

Regulatory Impact Statement: Regulation of pharmacy ownership

Decision sought	Analysis produced for the purpose of informing Cabinet decisions on regulation of pharmacy ownership under the Medical Products Bill	
Agency responsible	Ministry of Health	
Proposing Ministers	Hon Casey Costello, Associate Minister of Health	
Date finalised	27 June 2025	

Briefly describe the Minister's regulatory proposal

The Minister proposes that the restrictions on community pharmacy ownership under the Medicines Act 1981 not be carried over into the Medical Products Bill. This will enable community pharmacies to be owned by anyone, subject to a fit and proper person requirement. In order to protect professional standards and consumer safety, safeguards will be added, including the creation of a supervisory pharmacist position. The supervisory pharmacist will be responsible for compliance and standards of the company as a whole.

Summary: Problem definition and options

What is the policy problem?

The Medicines Act 1981 includes several restrictions on who may own a community pharmacy. Decisions are needed on whether or not to carry the restrictions over into the planned Medical Products Bill, which will replace the Medicines Act.

Under the Medicines Act, the three restrictions on pharmacy ownership are:

- Prescribers may not own an interest in a pharmacy without an exemption from the regulator (Medsafe).
- No person or company may operate, or hold majority ownership in, more than five pharmacies.
- All pharmacies, and companies which own pharmacies, must be majority-owned by pharmacists, and pharmacists must be in effective control of the company.

The impact of these restrictions on the pharmacy sector and patients is not clear. There are several chains operating, one of which includes more than 200 pharmacies. However the majority of community pharmacies (about 57%) are either independent or owned by small companies. We have not seen any clear evidence that the ownership restrictions contribute to patient safety or service quality. There are no equivalent ownership restrictions on any other area of health services in New Zealand, and it is not clear why pharmacies should be treated differently to (for example) medical clinics.

The **restriction on prescriber ownership** prevents pharmacist prescribers and practitionerowned health clinics holding an interest in a pharmacy, and is therefore a barrier to integrated health services. We support removing this restriction, and using professional standards to address conflicts of interest and other risks.

Although the letter of the **five pharmacy limit** is adhered to, the spirit of this restriction is not meaningfully upheld. Franchise-based chains make up around 30% of all community pharmacies, and another 13% belong to three non-franchise chains. It is not clear that the five pharmacy limit would deliver significant benefits even if it was more effective.

Removing the five pharmacy limit would free up regulator resource for more impactful work. It would remove a regulatory cost of further expansion by chain pharmacies, potentially at the expense of independent pharmacies which lack economies of scale. There is risk of market dominance by a small number of pharmacy chains; however there is no strong evidence that this will harm patients, and it may reduce costs for consumers.

The **pharmacist ownership and control requirement** is seen by most of the pharmacy sector as crucial to upholding professional standards and patient safety. We have not found significant evidence to support this argument, and consider that any risk could be addressed through less restrictive means. It is possible that removing this restriction could have a negative effect on pharmacist working conditions. There are potential benefits from removing this restriction, such as better use of regulator resource. In combination with removing other restrictions, removing this restriction could support healthcare innovation, such as multidisciplinary health clinics.

What is the policy objective?

We aim to support and improve public access to:

- community pharmacies
- medical products including prescription medicines
- health services that can be provided through community pharmacies, such as blood pressure checks and vaccination.

Indicators of access include the number and location of pharmacies in New Zealand, the number of pharmacies providing additional health services, consumer views on pharmacy services, and the number of pharmacists practising in New Zealand.

We also aim to support the pharmacy workforce by supporting good working conditions.

What policy options have been considered, including any alternatives to regulation?

The options considered in this analysis are:

- Option 1: Status quo: retain current regulatory settings, with clarified requirements
- Option 2: More meaningful ownership and control requirements
- Option 3: Remove pharmacy ownership restrictions and introduce safeguards to better protect service quality and patient safety.

What consultation has been undertaken?

The Ministry has engaged with key stakeholders on this issue. Representatives of the pharmacy sector broadly support continuing the status quo, as they consider this will best protect patient interests. There is less sector support for the prescriber ownership restriction than for the other two restrictions. The Commerce Commission and MBIE's competition division support removing the restrictions.

This analysis has drawn on several years of engagement on pharmacy ownership, especially in connection with the Therapeutic Products Bill.

Is the preferred option in the Cabinet paper the same as preferred option in the RIS?

Yes.

Summary: Minister's preferred option in the Cabinet paper

Costs (Core information)

Outline the key monetised and non-monetised costs, where those costs fall (e.g. what people or organisations, or environments), and the nature of those impacts (e.g. direct or indirect)

This proposal has no direct costs to the Crown or any other party, relative to the status quo.

There may be some compliance costs to pharmacy companies from the new safeguards. However these are largely based on existing compulsory conditions to pharmacy licences, so impact is expected to be small, and to be outweighed by the savings outlined below.

The new safeguards may also require more Crown resources to ensure meaningful compliance. This cost will be partially offset by redirection of resources currently used to assess compliance with ownership requirements.

This proposal may improve competition by removing some of the costs of expansion of chain pharmacies. However independent pharmacies may have difficulty competing with chains, due to not having economies of scale. It is therefore possible that this proposal will reduce market diversity by reducing the number of independent pharmacies.

Internationally, pharmacy deregulation is associated with higher workloads for pharmacists. However it is not clear that ownership changes cause higher workloads.

Benefits (Core information)

Outline the key monetised and non-monetised benefits, where those benefits fall (e.g. what people or organisations, or environments), and the nature of those impacts (e.g. direct or indirect)

This proposal will enable Medsafe and Ministry of Health resources to be redirected from assessment of pharmacy ownership structures into other regulatory work, such as overseeing operation of the safeguards in this proposal.

This proposal will reduce compliance and administrative costs for pharmacy companies. We are not able to quantify these savings, as this involves internal company information and will vary significantly depending on the size and current structure of each business.

The savings will be biggest for larger pharmacy businesses, which will no longer need to be divided into smaller companies. Simpler corporate structures should better enable

economies of scale, and eliminate work currently required to establish and operate many small companies within the overall business.

Smaller pharmacy companies, including independent pharmacies, will also have reduced compliance costs due to not having to demonstrate their ownership.

As discussed above, this proposal may have positive or negative effects on market diversity.

Balance of benefits and costs (Core information)

Does the RIS indicate that the benefits of the Minister's preferred option are likely to outweigh the costs?

