Coversheet: Pharmacy ownership and licensing

Advising agency	*Ministry of Health*
Decision sought	*This impact analysis informs decisions on the future of restrictions on the ownership of community pharmacies and associated licensing questions, contained in the Cabinet paper 'Pharmacy ownership and licensing'.*
Proposing Minister	*Hon Andrew Little, Minister of Health*

Summary: Problem and proposed approach

Problem definition

What problem or opportunity does this proposal seek to address? Why is Government intervention required?

The Medicines Act 1981 restricts ownership of community (retail) pharmacy businesses. In essence, the majority interest in a community pharmacy may be held only by a qualified pharmacist with a current practising certificate, or a company in which such a pharmacist or pharmacists have more than 50 percent of share capital and is/are also in effective control of the pharmacy.

Since regulatory changes in 2004, legislative provisions have allowed a range of business arrangements to develop that comply with the letter of the law, but not the original intention of preventing ownership of multiple pharmacies (beyond an expanded limit of five pharmacies per company or individual).

The ownership restrictions do not meet the Government's standards for good regulatory practice. They do not best support the shared Government/sector objectives for pharmacy services, particularly around integrated and innovative models of patient care, equitable access to medicines and pharmacy services, and fully utilising the unique skill set of pharmacists.

The Medicines Act will be repealed and replaced by a new Therapeutic Products Act, giving the Government the opportunity to ensure that best practice regulation is in place, i.e. regulation that is:

- proportionate to the risk it is managing (quality, safety and access to pharmacist services and therapeutic products),
- sufficiently future-proofed to accommodate innovation, and
- the most cost-effective way of protecting consumers.

The government also has an objective of ensuring equitable access to medicines through community pharmacies.

Another type of ownership restriction applies to healthcare professionals who may prescribe medicines. They may not hold any interest in a pharmacy without specific authorisation from the licensing authority. This analysis also considers whether to continue this restriction ('prescriber interests in pharmacies').

Summary of preferred option

How will the agency's preferred approach work to bring about the desired change? Why is this the preferred option? Why is it feasible? Is the preferred approach likely to be reflected in the Cabinet paper?

This impact statement analyses the impact of the status quo against two options that were consulted on during consultation on the draft Therapeutic Products Bill:

- Option 1 (the status quo) is to continue the current restrictions on who may own a pharmacy.
- Option 2 would strengthen the link between ownership and effective control of pharmacies, to limit the continued corporatisation of the sector.
- Option 3 would remove ownership restrictions, while retaining and strengthening professional control of pharmacy activity by pharmacists.

Option 3 is the Ministry of Health's preferred option. We consider it would best allow innovation in patient care and improved consumer access to medicines and pharmacy services. It would best enable the normal functioning of a competitive market and enhance consumer welfare.

The Ministry's preferred option for prescriber interests in pharmacies is to remove the current restrictions. The accompanying cabinet paper recommends this option.

Section B: Summary impacts: benefits and costs

Who are the main expected beneficiaries and what is the nature of the expected benefit?

Patients/consumers: benefit from lower costs, better access and more targeted services.

Regulated parties: no longer required to create and demonstrate particular capital and governance arrangements; better opportunity to provide innovative services.

Regulators and professional bodies: reduced audit and compliance activity for ownership and financial matters.

Prescriber interests in pharmacies: enables more integrated healthcare services, especially between general practices and pharmacies. Enables better services to remote or otherwise vulnerable communities.

Where do the costs fall?

Regulated parties: increased access by patients/consumers to medicines and pharmacy services may reduce profitability for some businesses.

Regulators: increased vigilance for ensuring that the supervisory pharmacist and responsible person have the necessary authority to carry out their obligations without undue influence from the pharmacy owner.

Wider government: increased vigilance by Commerce Commission required to monitor market concentration; possible need for increased involvement from Employment Relations

Authority to complement provisions in Bill that protect employee pharmacists from undue influence from owners.

What are the likely risks and unintended impacts? how significant are they and how will they be minimised or mitigated?

Managing quality and safety risks to public

Some people opposed to removing ownership restrictions express concerns that the safety and quality of therapeutic products would decrease. There is no evidence from international research to support this.

The proposed new role of a supervisory pharmacist will strengthen oversight of quality management systems that impact pharmacy and pharmacist practice and the safe provision of therapeutic products.

The existing regulatory controls on product quality, safety and efficacy, and professional qualifications and standards, will continue.

Competition

It is likely that the current trend of increased horizontal integration in the pharmacy sector will continue. Large corporates are already involved in the sector, using modified ownership arrangements to remain within the letter of the law. Further development of pharmacy chains following removal of ownership restrictions would be managed using existing market regulation that applies to all sectors. The Commerce Commission would continue to be responsible for monitoring the industry for any abuse of dominance or cartel behaviour, under the Commerce Act 1986.

Access to medicines and pharmacy services

Some concerns are expressed that access to pharmacy products and services, particularly in remote areas, would decrease.

DHBs commission pharmacy services through service contracts, and local commissioning by DHBs is a key enabler to ensure services are available to meet the needs of the local community and address inequities[1].

Separating ownership from providing pharmacy services would support the shift to more tailored commissioning of pharmacy services. It would also allow more innovative approaches to service delivery, including to remote or disadvantaged communities.

Prescriber interests in pharmacies

The current restrictions reflect concern about prescribing behaviour being influenced by financial benefits.

Two complementary regulatory regimes work to avoid and address any inappropriate prescribing. Pharmacists' professional ethics, scope of practice and disciplinary regime are regulated under the Health Practitioners Competence Assurance Act by the Responsible Authority (the Pharmacy Council). Other prescribers (e.g. doctors, nurses, midwives) are similarly regulated. The pharmacy licensing authority (in the Ministry of Health) sets and monitors fit-and-proper person requirements for pharmacy licence-

1 This paper is written in the context of the current DHB system, as though this will change, the design of the future model is yet to be determined.

holders, and sets licence conditions (which can be specified generally or for particular licences).

