriately trained, motivated, supported and flexible workforce is essential to provide high-quality and sustainable health and disability services [...] to ensure rural communities have equitable and effective access to health care services.⁶⁵

Maintaining the rural community pharmacy is important to improve the quality of health care delivered to rural populations, particularly outside normal working hours as many rural practitioners are devolving after-hours work to regional centres reducing local after-hours medical care (e.g. evenings and weekends).

The economic viability of pharmacies in rural areas and smaller towns is an ongoing concern that is also complicated by difficulties in attracting and retaining staff.⁶³ We expect this would be compounded by deregulating ownership of pharmacies.

In many of the under-served rural areas of New Zealand, there is a heavy reliance on the medicine 'depots' that have been established.⁶³ A 'depot' is a remote shop or clinic approved by the Ministry of Health to receive and hold dispensed medicines for collection and provide a limited range of pharmacy or pharmacist-only classified medicines. However, these shops do not have a health professional available to provide advice on how to use the medicine or assist with assessing and recommending the very limited range of over the counter medicines or provide any of the other pharmacist or pharmacy delivered services available through pharmacies elsewhere.

Costs

Rudholm (2008) notes that the increase in availability of pharmacies is achieved at the "expense of increased cost

for the individual pharmacies which competed on localisation instead of price."⁶⁶

The costs of operating rural pharmacies are considered to be higher than the operating costs of urban city businesses. The rural location incurs extra costs for the delivery of medicines by courier to the pharmacy or to customers, the slower turnover of stock in low population areas lead to increased capital depreciation, staffing vacancies are more difficult to recruit to and the additional expense of hiring locums is higher as it often includes additional travel expenses and sometimes accommodation costs.⁶⁷

Rural pharmacies also have higher risks and costs related to procurement and stock-holding of pharmaceuticals.⁶⁸ To further support the supply of pharmaceuticals in rural areas, it has been recommended by District Health Boards Central Technical Advisory Service (Central TAS) that doctors have a greater role in dispensing medicines.⁶⁸ Considering current recognition of an increasingly fragile rural medical workforce, that is already working longer hours than their urban colleagues, the appetite for such a move would appear remarkably low,⁶⁹ particularly considering the pharmaceutical stock-control issues would remain.

Overseas experience has demonstrated that the perceived financial savings on therapeutic product costs are not realised for the patient or government.²¹

Effect on Government, Regulators, and Funders

Deregulation, corporatisation and the perceived loss of professional autonomy will be detrimental to the pharmacy profession and the development of integrated care and collaboration between the pharmacy and medical professions.³⁰ This presents significant barriers to implementation of the Pharmacy Action Plan¹ which relies on "one team" operating in a high-trust system, sharing information and care plans with greater integration of care between pharmacists and doctors to enable "all New Zealand to live well, get well and stay well".⁶ There will also be an adverse effect on achieving the five themes identified in the New Zealand Health Strategy⁶: people-powered, closer to home, value and high performance, one team and a smart system.

International comparisons of the impact of regulatory changes at the national level are complex because indicators are linked to the underlying policy environment in the countries. In pharmaceutical policy analysis, challenges such as doing research that considers national/local context, and an understanding that policy research requires a fluid, ongoing process, have to be considered.²¹

European community pharmacy systems and policies have undergone several changes over the last two decades. This has ranged from single stand-alone changes such as changes in pharmacy remuneration or the introduction of a specific pharmacy service, to major organisational changes such as new contracts in England in 2005, and comprehensive changes in community pharmacy regulation and organisation in Iceland (1996), Norway (2001) and Sweden (2009).²¹

There are several reasons that have precipitated changes in community pharmacy systems and policies:

- In 1990, Hepler and Strand advocated for a patient-focused role and had called on pharmacists to adopt pharmaceutical care as their professional vocation, and

the role of pharmacists has extended from dispensers of medicines to healthcare professionals who are responsible for the safe, effective and rational use of medicines.⁷⁰