We expect the benefits of this proposal to outweigh the costs. Crown resources will be redirected into more meaningful regulatory work. Compliance costs will also be reduced for pharmacy companies.

Implementation

How will the proposal be implemented, who will implement it, and what are the risks?

This policy will be implemented via the Medical Products Bill, which will not carry over pharmacy ownership restrictions from the Medicines Act. The Bill will include the safeguards. Compliance with the safeguards will be monitored and enforced by the medical products regulator. All the safeguards except the supervisory pharmacist role are based on current pharmacy licence requirements and so should not require a long transition period. A transition period will be needed for pharmacy companies to appoint and train supervisory pharmacists.

Limitations and Constraints on Analysis

The government has a clear focus on removing or reducing regulation, particularly when it does not deliver a clear benefit. As a result, we have not looked at options involving stronger restrictions on pharmacy ownership, although we have looked at more meaningfully applying current restrictions.

There is extensive international evidence on pharmacy regulation, including deregulation. However the regulatory context differs from country to country, and so it is difficult to know whether outcomes relate to any specific restriction. For example, some countries have restrictions on the number and location of pharmacies as well as ownership, so post-deregulation changes may be linked to removal of broader restrictions rather than ownership restrictions specifically. Factors such as pharmaceutical funding and regulation of over-the-counter medicine sales are also likely to influence outcomes.

I have read the Regulatory Impact Statement and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the preferred option.

Signed by the responsible Manager(s)

Tim Vines

Date: 6 August 2025

Quality Assurance Statement

Reviewing Agency: Ministry of Health QA rating: Meets

Panel Comment:

The Ministry of Health QA panel has reviewed the Impact Statement titled "Regulation of pharmacy ownership", produced by the Ministry of Health and dated June 2025.

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

The Impact Statement is clear, concise, consulted, complete and convincing. The analysis is balanced in its presentation of the information. Impacts are identified and appropriately assessed.

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

- This section outlines current regulation of pharmacy ownership, the historical background of ownership restrictions, and how pharmacy ownership is regulated in other countries. It then outlines numbers and ownership of pharmacies in New Zealand, and pharmacy workforce numbers.
- 2. This document looks solely at pharmacy ownership. Regulation of pharmacy activities such as dispensing will be addressed as part of broader development of the Medical Products Bill. For example the following elements of the current system are likely to be carried over from the Medicines Act into the Medical Products Bill:
 - a. pharmacies must be under the "immediate supervision and control" of a registered pharmacist
 - b. a "fit and proper person" requirement for licence holders, including pharmacy licence holders
 - c. the ability to revoke a pharmacy licence in response to non-compliance.
- Professional regulation of pharmacists will be addressed as part of a separate Ministry of Health review of the Health Practitioners Competence Assurance Act 2003 (the HPCA Act).
- 4. The Medical Products Bill will not address funding of products or services, including pharmacy services funding.

Current pharmacy ownership restrictions

- 5. The Medicines Act 1981 uses licensing criteria, including the ownership criteria outlined below, to restrict who may own a community (retail) pharmacy. The ownership criteria do not apply to Health New Zealand, or to hospital pharmacies generally.
- 6. There are three ownership restrictions in the Medicines Act:
 - a. **The prescriber ownership restriction:** Under section 42C, no prescriber (including a pharmacist prescriber) may hold an interest in a pharmacy without an exemption from the licensing authority (Medsafe).
 - b. **The pharmacist ownership requirement:** Under sections 55D and 55E, a company may operate a pharmacy only if more than 50 percent of the share capital is owned by one or more pharmacists with 'effective control' of the company. The only person who may operate a pharmacy or hold a majority interest in a pharmacy is a pharmacist.
 - c. **The five pharmacy limit:** Under section 55F, no person or company may operate or hold a majority interest in more than five pharmacies.
- 7. Medsafe may exempt a prescriber from the prescriber ownership restriction. This has been done to enable pharmacist prescribers to own minority stakes in pharmacies.
- 8. An exemption from the pharmacist ownership requirement can be made via Order in Council, under section 105C of the Medicines Act. The responsible Minister must not recommend an Order under this provision unless they consider that doing so will improve health services or access to services, or that the Order is needed to meet the needs of a community in a specific location. No such Order has ever been made.
- 9. There is no ability to grant an exemption from the five pharmacy limit.
- 10. Under the pharmacy licensing system, pharmacist owners are also the 'responsible persons' who are responsible for the day-to-day operations of the pharmacy. This includes compliance with the Medicines Act and the Code of Health and Disability

- Consumers' Rights. Responsible persons must also ensure that appropriate quality and risk management systems are in place, and that the pharmacy is suitably resourced.
- 11. There are no ownership restrictions on any other kind of health service provider in New Zealand.

History and rationale for ownership restrictions

- 12. The first pharmacy ownership restrictions in New Zealand seem to have been introduced under the Industrial Efficiency Act 1936, which was intended to regulate certain industries in order to make them more efficient. Previously, a pharmacist had to be in charge of a pharmacy operation, but anyone could own the pharmacy.
- 13. In 1957, the Pharmacy Act was amended to provide that no person other than a chemist (pharmacist) could establish or operate a pharmacy, except with the consent of the licensing body. It also specified that company owners could not own or part-own more than one pharmacy without consent. The only companies allowed to own a pharmacy were those at least 75% owned by one or more pharmacists. Parliamentary debate at this time focused on protection of existing pharmacy businesses, rather than patient safety or service quality.
- 14. The 1957 restrictions remained in place until 2003, when the HPCA Act was passed and the Pharmacy Act repealed. At this point, the pharmacy ownership provisions were transferred into the Medicines Act and the ownership restrictions relaxed. One person could now own or have majority ownership in up to five pharmacies, and minority ownership in an unlimited number of pharmacies. The pharmacist ownership requirement was also reduced from 75% to more than 50%. The restriction on prescribers holding interests in pharmacies was introduced at this time.
- 15. Parliamentary debates on the HPCA Act show that the pharmacist ownership restriction was seen by supporters as necessary to ensure professional standards were prioritised over profit. The prescriber ownership restriction and the five pharmacy limit were not discussed.
- 16. The pharmacy ownership provisions in the Medicines Act have not been changed since 2003, except to exempt Health New Zealand from ownership requirements.