While pharmacists' professional standards are primarily regulated under the HPCA Act, the draft Bill also contains measures to address potential conflicts of interest and unprofessional behaviour. These include: clearer requirements and obligations for licence-holders and responsible persons; an obligation on responsible persons to report any non-compliance; and making it an offence for a licence-holder or manager to induce a health professional to act unprofessionally. Before the Bill is introduced to the House, officials will review these provisions and determine whether any additional measures are needed to provide safeguards around potential conflicts of interest and to ensure high professional standards.

The PHARMAC funding model has significantly reduced the potential gain from unnecessary prescribing, compared with 1981 when the Medicines Act came into force.

Section C: Evidence certainty and quality assurance

Agency rating of evidence certainty

Medium to high.

The last 20 years have seen an international trend towards removing restrictions on pharmacy ownership. Research tracking the impacts of policy changes, particularly in Europe, since the late 1990s has assessed impacts on price, service quality (including accessibility), changes in the number of pharmacies and the level of market concentration. No decline in safety following the end of ownership restrictions has been reported within this body of research. Although care is needed when interpreting this research for the New Zealand environment, it provides a sound basis for identifying risks and benefits of the preferred approach.

Prescriber interests in pharmacies: some pharmacists are already able to prescribe medicines, and the regulatory oversight mechanisms for the sector have found no evidence to warrant concern.

Quality assurance reviewing agency:

Papers and Regulatory Committee, Ministry of Health.

Quality assurance assessment:

The Ministry QA panel has reviewed the Impact Statement titled "Pharmacy ownership and licensing", produced by the Ministry of Health and dated 20 May 2021.

The panel considers that the Impact Statement meets the quality assurance criteria.

The Impact Statement is clear, concise, consulted, complete and convincing. The analysis addresses the decisions sought from Cabinet, is balanced in its presentation of the information and the major impacts are identified and assessed.

Impact statement: Pharmacy ownership and licensing

Section 1: General information

1.1 Purpose

The Ministry of Health is solely responsible for the analysis and advice set out in this regulatory impact statement, except as otherwise explicitly indicated.

This analysis and advice has been produced for the purpose of informing final decisions to proceed with a policy change to be taken by or on behalf of Cabinet.

1.2 Key limitations or constraints on analysis

Scope

Cabinet decisions made in 2015 and 2016 have shaped proposals for pharmacy ownership and licensing [SOC-15-MIN-0050; SOC-16-MIN-0025]. Other options have not been included in this analysis as they were not publicly consulted on in 2018.

Wider issues around control of the medicine supply chain and professional regulation of pharmacy services are not in scope for this analysis, as the current regime will be continued and strengthened when the Therapeutic Products Bill enters into force.

Changing landscape

This paper is written in the context of the current DHB system, as though this will change, the design of the future model is yet to be determined. How the health and disability sector reforms are implemented will affect the pharmacy sector, for example the contracting of community pharmacy services by DHBs.

Evidence of the problem

Regulatory changes in 2004 to partially relax pharmacy ownership restrictions resulted in legislative provisions that have allowed a range of business arrangements to develop that comply with the letter of the law, but not the original intention of preventing corporatisation of the sector. Experience shows these arrangements can be difficult to regulate.

Competition policy studies and international experience have demonstrated the opportunities that can be realised for patients/consumers and for the profession by removing pharmacy ownership restrictions.

Assumptions underpinning the impact analysis

Choice of the preferred option is supported by the Ministry's knowledge of the pharmacy sector and consideration of pharmacy ownership restrictions over many years, review of international studies, and analysis of submissions on the consultation document for the new therapeutic products regulatory scheme.

Quality of data used

Medium to high.

Limitations on consultation or testing

Options 2 and 3 were widely consulted on during consultation on the draft Therapeutic Products Bill during 2018/19. Option 1 (the status quo) was not consulted on, as it was not seen as meeting the criteria for best-practice regulation.

1.3 Responsible manager:

Fiona Ryan

Manager, Therapeutics

System Strategy and Policy

Ministry of Health

Date: 21 May 2021

Section 2: Problem definition and objectives

2.1 What is the current state within which action is proposed?

Pharmacy ownership restrictions

The Medicines Act 1981 currently restricts who may own a pharmacy, by setting ownership criteria as a condition for being granted a licence to operate a pharmacy. This regulatory impact statement deals with community (retail) pharmacies, which constitute more than 95% of pharmacies in New Zealand. There are specific provisions in the Act for pharmacies in a hospital and those (currently six) owned by friendly societies, which are outside the scope of this analysis.

A company may operate a pharmacy only if more than 50 percent of the share capital is owned by a pharmacist or pharmacists who has/have effective control of the company. The only person who may operate a pharmacy or hold a majority interest in a pharmacy is a pharmacist. (Less than 1 percent of pharmacies are owned by individuals.)

A new regulatory scheme for therapeutic products

The Government is developing a modern and comprehensive regulatory scheme for therapeutic products (e.g. medicines and medical devices). The Therapeutic Products Bill will repeal and replace the Medicines Act 1981.

As part of designing the new regulatory scheme for therapeutic products, it is necessary to decide whether to continue with such restrictions.

The pharmacy sector

The number of practising pharmacists in New Zealand is steadily growing, to more than 4,200 in 2020 (including intern pharmacists). The workforce is young, with over half of registered pharmacists in their 20s or 30s. Nearly 80 percent of pharmacists work in community pharmacies, filling around 48 million prescriptions each year and providing advice on medicines and the management of minor ailments. Pharmacists also work in pharmacies owned by district health boards (DHBs), which are outside the scope of this analysis.

There are around 1,100 community pharmacies in New Zealand, a ratio to population that is in line with the OECD average. A 2014 study showed that the number of pharmacies in New Zealand rose between 1955 to 1970, remained steady between 1970 and 1985, and then declined until 2005. It then rose slightly by 2010. Pharmacies have concentrated in urban areas but so has the population: the proportion of people living 5 km, or 25 km, away from a pharmacy did not change between 1995 and 2010.