- The increasing number of medicines have been reclassified from prescription-only to pharmacist-only or OTC status and in some countries (e.g. England) policy changes have supported pharmacy-assisted self-care of minor ailments so that pharmacists are considered as a first contact point for patients.²¹
- Pharmacy margins have been redesigned to reward new pharmacy services, and/or they are cut due to financial constraints in the economy.²¹
- Regulations and policies related to the overall pharmaceutical system can impact on the work of pharmacists, such as requiring flexibility from pharmacists in their stock-keeping and medicines management.²¹
- Reforms in community pharmacy have been implemented because a specific extent of regulation has been considered beneficial for achieving defined policy goals.²¹

The Icelandic government attempted to save drug expenditure through price competition and discounts from pharmaceutical companies. However, "governmental subsidies were not affected; indeed, they continued to increase after the implementation of the new policies."²⁸

The Norwegian Department of Health commissioned an evaluation which showed that although the integrated groups have managed to negotiate discounts from pharmaceutical companies, in particular for generic drugs, these discounts "have not been transferred to consumers or to the national government in the form of reduced subsidies."²¹ Additionally, deregulation in community pharmacy was not found to decrease OTC pharmaceutical costs.²⁴

In Sweden, the State Treasury evaluation of deregulation concluded:

The policy aims of increased accessibility and lower expenditure have been met largely but the goals of better service quality and a broader range of services, as well as the aim of maintaining competence and safety in pharmaceutical supply, have only been met to some extent.²¹

The evaluations of the Agency for Growth Policy Analysis in Sweden assessed the deregulation and found, that “new pharmacies were established in urban areas and not in rural areas and the prices of OTC medicines did not decrease.”²¹ The Consumers Agency, another Swedish state authority, confirmed, the “increased accessibility of pharmacies and other dispensaries but highlighted a deterioration in pharmacy staff skills and information services according [to] consumers’ perception.”²¹

Deregulation of pharmacy ownership in New Zealand will not achieve the financial savings that the government hopes to achieve and will likely have a detrimental effect on pharmacy services.

The Ministry suggest that deregulation will simplify the ownership licence regulations and reduce the time and effort by pharmacists, however, under a deregulated system, pharmacists will still have to meet licensing compliance requirements and so deregulation will not save time and money in this area.

Rather than removing ownership restrictions that will drastically reduce the level and quality of health care by pharmacists, we recommend the government focus on factors that enable more pharmacies to provide equitable access to a greater range of beneficial pharmacy services that are integrated with the wider healthcare team.

Some European governments provide subsidies to support the viability of rural pharmacies. In England, rural pharmacies were subsidised under the Essential Small Pharmacy Local Pharmaceutical Services scheme⁷² and in Denmark, a tax equalisation scheme is in place under the Pharmaceutical Health Information System Pharma Profile to support pharmacies with lower turnover.²⁴

The smaller independent pharmacies in New Zealand which provide an extremely valuable provision of care to their local communities (often rural or with socio-economic deprivation and high morbidity) need to be supported and protected by regulations around pharmacy ownership, not jeopardised by deregulation.

Regulatory Policy and Function

In the Pharmacy Action Plan, the Ministry notes that our health system is facing a number of challenges:¹

- Our ageing population and the growing burden of long-term conditions;
- Our ageing and unevenly distributed workforce;
- Access and equity to improve health outcomes for Māori, Pacific, and other priority populations;
- Health Literacy – the capacity to find, interpret and use information and health services effectively;
- Information and technology;
- Fiscal sustainability.

Whilst the government recognises pharmacy as part of the ‘one-team’ of integrated healthcare who can address these challenges to the health services in New Zealand, the Society believes additional regulatory changes are

required to facilitate the operational efficiencies and service innovation required to enable investment in pharmacy, upskill the workforce and support new pharmacy services to overcome these challenges.

As discussed previously, there are opportunities for efficiencies to be made in the therapeutic products supply system and by the reduction in compliance costs/bureaucracy. These opportunities can be realised through changes in Pharmac and the audit of pharmacies.