The Countdown Pharmacy case

- 17. Section 55D of the Medicines Act requires pharmacists to have "effective control" of any company which owns a pharmacy. Effective control is not defined in the Medicines Act. In 2023 the High Court ruled on a case involving a Countdown pharmacy. The Court clarified the test for effective control, finding that "effective control" means that pharmacists must have meaningful control over the company, including on matters such as board composition.
- 18. Following the Court's decision, Medsafe issued new principles for determining whether pharmacists have effective control of a company. These include pharmacists having a majority of voting rights, and constituting the majority of board directors and the shareholders' quorum. Pharmacists must also be able to make "the final decisive decision on behalf of the company" and to make decisions at board level that may impact on patient health and safety.
- 19. The new test required some pharmacy companies to change their governance structures, for example by adding another pharmacist director, so that pharmacists have a board majority.
- 20. The case has not resulted in any obvious operational changes to any of the chain pharmacies.

Pharmacy ownership regulation in other countries

- 21. All three of New Zealand's pharmacy ownership restrictions can be found in other countries, but none are universal.
- 22. In summary:
 - a. Prescriber ownership restrictions: Due to international variations on who can prescribe, it is difficult to compare regulation of prescriber ownership. However some jurisdictions ban doctors from owning pharmacies, including Australia, various western European countries, and some parts of the United States.
 - b. **Pharmacist ownership requirements:** A few European countries have a majority ownership requirement similar to New Zealand's, while Australia and some other European countries ban any non-pharmacist ownership. Most European countries and US states do not require pharmacies to be owned by pharmacists. A few European countries ban 'vertical ownership', for example by pharmaceutical companies or health insurance companies.
 - c. Limit on number of pharmacies owned: A majority of European countries, as well as Australia, have limits on the number of pharmacies which can be owned by a company or person. These countries either ban multiple ownership entirely, restrict it to a small number of pharmacies (typically four), or limit the market share within a country or area.
- 23. There is no overall trend towards or away from pharmacy ownership regulation, with various European countries moving in both directions over the last decade.
- 24. Overall, pharmacy ownership is most regulated in Australia and central mainland Europe, and least regulated in the United Kingdom, most parts of the United States, and in eastern Europe. In Europe, the most common type of restriction is on the number of pharmacies a person or company may own.

Pharmacies and pharmacy ownership in New Zealand

- 25. In September 2024 there were 1,084 licensed pharmacies in New Zealand. This includes 31 pharmacies registered to Health New Zealand (nearly all in hospitals). Based on pharmacy and company names, there appear to be 23 Bargain Chemists, 45 Woolworths (previously Countdown) Pharmacies, 51 Life Pharmacies, 54 Chemist Warehouses, and 269 Unichem Pharmacies.
- 26. In 2024, the Green Cross Health website said that the company "represent[s] more than 330 community pharmacies through New Zealand... and hold[s] equity interests in 84 of these pharmacies". Based on a Pharmaceutical Society report, we understand that pharmacies represented by Green Cross are mostly Unichem and Life Pharmacy franchises.
- 27. Some pharmacy chains have highly complex ownership arrangements. Some pharmacies are owned by companies which are part-owned by other companies, with overlapping ownership and directorship between the various companies. Non-franchise chain pharmacies are owned (either individually or in clusters) by companies with almost identical names and significant overlap of directors and shareholders.
- 28. Based on company and pharmacy names, it appears that around 57% of all community pharmacies are either independent, or belong to companies or chains with fewer than 10 pharmacies. This does not include pharmacies that are franchises of larger brands, such as Unichem and Life Pharmacies.

Access to pharmacies in New Zealand

29. In 2014, 86.4% of the New Zealand population lived within five kilometres of a pharmacy, and 98% lived within 25 kilometres. We do not have data on the extent to which distance

may be an access barrier. However Ministry of Health engagement with rural communities has found that those communities can experience difficulties in accessing pharmacies.

The New Zealand pharmacy workforce

- 30. In June 2024 there were 4,458 practising pharmacists in New Zealand, including 213 intern pharmacists. There are 7.95 practising pharmacists per 10,000 people in New Zealand, compared to 9.3 in Australia. The ratio of pharmacists to population varies throughout the country, with rural areas tending to have fewer pharmacists per 10,000 people. Three-quarters of practising pharmacists work in community pharmacies, with most of the rest working in hospital pharmacies.
- 31. A Pharmaceutical Society survey in 2024 found that 94 percent of community pharmacy respondents had experienced staff shortages in the previous 6 to 12 months. Workloads have also increased in recent years, with contributing factors including patients being unable to access GPs, and medicine supply shortages.

What is the policy problem or opportunity?

- 32. The requirements and rationale of the pharmacy ownership restrictions are unclear. This makes the law difficult to meaningfully apply and enforce, with a high risk of legal challenge. Assessing and enforcing pharmacy ownership consumes public resources without necessarily delivering any benefit or protection to patients or the health system.
- 33. The Medical Products Bill is an opportunity to either remove the restrictions, or to clarify and improve them so that they deliver a clear benefit.
- 34. This section looks at each of the three ownership restrictions:
 - a. Restrictions on prescribers holding interests in pharmacies
 - b. The requirement for pharmacies to be more than 50 percent owned by pharmacists, and for pharmacists to have effective control of pharmacy companies
 - c. The ban on any person or company operating or holding a majority interest in more than five pharmacies.

Restriction on prescriber ownership

- 35. Section 42C of the Medicines Act states that no prescriber can hold any interest in a pharmacy without an exemption from the licensing authority (Medsafe). An exemption can only be granted if the authority is satisfied that any conflicts of interest are properly addressed. Exemptions are generally only granted to enable a prescribing pharmacist to hold a minority interest in a pharmacy company. In these cases there will be a condition that a prescriber cannot dispense their own prescriptions.
- 36. The rationales for the prescriber ownership restriction are:
 - a. Prescribers who own a pharmacy would have an incentive to over-prescribe, in order to generate dispensing fees if the medicine is dispensed through their pharmacy.
 - b. Prescribers who own a pharmacy could direct their patients to their pharmacy, creating an unfair advantage for that pharmacy.
 - c. It is not good practice for a prescriber to dispense their own prescriptions, as this eliminates an independent review of the prescription.
- 37. The prescriber ownership restriction reduces the risk of the issues above, but does not prevent any of them. Non-pharmacist prescribers can have an interest in a pharmacy without owning it, for example if the pharmacy is renting space in a practitioner-owned