The Pharmaceutical Society of New Zealand represents over 4,000 pharmacists and pharmacy technicians. The Pharmacy Guild of New Zealand represents owners of community pharmacies. The Independent Pharmacists' Association was formed recently (since consultation on the Bill) to represent pharmacists who are not owners, such as locums and employees. The Pharmacy Defence Association assists pharmacists with professional indemnity or liability claims. The Pharmacy Council is the Responsible Authority for the profession under the Health Practitioners Competence Assurance (HPCA) Act. It ensures pharmacists are qualified, registered

and competent, sets ethical standards and oversees education and training programmes.

Sector strategy

Work is under way to refresh the Pharmacy Action Plan[2], which is the main strategic document for the sector. The current Plan describes a future in which pharmacy services are delivered in innovative ways across a broad range of settings, so that all New Zealanders have equitable access to medicines and health care services. The aim of the Plan is to unlock pharmacists' full potential, so they can deliver maximum value to the health system and contribute to the objectives of the New Zealand Health Strategy.

2.2 What regulatory system(s) are already in place?

Regulation of pharmacists and pharmacy services

There are currently three main facets to how pharmacists and pharmacy services are regulated:

- Pharmacist qualifications, professional standards, scope of practice and accountability mechanisms are regulated under the Health Practitioners Competence Assurance (HPCA) Act 2003. The relevant Responsible Authority is the Pharmacy Council. This will continue when the Bill comes into force.
- The quality and safety of medicines (including supply, storage, compounding, dispensing and sale) is regulated through the licensing of pharmacies and pharmacy practice activities under the Medicines Act 1981. This will continue and be strengthened as necessary in the Bill. (Provisions in the Misuse of Drugs Act 1975 relating to medicines that are also controlled drugs will continue.)
- Who may own a pharmacy is restricted under provisions in the Medicines Act 1981.

This analysis deals primarily with the third issue — restrictions on the ownership of pharmacies — and touches on relevant aspects of the licensing of pharmacy activities.

Ownership restrictions

Restrictions on who may own a pharmacy are unique among healthcare providers to the pharmacy sector. They were introduced more than 80 years ago to ensure that pharmacies remained as small businesses — the 'one pharmacist, one pharmacy' model — and not to ensure patient safety.

The restrictions were part of a government plan in the 1930s for the pharmacy sector. They were altered slightly over time, before the strict 'one pharmacist, one pharmacy' model that had existed for nearly 70 years was partially relaxed in 2004.

The 2004 provisions are the status quo. Under these rules, the only person able to hold a majority interest in a pharmacy is a qualified pharmacist with a current practising certificate. A company may hold a pharmacy licence only if a pharmacist(s)

2 Ministry of Health (2016) *Pharmacy action plan: 2016 to 2020*. Note that a refreshed action plan is in preparation.

has more than 50 percent of share capital and is/are in effective control of the company. A company may not operate more than five pharmacies, and an individual may not hold the majority interest in more than five pharmacies. Less than 1 percent of community pharmacies are owned individually, rather than by a company.

Since 2004 the ownership requirements have not been well defined, particularly the terms 'share capital' and 'effective control'. For example, while a pharmacist is limited to holding the majority interest in no more than five pharmacies, this does not preclude a pharmacist holding a minority interest in an unlimited number of pharmacies. This means that two or more pharmacists may together hold the majority interest in an unlimited number of pharmacies.

Different business arrangements have developed that comply with the letter of the law but not the original intention, and some seem to have been set up to avoid the intention of the ownership rules. These complex arrangements are not easy for the licensing authority (part of the Ministry of Health) to administer, and have eroded the nexus between ownership and effective control of a pharmacy. They have allowed de facto corporatisation of the sector: many pharmacies are part of chains, and pharmacies exist as part of supermarkets.

The changes reflect a shift from the traditional model of a pharmacist-owner being the pharmacist in day-to-day control of a pharmacy, to one where the pharmacist-owner determines the extent of their engagement in the business.

Other market factors

Access to therapeutic products and clinical advice is governed via Crown funding agreements with district health boards, which the DHBs translate into contracts for the provision of pharmacy services (discussed below).

Market structure and conduct are regulated under the Commerce Act 1986.

Shared objectives for pharmacy services

The role and functions of community pharmacies are set out in the Integrated Community Pharmacy Services Agreement that each community pharmacy provider has with its local DHB. The current agreement sets out these shared objectives for community pharmacy services:

- "The Ministry of Health, District Health Boards, PHARMAC, pharmacy service providers and a wide range of stakeholders in the primary care sector want to ensure that community pharmacy services are provided in an integrated manner and in a way that is fit for all New Zealanders.
- "They agree that community pharmacy services, as an integrated component of a people-powered, collaborative model of care, need to be delivered in innovative ways, across a broad range of settings, so that all New Zealanders have equitable access to medicines and health care services.
- "They also agree that the unique and complementary skill set of pharmacists as healthcare providers, and in particular as medicines management experts, needs to be fully utilised so as to enhance patient safety."

Prescriber interests in pharmacies

The Medicines Act 1981 prohibits a person who can prescribe medicines — even a pharmacist with prescribing rights — from holding an interest in a pharmacy, except where the licensing authority has given specific consent.

2.3 What is the policy problem or opportunity?

The ownership restrictions do not meet the Government's standards for good regulatory practice. They do not best support the shared Government/sector objectives for pharmacy services, particularly around integrated and innovative models of patient care, equitable access to medicines and pharmacy services, and fully utilising the unique skill set of pharmacists.

Continuation of the status quo

If current regulatory settings continue, we would expect to see continued tension between an outdated ownership model and demands from consumers and healthcare professionals for innovative models of service delivery. The current ownership restrictions are not well aligned with the shared Government/sector objectives for pharmacy services, particularly around integrated and innovative models of patient care, equitable access to medicines and pharmacy services, and fully utilising the unique skill set of pharmacists.

The new therapeutic products regulatory scheme (as established in the Bill) will allow for innovation in how and where the services will be provided, such as a mobile pharmacy reaching remote areas, pharmacists visiting rest homes or marae, or working as part of a multi-disciplinary team in the community.