A more empowered regulator, who is sufficiently resourced and empowered to regulate effectively and responsibly is a key part of the regulatory process. The regulator should focus on aspects of patient safety and less on compliance with unimportant regulations.

AT Kearney in ‘The Future of Community Pharmacy in England’ notes:

Pharmacists cannot do it alone. Government and regulators must provide an enabling environment and the profession needs to demonstrate leadership in the building the capabilities in the new model.³⁵

In order to optimise the future of community pharmacies, AT Kearney advise that the UK Government needs to “put into practice a policy of using the best professional for each intervention to ensure proper allocation of resources across the healthcare system.”³⁵

In Scotland, a service-orientated pharmacy model has been developed in which both the Department of Health and the public health providers have key roles to play in setting the agenda for change, and aligning stakeholders across the spectrum of commissioners, clinicians, pharmacy contractors and patients.³⁵ This had led to the creation of a collective health service with “solid foundations of cooperation and collaboration.”³⁵

Future Viability of Community Pharmacies

The CPSA is the contract between individual District Health Boards and each individual pharmacy throughout New Zealand for the provision of pharmacy services.

Introduced in July 2012, the CPSA reflected a shift to a patient-centered pharmacy delivery model which encourages integration between health professionals. It has involved considerable engagement and collaboration between community pharmacies, District Health Boards, PHARMAC and the wider health sector. In New Zealand, funding changes under the CPSA since 2012, have led to declining retail sales. Together with an increase in staff wages, this has made a significant impact on pharmacies in decreasing profits. The Director of Moore Stephens Markhams accountancy firm commented on the third annual Pharmacy Benchmarking Survey: “The reality is that the number of prescriptions is increasing, [pharmacists are] doing more work for less money.”⁷³

The 2014 report ‘The Future of Community Pharmacy in England’ by consultants ‘AT Kearney’ note that UK pharmacies have also been under pressure for some time, as trading conditions become increasingly challenging.³⁵

The UK Pharmacy Access Scheme was developed to support community pharmacies who meet the criteria based on the “size and needs of each population”, with pharmacies that are a mile or more from another pharmacy being eligible for the funding. Members of the UK Parliament have recognised in reference to any potential community pharmacy closures “would significantly increase the pressure on our already over-stretched hospitals and GP surgeries.”⁷⁴

This review of New Zealand regulations is an opportunity to better utilise the unique skills and knowledge of pharmacists, enabling the profession to work at the top of their scope of practice. Regulatory change can also address barriers and enable implementation of new innovations of care and models of working as an active component of the 'one' integrated health care team by supporting people to live well in the community, and reducing demand on general practice and secondary care services.

Regulatory Authority - Pharmacy Licenses

The Ministry propose that pharmacy licenses will no longer be restricted to a physical location.

By removing the current restrictions relating to pharmacy ownership by a pharmacist, and sited at a specific location, the intended financial benefits will not be realised and the risk is that the autonomous professional role of the community pharmacist will be weakened and patient safety put at risk.

The international evidence and experience of deregulation and re-regulation of pharmacy ownership demonstrates the benefits regulatory protection from commercially-driven interests of non-pharmacist owners, and the risks to the extent and quality of care and services.^{21, 54-54}

To control pharmacy location (prevent urban clustering and support rural pharmacies) and equitable access to pharmacies, consideration must be given as to how the proposed new regulator can work with the District Health Boards to review how the geographical location of premises for new pharmacy licences are controlled to protect existing pharmacy businesses, and ensure equitable distribution of pharmacy services.

The Society recommends that a form of location controls can ensure pharmacy licence approval can consider geographical or demographic need in improving patient equity and access to pharmacy services.²¹ However, we acknowledge that further work needs to be done to determine the specific criteria.