- medical clinic.¹ Anecdotally, we are aware of doctors sending prescriptions to the pharmacy co-located with their clinic, rather than the patient's preferred pharmacy.
- 38. There is no restriction on pharmacists owning medical clinics which employ prescribers, even though this potentially creates a conflict of interest.
- 39. The prescriber ownership restriction prevents practitioner-owned health clinics from opening their own pharmacies. This could be reducing the number of pharmacies, however we have no evidence on this potential impact.
- 40. The condition that prescribing pharmacists cannot dispense their own prescriptions is likely to be preventing and addressing some inappropriate prescribing. However it may also be impeding timely access to medicines, especially in rural areas where another pharmacist may not be readily available.
- 41. The position of pharmacist prescriber was introduced in 2016, and has potential to improve access to medicines. As of June 2024, less than 2% of practising New Zealand pharmacists were prescribers. By comparison, around 30% of pharmacists in the United Kingdom are prescribers.
- 42. The prescriber ownership restriction may be disincentivising pharmacists from seeking prescriber status. However pharmacy stakeholders consider that limited funding and job opportunities for pharmacist prescribers are likely to be more important factors.

Pharmacy ownership and effective control

- 43. Ownership of pharmacies has been limited to pharmacists since at least 1957. Details of restrictions have changed at various times since then, most recently in 2023 when the meaning of 'effective control' was clarified by the High Court.
- 44. It is difficult to know what impact the pharmacist ownership restriction is having. International evidence (see below) associates pharmacy deregulation with an increase in pharmacy numbers and pharmacist workload, and with pharmacists reporting more conflicts between professional and commercial interests. However deregulation in these countries has tended to involve removal of restrictions on the number and location of pharmacies as well as ownership, so it is difficult to link any outcomes with removal of ownership restrictions.
- 45. We were unable to find any evidence linking ownership type to differences in regulatory compliance, patient safety, or quality of services. There is conflicting evidence on relationships between ownership type and services provided.
- 46. Assessing the ownership of pharmacy companies requires a significant amount of regulator resource. Regardless of the level of resource allocation, it may not always be possible to detect non-ownership mechanisms which reduce pharmacist control.

Restriction on number of pharmacies owned and operated

- 47. Under the status quo, the five pharmacy limit has encouraged development of complex ownership structures in some chains. Some ownership structures appear to have been designed to comply with the letter of the law while defeating its intent.
- 48. In many cases, ownership and control of a large number of pharmacies is held by a small number of people, for example through one person owning a minority stake in dozens of pharmacies. While the companies are majority owned and controlled by pharmacists, the number of pharmacist owners is small relative to the size of some chains. This limits the autonomy and control of the pharmacists who actually work in each pharmacy.

¹ If the tenancy arrangement included clauses relating to the operation of the pharmacy, this could constitute a financial interest.

- 49. Regardless of the nature and reason for complexity, companies with complex structures tend to be more difficult to regulate, as it can be difficult and time-consuming to determine who meaningfully owns or controls a company. It is also likely to be operationally inefficient for the companies.
- 50. Chain structures can enable economies of scale, which in some cases enables reduced prices for customers. For example the three non-franchise pharmacy chains pay the prescription medicine co-payment on behalf of the patient. This means that patients who are not already exempt from co-payments are able to collect their medicines free of charge. The 2023/24 New Zealand Health Survey estimated that around 191,000 adults did not fill a prescription because of the cost.
- 51. In 2023, the Ministry of Health engaged with the public on pharmacy services, and heard that the co-payment was a barrier. However some participants said that the 'big brand' pharmacies provided a lower quality of service, and that they preferred to go to a different pharmacy even though that meant paying the co-payment.
- 52. A recent New Zealand study of people with diabetes found *lower* rates of medicine adherence (including but not limited to collecting the medicine) amongst users of chain and independent pharmacies that did not charge the co-payment.

International evidence

- 53. There is a large body of international evidence on pharmacy regulation, including the impact of deregulation, and comparisons between jurisdictions with different levels of regulation. However it is difficult to link outcomes with ownership restrictions, as deregulation tends to involve changes to the broader regulatory landscape. Other factors such as funding models also play an important part, and make comparisons difficult.
- 54. There is no strong evidence that approaches to ownership lead to differences in service quality or impact on patients. There is some evidence that deregulation is associated with higher pharmacist workloads and other negative impacts on the pharmacist workforce. The reason for this is not clear, but may be due to the number of pharmacies increasing, without any concurrent increase in the number of pharmacists.
- 55. Studies of pharmacy deregulation in various European countries shows that deregulation tends to result in an increased number of pharmacies, especially in urban areas.

 Deregulation is also associated with higher pharmacist workloads, and with pharmacists reporting greater conflicts between professional and commercial interests. However care should be taken in attributing these changes to removal of ownership restrictions, as deregulation tended to involve removal of a wide range of restrictions rather than just ownership restrictions.
- 56. Pharmacy chains have spread in most countries which do not actively prevent them, including some countries (such as Australia) with strict ownership restrictions and no recent regulatory change.
- 57. European and United States studies have compared pharmacy services in regulated and deregulated countries, and compared services provided by independent and chain pharmacies. These have found that ownership does not seem to have any impact on access, pharmacist autonomy or patient satisfaction. However a United States study found that pharmacy employees in independent pharmacies had greater job satisfaction than those in chain pharmacies.
- 58. Evidence from the United States shows that independent pharmacies there are significantly less likely than chain pharmacies to provide potentially controversial products and services such as emergency contraceptives and drug harm reduction services. Evidence from the United Kingdom is more mixed, with supermarket

pharmacies and small and medium chains being less likely to provide controversial products and services, and large chains and independents being more likely.

What objectives are sought in relation to the policy problem?

- 59. The Government's priorities for the health system, set out in the Government Policy Statement on Health, are access, timeliness, quality, workforce and infrastructure. All of these could be affected by pharmacy ownership regulation.
- 60. More broadly, the Government has a focus on growing the economy, including by reducing unnecessary regulation.

Access

- 61. The Government expects that every person, regardless of where they live in New Zealand, has equitable access to the health care and services they need. For pharmacies, this means that all New Zealanders have reasonable access to a community pharmacy. This can be supported through ownership regulation that supports pharmacies to operate throughout New Zealand, including in rural areas.
- 62. Pharmacies can also support access by providing health services such as vaccination, prescribing, and blood pressure tests, and by reducing costs to the consumer.