These changes will further demonstrate the limitations posed by the current ownership restrictions, and the need for a direct correlation between a pharmacist owning a business in a fixed location and the same pharmacist providing the services in those premises.

Maintaining the ownership restrictions would limit the opportunity to innovate. For instance, healthcare service providers (such as iwi organisations) would be prevented from establishing pharmacies to serve particular areas or consumer groups, that would be managed by a pharmacist, with patient safety and service quality assured by the regulatory regime created by the Therapeutic Products Bill and the HPCA Act.

The status quo is not effective in achieving the original aim of keeping pharmacies as small businesses, as corporatisation has already occurred in the pharmacy sector. Retaining it would see the licensing authority continue to apply resources to scrutinising business arrangements rather than solely focussing on quality and safety.

Loss or harm being experienced

The status quo:

- limits, and will increasingly limit, innovation in service provision (discussed above)
- limits access to capital, compared with open ownership, which can in turn restrict innovation
- reduces consumer (patient) welfare through higher costs and restricted access (based on international evidence, discussed below).

International evidence

The last 20 years have seen an international trend towards removing restrictions on pharmacy ownership. Research tracking the impacts of policy changes in Europe (particularly the UK, Ireland, the Netherlands, Norway, Sweden and Iceland) since the late 1990s has focused on impacts on price, service quality (including accessibility), changes in the number of pharmacies and the level of market concentration.

No decline in safety following the end of ownership restrictions has been reported within this body of research.

An Organization for Economic Cooperation and Development study in 2014 that followed removal of ownership restrictions in some European countries found:

- a general increase in the accessibility of medicines, partly related to the establishment of new pharmacies
- relatively rapid development of pharmacy chains
- the tendency for new pharmacies to be established in urban areas, while in rural areas with an existing pharmacy few or no pharmacies opened, but no decreases were observed either
- an overall increase in opening hours
- some distortion of competition occurring when some market players (e.g. wholesalers) gained market dominance and aligned the pharmacy product range to those they supplied, which limited the availability of less frequently-requested medicines.

A study conducted for the European Commission in 2007 found clear evidence that regulation of operating requirements (particularly ownership restrictions on non-pharmacists) reduced both productivity in the sector and consumer welfare.

Prescriber interests in pharmacies

Some pharmacists are already able to prescribe medicines, and the regulatory oversight mechanisms for the sector have found no evidence to warrant concern. We share the view of many in the sector that the restriction on prescriber interests in pharmacies limits expansion of pharmacists' professional services, including to mitigate capacity constraints in primary healthcare. It is a barrier to developing truly integrated healthcare services, especially between general practices and pharmacies. It is likely to limit services to remote or otherwise vulnerable communities.

2.4 What do stakeholders think about the problem?

Stakeholders

Key stakeholders in the pharmacy sector and the provision of pharmacy services include:

- pharmacists and their representative organisation (Pharmaceutical Society of New Zealand)
- pharmacy owners and their representative organisation (Pharmacy Guild of New Zealand)
- Independent Pharmacists' Association, representing pharmacists who are not pharmacy owners
- Pharmacy Council (the Responsible Organisation under the Health Practitioners Competence Assurance Act)
- consumers (patients) and representative organisations (e.g. Consumer New Zealand)
- retail groups already involved in the pharmacy sector (e.g. pharmacy chains and supermarkets), and the representative organisation Retail New Zealand
- district health boards
- other healthcare professionals, particularly those who may prescribe medicines.

Consultation

In December 2018, Cabinet agreed that an exposure draft of the Therapeutic Products Bill (the Bill) and an accompanying consultation document be released to enable stakeholders to engage with the detail of the Bill, and for it to be amended before it enters the parliamentary process [CAB-18-MIN-0609 and SWC-18-MIN-0176].

Consultation closed in April 2019. In addition to receiving written submissions, the Ministry of Health held several forums to discuss the Bill and the intended regulatory scheme. The Ministry also held several meetings, webinars, and videoconferences with particular individuals and groups, including representatives of the pharmacy sector and pharmacists.

The exposure draft of the Bill did not contain provisions relating to pharmacy ownership, but the issue was canvassed in the accompanying consultation document[3].

Two options were consulted on:

- option 2: strengthening the link between ownership and control
- option 3: no ownership restrictions, with enhanced pharmacist control of quality systems and practices within the pharmacy.

The status quo of retaining ownership restrictions (option 1 below) was not consulted on, as it is seen as poor regulation without clear policy objectives. Nevertheless, the option of retaining the status quo is analysed in this impact statement, along with options 2 and 3 above.

3 Ministry of Health (2018) Therapeutic products regulatory scheme consultation document.

Submitters' views

Submissions by individual pharmacists or pharmacy businesses were overwhelmingly in favour of strengthened controls (59:1), though the 60 making comments are only a small minority of that sector (around 4,200 practising pharmacists and 1,100 pharmacies). Other individuals were evenly divided in their support between the two options.

Groups representing the pharmacy profession and pharmacy owners supported strengthening ownership restrictions. DHBs and other health providers tended to favour removing the restrictions. Associations or colleges of health professionals, including responsible authorities under the HPCA Act, had little to say on the matter.

Submissions are summarised below.

Support for retaining or strengthening ownership restrictions

The two representative organisations, the Pharmaceutical Society (representing pharmacists) and the Pharmacy Guild (representing pharmacy owners), have long opposed open ownership. About 60 individual pharmacists or pharmacy businesses also made submissions opposing any change.

This position is premised on the belief that pharmacist ownership of a pharmacy is necessary to ensure the quality of pharmacy services and the safety of consumers. They argue that pharmacist-owners have a greater focus on patients and delivering personalised care to their communities than an employee would. Arguments against removing ownership restrictions included fears of a focus on profits over patients; reduction in patient safety; poorer working conditions for pharmacists; and ending the special status of pharmacies.

Support for removing ownership restrictions

Support for removing ownership restrictions came from a range of submitters, including health professionals, Retail New Zealand and the two main supermarket chains.