Commerce Act

The Commerce Act 1986 promotes competition in markets within New Zealand. It prohibits conduct that restricts competition (restrictive trade practices) and the purchase of a business's shares or assets if that purchase leads to a substantial lessening of competition in the market.⁷⁵

Under deregulation overseas, corporatisation of the community pharmacy market has led to a substantial lessening of competition, due to a high combined market share, horizontal and vertical integration, difficulties entering the market, buyers have limited power and an increased potential for coordinated behaviour. Under the Commerce Act, the Commerce Commission has a role to play in preventing anti-competitive mergers from going ahead.⁷⁶

Overseas, deregulation has led to increased corporatisation and consolidation of the community pharmacy market and this would be a risk for anti-competitive pricing of therapeutic products in New Zealand.

Pharmaceutical Expenditure and Financial Sustainability

The Ministry of Health has stated that following deregulation, one of the outcomes they would hope to achieve would be *"greater economies of scale and more buying power may result in lower distribution costs and therefore lower prices."*²⁰

However, a comprehensive study in Europe by Vogler found:

No indication for an association between the extent of regulation (information from the literature review and the questionnaire survey) and the amount of total, or public, pharmaceutical expenditure.²¹

In New Zealand, the purchasing and distribution of medicines are unique and is controlled by PHARMAC and the Pharmaceutical Schedule. Overseas, experiences of deregulation have reported an increased competition aiming to reduce the price of pharmaceuticals, however, this does not translate to New Zealand practice where the price and margin of pharmaceuticals are controlled by Pharmac – who have a competitive tendering process for the cost of pharmaceuticals.

Pharmaceutical expenditure is influenced by a range of policies impacting both price (e.g. price control at factory price level, external price referencing, goods and services tax) and volume (e.g. prescription limits for doctors, pharmaceutical budgets).

Prices of medicines, at least of reimbursable and/or prescription-only medicines, are regulated in most European countries, and even with deregulation of community pharmacy, pharmacy margins continue to be regulated. Therefore, an association between the extent of regulation in the pharmacy sector and prices of the reimbursable and prescription-only medicines is not very likely.

In some countries, pharmacists have discretion about which brand of a medicine can be supplied when dispensing a prescription, and in some circumstances dispensing a cheaper generic brand may provide a greater profit for the pharmacy. In Iceland and Norway, any discounts from pharmaceutical companies, in particular for generic drugs, have not been transferred to consumers or to the national government in the form of reduced subsidies.²⁸

In New Zealand, generic substitution is not always an option, as medicine choice is determined predominantly by which medicine brand has a government subsidy as outlined in Pharmac's Pharmaceutical Schedule. Also, the actual price of that medicine, including the margin, is fixed and determined through the Community Pharmacy Services Agreement, Central TAS.⁶⁸

From the European experience of deregulation, Vogler noted:

The remuneration to pharmacies for their dispensing of (publicly funded) medicines is only one element of pharmaceutical expenditure, and it is likely to be much less relevant than key drivers of pharmaceutical expenditure such as the introduction of new high-cost medicines and an ageing population.²¹

In New Zealand, due to the government controls on the price of pharmaceuticals and the set dispensing fee, other opportunities include restricting the volume of prescriptions. New Zealand policy-makers could undertake efforts to enhance a more rational use of medicines, particularly the management of long-term conditions and the ageing population, which could impact pharmaceutical expenditure in a cost-containing way.

Policy-makers can encourage pharmacists to play a key role in medicines management by designing the pharmacy remuneration in a way to provide pharmacists with incentives to manage the supply of dispensed medicines cost-effectively, such as reducing the bureaucracy (certified copies of prescriptions) required to enable a first

dispensing of a new and expensive medicine to be supplied in instalments.

Regulations could potentially place some restrictions and controls and allow pharmacies to trade between each other and with medical centres, residential care facilities etc. A permit allowing the pharmacy licence to be recognised as a wholesaling licence could bring advantages of bulk supply and accommodate larger pack sizes to be supplied which could provide efficiencies within the supply chain with a reduced number of prescriptions and reduced dispensing costs.

Where current efficiencies in the system can be gained through reviewing aspects of regulation that places barriers and compliance burdens on pharmacies. This would provide some of the efficiencies and pharmaceutical purchasing and distribution innovations/cost benefits the government seeks, while not compromising on the professionalism and care pharmacists provide to New Zealanders.