Timeliness

63. The timeliness priority builds on the access priority by emphasising that access should be prompt and efficient. Pharmacies can support timely access by providing some services, such as vaccination, which may not always be timely to access through other means. For analysis purposes, this document will merge timeliness into the access objective.

Quality

- 64. The Government expects that health care and services delivered in New Zealand are safe, easy to navigate, understandable and welcoming to users, and are continuously improving.
- 65. Professional standards for pharmacists will continue to be regulated under the HPCA Act. However it is important for pharmacy regulation to ensure that pharmacists can uphold these standards, and are not pressured or compelled to prioritise profit over patient interests. Pharmacy regulation should also support service innovation, and adoption of initiatives to improve service quality.
- 66. The quality of medical products supplied in pharmacies will be addressed through other elements of the Medical Products Bill, and are outside the scope of this analysis.

Workforce

67. Like other health professions, pharmacists are experiencing workforce shortages and overwork. Regulation of pharmacies should support reasonable conditions for the pharmacy workforce. It should also support pharmacists and other pharmacy staff to improve their skills and qualifications.

Infrastructure

68. The Government expects that the health system has the digital and physical infrastructure it needs to meet people's needs now and into the future. There have been several recent developments in digital infrastructure used by pharmacies, in particular expansion of the electronic prescription service. This analysis includes infrastructure in the access and quality objectives, to the extent that infrastructure contributes to those objectives.

Right touch regulation

69. The Government has a strong focus on reducing unnecessary regulation, particularly where this can affect costs of living and economic growth. Pharmacy regulation should not go beyond what is needed to achieve the outcomes above, or to deliver better health outcomes.

What consultation has been undertaken?

- 70. This regulatory impact analysis draws on several years of consultation, particularly in relation to the Therapeutic Products Bill. The Ministry of Health has canvassed views on removing ownership requirements, in conjunction with safeguards such as a new supervisory pharmacist role with responsibility for company compliance. The Pharmaceutical Society published a comprehensive review paper and position statement in response.
- 71. The Therapeutic Products Bill did not make any changes to pharmacy ownership requirements. At the invitation of the Minister of Health, several key stakeholders used their submissions on that Bill to state their views on pharmacy ownership.
- 72. The Independent Community Pharmacy Group released a position paper on pharmacy ownership regulation in September 2023, following the Countdown judgement.
- 73. The Ministry of Health and various stakeholders have also engaged directly with each other on this topic over several years.
- 74. In preparing this document, the Ministry of Health has drawn on previously expressed stakeholder and public views, mostly relating to the Therapeutic Products Bill, but also community engagement on pharmacy services. The Ministry has also re-engaged with the Pharmacy Council, the Pharmaceutical Society, and the Pharmacy Guild on this issue.

Section 2: Assessing options to address the policy problem

What criteria will be used to compare options to the status quo?

- 75. The criteria are:
 - a. Access: does the option support people to access pharmacies and pharmacy services throughout New Zealand, and does it support pharmacies to provide timely access to a range of health services?
 - b. **Quality:** does the option support pharmacists to prioritise patient interests, and does it support pharmacies to innovate and adopt service quality initiatives?
 - c. Workforce: does the option support reasonable conditions for the pharmacy workforce, and does it support them to maintain professional standards and to upskill?
 - d. Right touch regulation: does the option regulate pharmacy ownership only to the extent required to achieve the other criteria? Does it enable efficient use of public resources?

What scope will options be considered within?

- 76. This analysis assumes that regulation of pharmacies will continue via a licensing system, and that pharmacy services will continue to be delivered primarily by pharmacists and/or under pharmacist supervision. This is necessary to manage the risks associated with many medicines, particularly prescription medicines and controlled drugs.
- 77. Reverting to earlier limits to pharmacy ownership (a one pharmacy limit, and/or 75% pharmacist control) has not been considered. These changes would either have to

exempt existing businesses – which would severely undermine the impact of the policy – or encounter significant challenges around property rights. They would also go against the Government's focus of reducing regulation.

What options are being considered?

- 78. This analysis considers three options:
 - a. Option 1: the status quo (with clarified requirements)
 - b. **Option 2: strengthening existing ownership restrictions:** reworking current restrictions to more effectively restrict growth of chain pharmacies
 - c. **Option 3: removing ownership restrictions:** enabling anyone to own a pharmacy, and/or allowing people and companies to own more than five pharmacies.
- 79. Each option is analysed in relation to the three current ownership restrictions:
 - a. the prescriber ownership restriction
 - b. the pharmacist ownership and control requirement
 - c. the five pharmacy limit.
- 80. Each element within the three options can be mixed and matched: for example one restriction could be retained, another strengthened, and another removed.

Option One – Status Quo: retain current regulatory settings, with clarified requirements

- 81. The existing restrictions on pharmacy ownership, currently in the Medicines Act, would be retained. Specifically:
 - a. prescribers would not be allowed to hold interests in pharmacies unless an exemption is granted
 - b. pharmacies, and companies that own pharmacies, would have to be majority owned and effectively controlled by pharmacists
 - c. no person or company would be able to own a majority interest in more than five pharmacies, but there would be no upper limit on the number of minority interests which could be held.
- 82. The wording of the Medicines Act reflects outdated drafting styles, and lacks clarity. The Countdown case has clarified some elements of the status quo on majority ownership and control by pharmacists. Specifically, pharmacist owners must be able to make majority decisions, even if opposed by non-pharmacist owners. However this test is found in case law, and could be changed by a future decision.
- 83. If pharmacy ownership restrictions are retained, the clarification of the test in the Countdown case could be reflected in primary and secondary legislation, along with other changes to clarify regulation.
- 84. Section 105C of the Medicines Act enables Orders in Council to be made exempting any person or class of person from the pharmacist ownership restriction. This power has never been used. The criteria in s105C are subjective, and any decision on an exemption could be vulnerable to legal challenge.
- 85. If the status quo is retained, further policy work could be done on whether to enable exemptions, and under what circumstances.

Option Two - more meaningful ownership and control requirements

86. This option is aimed at more meaningfully applying the spirit as well as the letter of the current restrictions. It would apply ownership restrictions to better ensure meaningful pharmacist control, and ensure that no-one has responsibility for more than five pharmacies.