Arguments in favour of open ownership included relying on professional regulation to ensure patient safety and service quality, rather than the proxy of ownership; greater potential for investment and innovation; and consumer benefits of lower prices and better access. Other arguments included that ownership controls are not working as intended, and present pharmacists with dual and possibly conflicting obligations.

Prescriber interests in pharmacies

The consultation document accompanying the Bill asked whether this restriction was still required, and about the risks and benefits of removing it.

Many individual pharmacies made submissions supported retaining the restriction. They asserted that removing the restriction would incentivise prescribers to write more prescriptions and to influence patients to patronise pharmacies in which they had an interest. Nevertheless, there was still general support for pharmacist-prescribers to be allowed to own pharmacies, as conflicts of interest "could be managed". The Pharmacy Guild, representing pharmacy owners, supported retaining the restriction.

The Pharmaceutical Society, representing pharmacists, supported removing the restriction. It pointed out that some pharmacists are already prescribers and said the restriction must be removed to allow for expansion of pharmacists' professional

services (including to mitigate capacity constraints in the primary care sector). It was confident that any risks could be managed through appropriate regulations.

Submissions supporting removal also came from individual pharmacies, a large pharmacy group, academics, DHBs, consumer groups and industry organisations. The Health Quality and Safety Commission (a Crown entity) noted the restriction was a barrier to integrated healthcare services, and limited services to remote or otherwise vulnerable communities.

Consistency of rules was another reason advanced; e.g. pharmacists can invest in a general practice, but the reverse is restricted. Some pointed out that the PHARMAC funding model has significantly reduced the potential gain from unnecessary prescribing, compared with 1981 when the Medicines Act came into force.

2.5 What are the objectives sought in relation to the identified problem?

Government objectives for the community pharmacy sector are to:

Ensure the safety of therapeutic products

Therapeutic products have to meet complex manufacturing, distribution, and storage requirements if they are to be safe for use. Consumers need assurance that products they use are what they say they are and perform as intended.

Ensure equitable access to pharmacy services

A delay or inability to access pharmacy services can have a range of impacts, from no or minor harm, to serious harm or even death. Access to therapeutic products needs to be easy, timely, affordable and reliable. Access to advice needs to be in a form understood by the consumer, accurate and appropriate to patient needs.

Ensure high service quality

Consumers need assurance that they receive the right product, at the right dose, and for the right amount of time. Consumers also need to be sufficiently and accurately informed about the use of a product, and any potential interactions between products.

Support innovation in service delivery

Pharmacy services are evolving, because of technological advancements, changing consumer expectations and innovation in how best to meet differing levels of need. Consumers want access to a range of products, and different options for accessing and using those products, including advice.

Pharmacists are experts in medicine management and have the required clinical skills and knowledge to provide services beyond core dispensing and advising activities. Innovation can save costs and free up pharmacist time to provide higher-value, integrated clinical services. It can help ensure equitable access to products and services.

Support regulatory system efficiency

The regulatory system needs to be fit for purpose, follow good regulatory practice guidelines, and be sufficiently flexible and future-proof. Efficient regulatory schemes minimise the cost of regulation to government and the sector, and free up resources so the regulator can focus on the most appropriate regulatory goals.

Support local benefit

Pharmacies and pharmacists play an important role in their communities' health promotion, prevention and early intervention activities. Community pharmacies with a local focus support a healthy community and support DHBs' efforts to improve the care of their local population.

Section 3: Option identification

3.1 What options are available to address the problem?

This analysis considers three, mutually-exclusive options for pharmacy ownership. How each would address the regulatory problem and opportunities for the sector is addressed in section 4 below, against the objectives in section 2.5 above.

Experience from other countries has been considered in some depth, and there is a brief summary in section 2.3 above.

Option 1 (the status quo): retain current regulatory settings

The existing policy for restricting pharmacy ownership, currently implemented in the Medicines Act 1981, would be retained. As it is intended for the Medicines Act to be repealed by the Bill, a legislative 'home' for continuing these policy settings for business ownership would have to be identified.

Option 2: strengthen the link between ownership and control

This option would retain and tighten pharmacist ownership requirements as a criterion for gaining a pharmacy licence. It would require that a pharmacist (or more than one pharmacist) must have financial, governance and operational control of any given pharmacy business. This would be achieved through two requirements:

- majority pharmacy ownership, so a pharmacist(s) receives the majority of financial benefits and has/have the majority of governance rights
- effective control, with a pharmacist(s) having management and operational control over the pharmacy's systems and practices.

If this strengthened ownership regime were to be introduced, many implementation details would still need to be decided. These include whether:

- the same pharmacist(s) must have both majority ownership and effective control, as at present, or whether a pharmacist-owner could employ another pharmacist to manage the business
- the five-pharmacy limit should be retained.

Such a move to tighten ownership restrictions would require a transition period to mitigate the impact on the community pharmacy sector. This period, over say five years, would sequence requirements for pharmacists to demonstrate majority control and governance rights, and for non-pharmacists to divest their financial interests. Early assessments suggest that between 50 and 80 percent of pharmacies would likely have to change their business arrangements as a result. In addition, pharmacists who contribute to the effective control of more than five pharmacies would need to change their business arrangements to meet a clarified five-pharmacy limit (if it were to be retained). The potential level of disruption reflects the way the sector has evolved since the ownership requirements were loosened in 2004.

Pharmacies owned and operated by a DHB would continue to be exempt from these requirements. Further consideration would be required about whether to continue exempting the six pharmacies owned by (not-for-profit) friendly societies. For historical reasons, these have been exempt from ownership restrictions.

The strengthened ownership restrictions of option 2 would be clearer than current provisions about the degree of ownership restrictions being sought, and would address the trend towards corporate ownership of pharmacies, which is of concern to many in the pharmacy sector.

This option would cause significant disruption to the pharmacy sector and remove property rights from some current pharmacy owners. As with option 1 (status quo), there is no clear policy rationale for this option, as there is no clear link between ownership restrictions and the quality of pharmacy services or public safety.