The assumption of lower medicine prices after deregulation might be relevant for non-reimbursable OTC medicines whose prices are not regulated. Price studies on OTC medicines are rare. A report by the OECD notes how existing price surveys have not provided any evidence of increased price competition with OTC medicines, and but distortion of competition due to unbalanced market power or uneven accessibility in countries with less regulated pharmacy sectors.²⁴

As current legislative provisions prevent financial incentives, but price setting and funding of pharmaceuticals and their supply is regulated by Pharmac and is outside of any ownership restriction, removing ownership restrictions does not lead to equity in greater competition or reduced costs for the patient.

Looking only at the price perspective, Australian consumer group 'Choice' recently published a comparison of the prices of a range of over-the-counter medicines in supermarkets and pharmacies⁷⁷:

- In general, pharmacies equalled or beat supermarkets on price when comparing brand for brand, and with larger pack sizes available in pharmacies, the price per dose was even cheaper.
- Pharmacies often sell cheaper brands than the name brands sold in supermarkets, offering greater savings. The main exception was generic ibuprofen, which was cheaper in supermarkets.
- More effective active ingredients, stronger doses, and a broader range of medicines for many conditions are available in pharmacies.

The authors concluded by noting:

While we weren't investigating customer service issues, we noted that in the pharmacies we went to, we were often offered assistance, usually by more than one person. There may be better options than the specific medication you're considering, so it's worth asking for advice.⁷⁷

Overseas experience suggests that corporate pharmacy owners are motivated by profits and sales targets.⁴⁹ Aditya Chakraborty, writing in the UK Guardian newspaper (2016), suggests that corporate business owners are:

Lawfully exploiting the opportunities afforded them by globalisation and new technology, they hand over as little tax as possible to the countries on whose infrastructure and protections they rely, squeeze pay and conditions for employees even while handing out lavish rewards to managers, and underinvest in staff so as to over-reward shareholders.⁴⁹

For the local economy, profits for corporate business owners are more likely to be taken overseas, out of the New Zealand economy⁴⁹. Compared to the independent or franchised pharmacy owners whose profits are more likely to be reinvested the local economy.

Conclusion

The Society recommends that restrictions to pharmacy ownership remain in place, although cautiously support appropriate models for mixed ownership with medical practitioners. We recommend that changes to the regulatory regime for therapeutic products be instead focussed on reducing the burden of regulatory compliance placed on pharmacists. This will enable community pharmacies to operate more efficiently and, in doing so, free up capacity to innovate new and cost-effective pharmacy services.

In particular, we recommend:

- **An enhanced and appropriately resourced pharmacy licensing authority.** This body should be given the authority, powers and capability to ensure licensing effectively supports safe, responsible, high-quality and equitable pharmacy health care services. These powers could include the power to decline or withdraw licences to achieve the objectives of regulation, and the discretion to evaluate local health care needs and the location of existing services when considering applications for pharmacy licences.
- **A more pragmatic approach to the administrative processes for dispensing and supply of medicines.**

Currently, very specific rules and processes govern matters such as the permitted quantities, timeframes, and record-keeping requirements around dispensing, and the mechanisms by which pharmacists can supply medicines to other registered health professionals. More flexibility around these processes would reduce the bureaucratic overhead for pharmacists.

- **Streamlining of regulatory functions among agencies.** PHARMAC, DHBs and Medsafe are each mandated with a specific role in the management and funding of the pharmaceutical supply chain. From the pharmacy perspective, the process can often operate as three silos, with inconsistencies and gaps that create additional work for frontline pharmacists. For example, PHARMAC funding of medicines that do not have Medsafe registration approval requires extra engagement by the pharmacist with prescribers and patients. Addressing these sorts of issues will support community pharmacies to operate more efficiently.

A more comprehensive comment and presentation of recommendations will be possible when the exposure draft of the new Therapeutic Products Bill is released.