87. Under the status quo, there appears to be meaningful compliance with the prescriber ownership restriction, so this option does not include any changes to that restriction.

Meaningful control by pharmacists

- 88. This option would codify the Countdown test in primary legislation, and potentially set additional requirements preventing any mechanism which deprived pharmacist owners of effective control.
- 89. In 2019, the Ministry of Health consulted on ensuring pharmacist control of pharmacy activities by strengthening the ownership requirements. Pharmacists overwhelmingly supported this option in preference to removing ownership requirements. Patient groups also tended to support this option. Other groups, such as practitioner organisations and healthcare providers, were split on which option they preferred.
- 90. More recently, the Independent Community Pharmacy Group issued a position paper supporting strengthening ownership restrictions, potentially by increasing the ownership requirement to 75%.
- 91. If effective, this option would address concerns about pharmacists being pressured by non-pharmacist owners to lower professional standards. However it is not clear that this is a problem linked specifically to non-pharmacist control. The concerns may be more effectively addressed through other means, such as the safeguards under option three.
- 92. It will also be extremely difficult to detect all situations where the pharmacist owners do not have effective control of a pharmacy. There is risk that this option will create or perpetuate situations where a pharmacist is legally responsible for a pharmacy, but does not have meaningful effective control. As well as failing to deliver the intent of the policy, this involves legal risk for the pharmacist.
- 93. Meaningful implementation of this option would require significantly increased regulatory resources. The regulator would also need strong investigative powers where an offence is alleged.

Limiting ownership to five pharmacies

- 94. While all pharmacy companies appear to be technically compliant with the five pharmacy ownership limit, the intent of the policy is not being met. There are six chains with more than 20 pharmacies, one of which has more than 200 pharmacies. The Countdown case has not affected operation of the chains in any obvious way.
- 95. As discussed below, most stakeholders appear to support the five-pharmacy limit. They have generally not called for stronger restrictions, although in some cases this would be consistent with their broader views. Woolworths New Zealand has said (before the Countdown case) that they are "comfortable" with the status quo, but oppose further restrictions on non-pharmacist involvement in pharmacies.
- 96. Under this option, the law would be strengthened to ensure that no company or person has meaningful influence over more than five pharmacies. Work would be needed on exactly how to implement this option. The simplest way would be to provide that no person or company may own any interest (as opposed to a majority interest) in more than five pharmacies. No person could be a responsible person for more than five pharmacies.
- 97. This option is unlikely to have any meaningful impact on franchise-based chains. Even if franchising was somehow outlawed, it would be difficult (and undesirable) to prevent independent pharmacies from banding together to share costs such as advertising and bulk purchasing. Members of these groups would have an advantage over fully independent pharmacies in the same way as franchise-based chains.

- 98. Under this option, the non-franchise chains would be compelled to change their ownership structures. The most likely outcome is a shift to a franchise-based model. It is not clear that this would result in any significant changes to the market or patient choice.
- 99. There is a possibility that breaking up the non-franchise chains would result in closure of some pharmacies, if less economic pharmacies are being supported by more profitable stores. However the chains tend to be concentrated in areas which have other pharmacies, so there is unlikely to be significant impact on access.
- 100. The inability to form large chains would make some economies of scale difficult to achieve. This could have a negative effect on service quality, for example by making it harder for pharmacies to adopt new technologies.

Option Three – remove ownership restrictions, and add safeguards

- 101. This option would remove ownership restrictions. It would also introduce some safeguards to avoid adverse impacts of the changes.
- 102. As noted above, these potential changes are independent it is possible to remove some restrictions but not others.

Removing the restriction on prescriber ownership

- 103. This option would remove the restriction on prescribers owning interests in pharmacies. This would enable more pharmacist owners to obtain prescriber status, and enable partownership of pharmacies by medical clinics that are owned by practitioners. If the pharmacist ownership restriction was also removed, this option would enable full ownership of pharmacies by medical clinics.
- 104. The Ministry consulted on removing the prescriber ownership restriction in the late 2010s. There were mixed views from pharmacists and other stakeholders, with some supporting change and others opposing. The Pharmaceutical Society and the Health Quality and Safety Commission noted that the restriction was a barrier to more integrated health services. The Pharmacy Council also supported change for this reason. More recently, Health New Zealand supports removing this restriction for the reasons stated in this document.
- 105. The Commerce Commission supported removing all ownership restrictions in order to improve competition and reduce consumer costs. The Commerce Commission continues to support removing these restrictions, but notes that safeguards are needed to prevent prescribers from directing patients to their own pharmacies.
- 106. The Pharmacy Guild and the Clinical Advisory Pharmacists Association wanted the prescriber ownership restriction retained, with the Association seeing it as 'essential to avoid conflicts of interest'. They also said that patient safety could be at risk if there was no independent dispensing check.
- 107. The rationale for the prescriber ownership restriction appears to be that it is needed to prevent conflicts of interest. As noted earlier, the restriction has not prevented conflicts involving pharmacies which rent space from practitioner-owned medical clinics.
- 108. If a prescriber owns a pharmacy, the prescriber-owner has a direct financial interest in maximising the number of prescriptions dispensed through that pharmacy. While prescribers do not control which pharmacy a patient uses, in some areas consumer choice is limited.
- 109. Potential conflicts of interest are a common and normal part of health practice, and are managed through professional regulation and other means, such as prescribing audits. All kinds of health practitioner may make treatment recommendations which will profit the practitioner. Pharmacists in community pharmacies must manage conflicts of

- interest as a core part of their work, since they frequently make decisions on whether to recommend products which deliver a profit to their pharmacy.
- 110. One of the reasons why dispensing is generally carried out by pharmacists is to provide an opportunity to check that the medicine is suitable for the patient and their condition. Pharmacists play a crucial role in detecting inappropriate prescribing, and this could be undermined if the same person prescribes and dispenses a medicine. However this is not prevented by the prescriber ownership restriction, as pharmacies can employ pharmacist prescribers.
- 111. Safeguards are needed to reduce risk associated with prescribers dispensing their own prescriptions. However a blanket ban would inappropriately restrict medicines access, especially in rural areas and after hours. It is more appropriate to address this issue through professional standards and guidance.