Option 3: remove ownership restrictions, and enhance pharmacist control of quality systems and practices within the pharmacy

This option would separate ownership of pharmacies from the regulation of the quality and safety of pharmacy services. Any natural or legal person meeting the relevant requirements (such as fit-and-proper person requirements) could hold a licence to operate a pharmacy. A pharmacist would be responsible for the design of pharmacy systems and practice, and their implementation.

The Bill sets out that pharmacy services would continue to be provided only by registered pharmacists holding a current practising certificate. A new requirement would be established for pharmacy licence applicants to nominate a 'supervisory pharmacist', who would be responsible for quality management systems that impact pharmacy and pharmacist practice and the safe provision of therapeutic products. A pharmacist would still have to be in charge of the day-to-day operations of the pharmacy. Depending on the size of the business, one pharmacist might perform both the supervisory and day-to-day operational functions, or they could be split between two pharmacists.

Removing ownership requirements would put community pharmacies on the same footing as every other health profession within the scope of the HPCA Act. It would bring an updated approach to the pharmacy sector, consistent with a modern understanding of well-functioning markets. It would best enable some of the innovative patient care models envisaged in the Bill to be implemented. As for other health service providers, provisions in the Commerce Act 1986 exist to protect consumers in the event of market concentration.

Prescriber interests in pharmacies

The options considered are to retain or remove the current restrictions.

3.2 What criteria, in addition to monetary costs and benefits have been used to assess the likely impacts of the options under consideration?

As discussed in section 2.5 above, these are:

- ensure the safety of therapeutic products
- ensure equitable access to pharmacy services
- ensure high service quality
- support innovation in service delivery
- support regulatory system efficiency
- support local benefit.

3.3 What other options have been ruled out of scope, or not considered, and why?

Cabinet decisions made in 2015 and 2016 have shaped proposals for pharmacy ownership and licensing [SOC-15-MIN-0050; SOC-16-MIN-0025]. Officials could provide further advice on other options for regulating the pharmacy sector, however given the impact such changes would have on the sector, further consultation on any new proposed option would be required.

The option of removing ownership restrictions but introducing other market-control mechanisms, such as constraints on vertical (supplier/retailer) integration or horizontal integration (the maximum market share for a group or chain), have not been included in this analysis as they were not part of the options publicly consulted on in 2018.

Section 4: Impact analysis

Marginal impact: How does each of the options for pharmacy ownership identified in section 3.1 compare with taking no action under each of the criteria set out in section 3.2?

Key:

++	much better than the status quo	0	about the same as the status quo	–	worse than the status quo
+	better than the status quo			– –	much worse than the status quo

	Option 1: status quo	Option 2: strengthen ownership restrictions	Option 3: remove ownership restrictions and enhance pharmacist supervision
Safety	**0** No evidence of any safety concerns resulting from ownership restrictions. Licence-holders are already able to operate up to five pharmacies.	**0** No evidence of any safety concerns that need addressing through tightening ownership restrictions. Stronger link between the pharmacist-owner who holds the licence and their effective control of the pharmacy.	**+** The new position of supervisory pharmacist would be responsible for the quality management systems that impact pharmacy and pharmacist practice and the safe provision of therapeutic products No evidence that removing ownership restrictions reduces product safety or personal/community health.
Access	**0** Pharmacy access has not diminished. Some market differentiation is occurring (e.g. de facto chains and supermarket or discount pharmacies).	**–** Possible contraction in the number of pharmacies, because of tighter ownership and financial requirements Likely to restrict or reverse recent market differentiation.	**+ +** Better serves consumers, by enabling improved access and lower costs. Market would be able to develop naturally to meet needs of consumers and the profession. Would be supported by tailored commissioning by DHBs or other entity.
Service quality	**0** Service quality assured by other regulatory measures: product quality under the Therapeutic Products Bill, and professional standards under the HPCA Act.	**0** Service quality assured by other regulatory measures: product quality under the Therapeutic Products Bill, and professional standards under the HPCA Act.	**0** Service quality assured by other regulatory measures: product quality under the Therapeutic Products Bill, and professional standards under the HPCA Act.

	Option 1: status quo	Option 2: strengthen ownership restrictions	Option 3: remove ownership restrictions and enhance pharmacist supervision
Innovation	**0** Some innovation occurring and may continue. Limited to some extent by complex business arrangements necessitated by ownership restrictions.	**–** Restricts access to investment capital. Some innovations such as hub and spoke models for dispensing may not be legally available.	**+ +** Enables innovation with new models for delivering pharmacy services, including ones better suited to low-income consumers and remote or vulnerable communities
Regulatory system efficiency	**0** No linkage between ownership restrictions and service quality or public safety. Requires monitoring of ownership structures and financial arrangements.	**– –** No linkage between ownership restrictions and service quality or public safety. Likely to require closer monitoring of ownership structures and financial arrangements. Significant sector compliance costs, and business disruption during transition.	**+ +** Law is clear in its aims, and does not attempt to regulate the economy through health legislation.
Local benefit	**0** Pharmacy owners have a local focus and can be there for many years. Financial benefits accrue to local owners and may stay in the economy.	**0 / –** Pharmacy owners have a local focus and can be there for many years. Financial benefits accrue to local owners and may stay in the economy. Potential local impact of significant transition costs to the sector.	**+** Potential for existing locally-owned pharmacies to remain as market changes (e.g. as has happened in the UK). Likely to be more pharmacies in urban areas, with no reduction in rural areas. Would be supported by tailored commissioning by DHBs or other entity.
Overall assessment	**0** Status quo; no change	**–** Not recommended	**+ / + +** Ministry of Health preferred option

Section 5: Conclusions

5.1 What option, or combination of options is likely to best address the problem, meet the policy objectives and deliver the highest net benefits?

Preferred option

The Ministry of Health's preferred option is to remove pharmacy ownership restrictions (option 3), as proposed in the cabinet papers setting out the scope for the new therapeutic products regulatory scheme [SOC-15-SUB-0050 and SOC-16-SUB-0025]. This would put the pharmacy sector on the same footing as all other health professions within the scope of the HPCA Act.