Definitions and Glossary

Central TAS – Central Technical Advisory Service, a subsidiary organisation that provides national and regional technical and programme management and support services on behalf of District Health Boards, including implementation of the Community Pharmacy Services Agreement.

Chain pharmacies employ pharmacy managers who are salaried employees of head office (corporate/wholesaler/supermarket). Head office directs all marketing, merchandising, buying, professional programs, etc. An individual or corporation must own five or more stores to be considered a chain.⁷⁸

CPSA - Community Pharmacy Services Agreement, the contract between individual District Health Boards (DHB) and each individual pharmacy throughout New Zealand for the provision of pharmacy services.

Deregulation in the context of this review and position statement, refers to the removal of regulatory restrictions on the ownership of pharmacies to majority control by pharmacists.

DHB – District Health Board.

ECP or EHC – Emergency Contraceptive Pill / Emergency Hormonal Contraceptive.

EU – The European Union.

Franchising enables an individual owner pharmacist to operate as part of a larger group and purchase and market goods under the parent banner. It is increasingly used in the healthcare sector with the aim of enhancing quality and accessibility for patients, improving the efficiency and competitiveness of organisations and/or providing professionals with a supportive working environment.⁴⁴

Horizontal Integration refers to alignment and controls of purchasing, trade and/or service delivery among multiple pharmacies.

Independent pharmacies are not affiliated with any corporately run banner, franchise or chain program. The name of the store is unique to that store, and the owner has complete control over ordering, marketing strategies, store image, etc. The owner may own more than one store; however, it is generally accepted that five or more stores under single ownership constitute a chain pharmacy.⁷⁸

MBIE - Ministry of Business, Innovation and Employment.

Medicines Depot - a remote location where no pharmacist is present (eg. shop, petrol station etc) where prescriptions can be left for delivery or transmission to the pharmacy for dispensing and/or where dispensed medicines can be returned to for collection by the person for whom the medicine was prescribed. Some depots may be licenced to sell named pharmacy medicines.

MTA – Medicines Therapy Assessment. A form of medicines management review and/or service delivered by pharmacists.

MUR - Medicines Use Review. A form of medicines management review and/or service delivered by pharmacists.

NHS – National Health Service (United Kingdom).

NZMA - New Zealand Medical Association, the pan-professional medical organisation.

OECD - Organisation for Economic Co-operation and Development.

OTC - Over-the-counter. Usually in reference to medicines available for supply from a pharmacy without prescription.

PHARMAC – the Pharmaceutical Management Agency, New Zealand government agency that decides which pharmaceuticals to publicly fund.

Pharmacy Council of New Zealand – Responsible Authority for pharmacists, established under the Health Practitioners Competence Assurance Act 2003.

PHO – Primary Health Organisation.

Regulation or government control of pharmacy ownership enables equity and access for patients to be achieved by establishing geographic, demographic or needs-based criteria for new pharmacies.²¹

Reregulation is the reintroduction of government controls. Three European countries (Hungary, Estonia, and Latvia) have reregulated pharmacy ownership to reintroduce private ownership in the pharmacy sector²² or improve competition and encourage new competitors to enter the market.²⁵

Rural - Statistics New Zealand developed has seven categories to describe rural and urban New Zealand. Four categories are considered to be rural: highly rural/remote area, rural area with low urban influence, independent urban area and rural area with moderate urban influence.

Superintendent or 'Supervisory' Pharmacist is legally and ethically responsible for the professional standards of the entity that owns the pharmacy.⁸⁸

'The Act' – The Medicines Act 1981.

'The Ministry' – The New Zealand Ministry of Health.

'The Bill' - Therapeutic Products Bill – the proposed new legislation and regulatory regime that will replace the Medicines Act.

Urban - Statistics New Zealand developed has seven categories to describe rural and urban New Zealand. Three categories are considered to be urban: main urban areas, satellite urban areas, and independent urban communities.

Vertical Integration refers to alignment and controls of trade between pharmacies and a defined wholesaler.

WHO – World Health Organisation.

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