Removing the requirement for pharmacist majority ownership and control

- 112. This option would remove the pharmacist ownership and control requirement, so that any person or company could own and control a pharmacy, subject to a general 'fit and proper person' requirement.
- 113. The Ministry consulted on removing the pharmacist ownership requirement in the late 2010s, and several stakeholders commented on it in their submissions on the Therapeutic Products Bill. This option was opposed by the Pharmaceutical Society, the Pharmacy Guild, the Independent Community Pharmacy Group, and Green Cross Health. These stakeholders generally saw the pharmacist ownership requirement as key to maintaining professional standards, and said that removing the restriction would risk a focus on profit at the expense of patients and healthcare quality. Health New Zealand made similar points in 2025.
- 114. The Independent Community Pharmacy Group also said that independent pharmacies are best able to understand and serve their local communities. They cited examples of independent pharmacy staff carrying out a range of unfunded local activities including marae partnerships, house calls, and home deliveries. They also said that high-quality innovation and rural pharmacy services are most likely to be delivered by properly funded independent pharmacies, rather than large companies. This argument is supported by anecdotal evidence from public engagement on pharmacy services.
- 115. The Clinical Advisory Pharmacists Association said it its submission on the Therapeutic Products Bill that "there are many loopholes in the current legislation, [so] it would be more transparent to remove the pharmacist ownership restrictions but have tighter rules regarding the issues of conflict of interest".
- 116. In 2019, the Commerce Commission submitted that it was not aware of any New Zealand evidence on the impact of pharmacy ownership on public policy outcomes. However it said that international evidence indicates that deregulation increases competition, which in turn leads to lower prices, increased opening hours, and other consumer benefits. It continues to support removing ownership restrictions.
- 117. Access to pharmacies is difficult in many rural areas, and the restriction prevents iwi and other organisations from opening non-profit pharmacies in rural areas unless they can find a pharmacist willing to own a majority share.
- 118. Professional standards and regulation under the HPCA Act help to ensure pharmacists prioritise patient interests. Removing the pharmacist ownership requirement without any added safeguards could weaken the influence of professional standards over pharmacy activities, since pharmacists will not necessarily be responsible for the activity of a pharmacy company.
- 119. The proposed safeguards in this option are:

- a. Pharmacy activities such as dispensing would continue to be restricted to registered practitioners (usually pharmacists).
- Any person or company operating more than one pharmacy would need to designate a supervisory pharmacist. This role would be similar to the responsible person under the current system, but with greater clarity that they are responsible for the company's pharmacy policies and activities.
 Development of this safeguard will draw on the position of superintendent pharmacist in the United Kingdom.
- c. There would be a fit and proper person test for pharmacy licence holders and responsible people.
- d. It would be an offence for a pharmacy licence holder, or any senior manager, to induce a pharmacist (or other health practitioner) to act unprofessionally.
- e. License holders and managers would be required to ensure that pharmacists have the resources and authority to act professionally. This is similar to current conditions in pharmacy licences, and responsibilities of responsible people under the Medicines Act.
- 120. Professional regulation under the HPCA Act would continue to set standards for pharmacists, and non-legislative levers such as Health New Zealand contracts could also be used.
- 121. Removing the pharmacist ownership requirement would enable pharmacy ownership by a range of individuals and organisations, including corporations, healthcare providers, iwi, and non-profit entities. This could enable more pharmacies to be opened in rural and other under-served areas. It would also enable more corporate ownership of pharmacies, especially if the five pharmacy limit is also removed. This could result in some benefits to patients, such as the pharmacy paying prescription co-payments for patients, but there are also potential costs such as loss of services tailored to local communities.
- 122. There is a risk that this option would affect pharmacy service standards, despite the safeguards. Robust compliance processes would be needed to ensure that the safeguards are meaningfully enforced. Some of the resourcing for this could be met through freeing up of resources currently used for assessing pharmacy ownership. However more resource may be needed. Health New Zealand has expressed concern about potential impacts on its resources (which support its contracting activities for community pharmacies), particularly if the number of pharmacies increases.

Removing the five pharmacy limit

- 123. This option would remove the five pharmacy limit, enabling a person or company to own (or hold a majority interest in) an unlimited number of pharmacies.
- 124. Discussion of this option has tended to be combined with discussion of the pharmacist ownership requirement. Many stakeholder views on that requirement relate to chains and "corporate pharmacies" generally, so can be taken to encompass support for the five pharmacy limit. The Pharmacy Guild has specifically said that the two restrictions combine to prevent monopolies, and support locally-focused community pharmacies. The Independent Community Pharmacy Group also emphasises the importance of local ownership.
- 125. The Clinical Advisory Pharmacists Association has said that the five pharmacy limit "appears to be very arbitrary" and noted that "we are already seeing corporatisation through pharmacy chains". Health New Zealand supports removing the limit for broadly the same reasons. As discussed above, the Commerce Commission supports removing all ownership restrictions.

- 126. If the five pharmacy limit is removed, it is likely that non-franchise pharmacy chains would consolidate their ownership, so that every pharmacy in each chain is owned by the same company. This could provide efficiencies for the companies and should make the companies simpler and easier to regulate.
- 127. Under this option, chains would also be able to acquire or open new pharmacies without creating new companies. This could encourage growth of the chains, potentially at the expense of independent pharmacies. This could result in market dominance by a small number of players, as seen in some other New Zealand retail sectors and in many countries with deregulated pharmacy sectors.
- 128. The safeguards listed in the section above would also be introduced if the five pharmacy limit is removed. This would provide clarity around legal responsibility for actions at a company level.
- 129. As with removal of the pharmacist ownership requirement, it is difficult to know the impacts of a shift from independent pharmacies to chains. There is potential for the change to benefit consumers, for example if economies of scale enable practices such as paying the prescription co-payment, and faster adaptation of system improvements such as electronic prescribing.
- 130. However chain pharmacies may be less willing or able to implement initiatives which respond to specific local conditions. Deregulation and chain pharmacies are also associated with higher pharmacist workloads in several European countries.

How do the options compare to the status quo?