Under this option:

- safety would be enhanced by introducing the new role of supervisory pharmacist
- consumer access to therapeutic products and pharmacy services would be enhanced, through natural development of the market in response to different needs
- service quality would continue to be ensured by appropriate regulatory schemes
- innovation in service delivery would be most likely
- local pharmacies would be likely to remain, including because of tailored commissioning by DHBs (or another entity).

Assumptions and evidence

This conclusion is supported by the Ministry's knowledge of the pharmacy sector and consideration of pharmacy ownership restrictions over many years, review of international studies, and analysis of submissions on the consultation document for the new therapeutic products regulatory scheme.

Māori interests and Treaty of Waitangi implications

There was no strong Māori perspective provided during consultation on pharmacy ownership restrictions. Those who provided feedback did so in general terms, without specifically addressing the question of pharmacy ownership. Issues raised were about:

- reconfirming the need to do better in contracting and providing services that are tailored to best meet whānau needs
- seeking more opportunities to provide kaupapa Māori services
- pointing to the findings of the Wai 2575 inquiry, and reiterating that primary and community services are often not affordable, easily accessible or provided in a culturally-appropriate way.

The Ministry will engage with Māori to identify the key aspects of the new regulatory scheme for therapeutic products, including opportunities for changes to pharmacy ownership and improved access to medicines.

Stakeholder views

Stakeholder views are summarised in section 2.4.

Any of the three options analysed — keeping the status quo, strengthening ownership restrictions or removing ownership restrictions — is likely to be controversial. The preferred option would attract opposition from pharmacy sector representative organisations and many pharmacists, and support from consumer and retail sector representative organisations and businesses.

Prescriber interests in pharmacies

The Ministry's preferred option is to not continue restricting healthcare professionals with prescribing rights from holding an interest in a pharmacy.

There is no evidence of problems arising from pharmacists who are able to prescribe medicines owning pharmacies.

Removing this ownership restriction is most likely to enable expansion of pharmacists' professional services, and support the development of integrated healthcare services, especially between general practices and pharmacies.

5.2 Summary table of costs and benefits of the preferred approach on pharmacy ownership

Additional costs of proposed approach compared with taking no action			
Affected parties	**Comment**	**Impact**	**Evidence certainty**
Regulated parties	Increased access by patients/consumers to medicines and pharmacy services may reduce profitability for some businesses.	Low	Low
Regulators	Increased vigilance for ensuring supervisory pharmacist and responsible person have necessary authority to carry out their obligations without undue influence from pharmacy owner. This would be within the scope of the existing pharmacy licensing and audit system.	Low	Medium. Overseas evidence suggests vigilance by regulating authority required to ensure authority not encroached on by owner.
Wider government	Increased vigilance by Commerce Commission required to monitor market concentration. Possible slight need for increased support from Employment Relations Authority, to complement provisions in Bill that protect employee pharmacists from undue influence from owners	Low	High. Overseas evidence suggest increased market concentration following removal of ownership restrictions.
Other parties			
Total monetised cost			
Non-monetised costs		Low	

Expected benefits of proposed approach compared with taking no action			
Affected parties	**Comment**	**Impact**	**Evidence certainty**
Regulated parties	Better opportunity to provide innovative services Stronger, clearer, safety requirements. Costs reduced as no longer required to demonstrate governance arrangements.	Medium – High	High. Evidence from overseas suggests reduced compliance costs, but no change in safety.
Regulators	Reduced audit and compliance activity for ownership and financial matters.	Medium	High. Current regulator has indicated this option will require less resource to implement and audit. Regulator has indicated this option provides more clarity to regulating authorities
Wider government			
Other parties	Patients/consumers benefit from lower costs, better access and more targeted services	Medium – High	High. Overseas evidence and knowledge of market behaviour.
Total monetised benefit			
Non-monetised benefits		Medium – High	

5.3 What other impacts is this approach likely to have?

Market changes

We expect that removing ownership restrictions would see a continued increase in chain pharmacies (including pharmacies in supermarkets), and an overall increase in the availability of therapeutic products, particularly pharmacy-only medicines.

Section 6: Implementation and operation

6.1 How will the new arrangements work in practice?

The preferred option would be given effect by:

- not adding general pharmacy ownership restrictions to the draft Therapeutic Products Bill
- removing s 93 (Health practitioner prescriber must not hold interest in pharmacy business) from the draft Therapeutic Products Bill.

The preferred option would be implemented when the Therapeutic Products Bill comes into force and the Medicines Act 1981 is repealed.

The licensing authority would cease oversight of pharmacy financial and governance arrangements, when granting or renewing a pharmacy licence or auditing pharmacies. New business arrangements could evolve as owners wished and in response to consumers' needs.

6.2 What are the implementation risks?

Managing safety and quality risks to the public

There is no evidence that safety or medicines quality would reduce.

A range of open ownership models operate in other jurisdictions including the USA, Canada, European countries and the UK. Many of these have operated for a decade or two with no evidence of significant safety or quality concerns.

The new requirement for a supervisory pharmacist would strengthen independent professional oversight of pharmacy quality management systems and day-to-day pharmacy operations.

The Bill also contains provisions to prevent interference by the licence-holder in clinical decisions.

Technological changes in the sector have the potential to improve quality and safety while also improving efficiency. Open ownership has the greatest scope for investment and innovation in this type of technology, since it is likely that pharmacies will have better access to capital and scope for economies of scale.

Competition

The pharmacy sector would be regulated like any other business sector.

Large corporates are already involved in the pharmacy sector, using modified ownership arrangements to remain within the letter of the law. The speed at which de facto chains and supermarket pharmacies have achieved market penetration indicates the scale of efficiencies possible.

Further development of pharmacy chains following removal of ownership restrictions would be managed using existing market regulation that applies to all sectors. The Commerce Commission would continue to be responsible for monitoring the industry for any abuse of dominance or cartel behaviour, under the Commerce Act.

More diverse ownership options would support increasing market segmentation, with different services developing to meet the needs of different types of consumers (e.g. low-income consumers and those in remote areas).

Pharmacies in rural areas

International evidence is that with removal of ownership restrictions there are likely to be more pharmacies in urban areas, but no significant reduction in rural areas.

New Zealand's pharmacy commissioning model is well-placed to ensure access in rural areas. DHBs commission pharmacy services through service contracts (the integrated community pharmacy services agreement), and local commissioning by DHBs is a key enabler to ensure services are available to meet the needs of the local community and address access constraints. DHBs are considering how they can ensure that pharmacy networks within their regions deliver equitable access to a range of high-quality pharmacy and pharmacist services. To achieve this, DHBs have signalled a shift to a more deliberate approach to the commissioning of pharmacy services, including the development of support packages for rural and/or vulnerable communities.

Risks to rural areas would also be mitigated by innovative approaches to service delivery, such as mobile pharmacies, on-line pharmacies, telehealth consultations between pharmacist and patient, and different provider models (e.g. iwi-owned health providers able to employ a pharmacist). Supermarkets are present in some rural towns without pharmacies, so removing ownership restrictions could in some cases increase access.

Prescriber interests in pharmacies

Two complementary regulatory regimes work to avoid and address any inappropriate prescribing.

Pharmacists' professional ethics, scope of practice and disciplinary regime are regulated under the HPCA Act by the Responsible Authority (the Pharmacy Council). Other prescribers (e.g. doctors, nurses, midwives) are similarly regulated.

The licensing authority sets and monitors fit-and-proper person requirements for pharmacy licence-holders, and sets licence conditions (which can be specified generally or for particular licences).

While pharmacists' professional standards are primarily regulated under the HPCA Act, the draft Bill also contains measures to address potential conflicts of interest and unprofessional behaviour. These include: clearer requirements and obligations for licence-holders and responsible persons; an obligation on responsible persons to report any non-compliance; and making it an offence for a licence-holder or manager to induce a health professional to act unprofessionally. Before the Bill is introduced to the House, officials will review these provisions and determine whether any additional measures are needed to provide safeguards around potential conflicts of interest and to ensure high professional standards.

Section 7: Monitoring, evaluation and review

7.1 How will the impact of the new arrangements be monitored?

System-level monitoring and evaluation: pharmacies

Pharmacy audits

The regulator will continue the work of the current licensing authority in auditing pharmacy premises to ensure that pharmacy services to the public meet required quality standards.

The risk-based audit framework includes two main types of audit:

- full quality audit, assessing all services provided from the premises and undertaken with advance notice
- inspection audit, focussing on a subset of risk-based criteria and made without advance notice.

The regulator updates the pharmacy sector on audit findings and trends. The results are sent to all pharmacies in New Zealand and to sector representative organisations. There is a response group of sector representative organisations to provide a forum for discussions of trends identified and promote continuous quality improvement in the sector.

This audit programme aligns with a strategy for pharmacy audits developed by a group with government, DHB and sector representation. The strategy's focus areas are:

- ensure patients receive safe services
- improve standards of professional practice
- increase efficiency and effectiveness of audits
- ensure national consistency in audits and outcomes
- ensure accurate information on service funding.

Pharmacy services agreements

Every provider of community pharmacy services enters into an integrated community pharmacy services agreement (ICPSA) with its local DHB. The agreements set out how the parties will work collaboratively to implement sector-wide objectives for community pharmacy services, and describe services to be provided and funding for those services.

The ICPSA allows DHBs to commission pharmacy services to meet local and national needs, to enable delivery of the Pharmacy Action Plan and the New Zealand Health Strategy. The ICPSA came into effect in late 2018, and there is a nationally-agreed review programme for the agreement.

Some parts of the pharmacy audits use provisions of the ICPSA as references.

System-level monitoring and evaluation: pharmacists

The Pharmacy Council of New Zealand is the Responsible Authority for the pharmacy profession, and its functions are set out in s 118 of the Health Practitioners Competence Assurance (HPCA) Act 2003. These include setting scopes of practice and professional standards, prescribing qualifications and assuring ongoing competence, registering individuals and handling complaints and disciplinary matters. The HPCA Act also provides for a Health Practitioners Disciplinary Tribunal.

The Health and Disability Commissioner's role includes improving quality within the health sector, and holding providers to account.

Changes to monitoring and evaluation

There is already an extensive network of review, monitoring and evaluation mechanisms for the pharmacy sector. These mechanisms will continue, and will address any expected impacts and risks from removing pharmacy ownership restrictions:

Expected impact, risk or issue	Review, monitoring or evaluation mechanism
Safety Influence and autonomy of supervisory pharmacist	Pharmacy audits by Medsafe. Pharmacy Council regulation of professional pharmacist practice. Employment Relations Authority cases.
Access Consumer access to pharmacies	Review of ICPSA. Review by DHBs (or new entities) of community pharmacy commissioning.
Service quality	Existing mechanisms under Therapeutic Products Act and HPCA Act
Innovation	Market development trends reviewed by representative organisations, DHBs and the Ministry, and reflected in organisational, sector and regulatory planning.
Regulatory system efficiency	Licensing and auditing of pharmacies can focus solely on service quality, pharmacy standards and public safety.
Local benefit	Review of ICPSA. Review by DHBs (or new entities) of community pharmacy commissioning.

Prescriber interests in pharmacies

If prescribers were permitted to hold an interest in a pharmacy business, the new arrangements would need to be monitored to ensure that the regulatory scheme adequately manages any potential conflicts of interest. The existing monitoring and auditing regime is sufficient for this.

7.2 When and how will the new arrangements be reviewed?

Section 268 of the Bill requires the Minister to review the policy and operation of the Therapeutic Products Act five years after it comes into force, and every five years thereafter. The Minister must report on each review within 12 months, and present the report to the House of Representatives as soon as practicable after it is completed.

The Ministry's pharmacy team, including its Chief Advisor Pharmacy and Allied Health, have regular interaction with the pharmacy sector, which provides a forum for feedback on the new arrangements.