	Option One – Status Quo	Option Two – Strengthen ownership and control restrictions	Option 3 – Remove ownership restrictions and add safeguards
Access	0	0 Unlikely to have any significant impact on access	Could increase access by enabling health clinics and iwi to own pharmacies in rural and otherwise under-served areas
Quality	0	O Protection of independent pharmacies could encourage local initiatives Break-up of non-franchise chains would remove economies of scale and could slow uptake of more expensive (eg, digital) initiatives	O Potential for faster uptake of some initiatives Potential for reduced competition through growth of chains at the expense of independent pharmacies
Workforce	0	0 More security for independent pharmacist-owners Potentially fewer job opportunities for pharmacists unwilling or unable to purchase a pharmacy	Internationally, deregulation is associated with higher pharmacist workloads Possibly increased risk of conflict between professional standards and company interests
Right touch regulation	0	Significantly reduces commercial freedom Significant resources needed to assess and enforce compliance	+ + Removes ineffective regulation; enables redirection of regulatory resources Removes incentive to create complex company structures, making regulation easier and reducing burder on regulated parties
Overall assessment	0	Significant increase in regulation for no clear benefit	+ Simpler and lighter regulation and some potential patient benefits, but also some risks to competition, pharmacist workload, and possibly professional standards

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

- 131. Removing some or all restrictions (option 3) has some potential for improved access and service quality, but also carries risks to competition and workforce quality of life. Meaningfully restricting ownership and control (option 2) would significantly increase regulation and reduce economic freedom, without delivering any clear benefits.
- 132. In relation to specific elements, removing the prescriber ownership restriction may deliver benefits with the least risk. This change would enable health clinics to co-own pharmacies, and encourage more pharmacists to become prescribers. Potential conflicts of interest could be managed in the same way as other conflicts of interest.
- 133. There are potential benefits from removing the pharmacist ownership and five pharmacy limits. However there are also risks, particularly increased pharmacist workload, and dominance of the market by a small number of players. There may also be risk of increased conflict between professional standards and commercial imperatives. These risks are more strongly associated with removing the pharmacist ownership restriction, as it is not clear that the five pharmacy restriction is being meaningfully complied with.

Is the Minister's preferred option in the Cabinet paper the same as the agency's preferred option in the RIS?

134. Yes.

What are the marginal costs and benefits of the preferred option in the Cabinet paper?

Affected groups (identify)	Comment nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.	Impact \$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.	Evidence Certainty High, medium, or low, and explain reasoning in comment column.		
Additional costs of the preferred option compared to taking no action					
Pharmacists	Impact unclear: Potential reduction in professional autonomy Potential workload increases	Medium	Low		
Current pharmacy owners	More competition from chain pharmacies	Variable	Medium		
Regulator	Potential cost from regulating new safeguards	Low	High		
Consumers	Impact unclear: Potential reduction in competition	Low/medium	Low		

Affected groups (identify)	Comment nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.	Impact \$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.	Evidence Certainty High, medium, or low, and explain reasoning in comment column.		
	Some risk of fewer tailored local services				
Total monetised costs					
Non-monetised costs		Low/medium	Low/medium		
Additional benefits of the preferred option compared to taking no action					
Pharmacists	No clear benefits	None	Low		
Current pharmacy owners	Increased opportunities for expansion and investment Simpler company structures	High for some owners	High		
Regulator	Enables redeployment of regulatory resources Easier regulation due to simpler company structures	Medium	High		
Consumers	Potential for lower prices and more innovative services	Low	Low		
Others	Potential for iwi and prescribers to own pharmacies	Low/medium	Low		
Total monetised benefits					
Non-monetised benefits		Low/medium	Medium		

Section 3: Delivering an option

How will the proposal be implemented?

135. This analysis is based on removing all pharmacy ownership restrictions. If some or all restrictions are retained, they could be transferred from the Medicines Act into the Medical Products Bill, remain in the Medicines Act (as per the approach taken under the Therapeutic Products Act), or sit in other primary legislation. Regardless, there should be clarification to reflect the test in the Countdown case, and generally to improve drafting.

- 136. If all current restrictions are removed, the relevant parts of the Medicines Act would be repealed along with the rest of the Act. The Medical Products Bill would not include any pharmacy ownership restrictions other than general fit-and-proper person requirements.
- 137. The Medical Products Bill would also include new safeguards to mitigate risks from removing ownership restrictions. Specifically:
 - a. Any person or company operating more than one pharmacy would need to designate a supervisory pharmacist. This role would be similar to the responsible person under the current system, but with greater clarity that they are responsible for the compliance of the company and its pharmacies as a whole with medicines regulation and other pharmacy-related regulatory requirements. Policy development would draw on the Superintendent Pharmacist role in the United Kingdom. Individual pharmacies would continue to operate under the supervision of a pharmacist on location.
 - b. It would be an offence for a pharmacy licence holder, or any senior manager, to induce a pharmacist (or other health practitioner) to act unprofessionally. License holders and managers would also be required to ensure that pharmacists have the resources and authority to act professionally.
- 138. There are also likely to be further safeguards in secondary legislation, and pharmacy service contracts. These will be developed in engagement with the pharmacy sector, but could include regulations banning practices such as setting sales targets, or any encouragement to sell or recommend a specific product (except in alignment with guidance from a professional body or the Director-General of Health).
- 139. The regulator would be able to shift resource from assessment of ownership to more effective areas of pharmacy regulation, including developing guidance on the safeguards above. This guidance would need to be issued before the new legislation takes effect.
- 140. The proposal has the potential to increase Health New Zealand's workload, if the number of pharmacies increases and new pharmacies apply to join the integrated community pharmacy services agreement (ICPSA). The Ministry would work with Health New Zealand, during the development and implementation of the Medical Products Bill, to reduce and manage any impacts.
- 141. The Pharmacy Council, and potentially other practitioner authorities, would need to develop guidance on managing conflicts of interest around prescribing, and situations where a prescriber is able to dispense their own prescriptions. Other professional bodies, such as the Pharmaceutical Society, could potentially provide training for supervisory pharmacists.

How will the proposal be monitored, evaluated, and reviewed?

Pharmacy audits

- 142. As the regulator, Medsafe will continue to audit pharmacies to ensure that community pharmacy services meet required quality standards.
- 143. The risk-based audit framework includes two main types of audit:
 - a. full quality audit, assessing all services provided from a pharmacy and undertaken with advance notice
 - b. inspection audit, focussing on a subset of risk-based criteria and made without advance notice.
- 144. There are also follow-up audits, which are made without advance notice. Responses to complaints are also made without notice.

145. Medsafe will continue to update the pharmacy sector on audit findings and trends. The results are sent to all pharmacies in New Zealand and to sector representative organisations.

Pharmacy services agreements

- 146. Pharmacy services are publicly funded through the integrated community pharmacy services agreement (ICPSA) between Health New Zealand and each participating pharmacy. 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.
- 147. The ICPSA allows Health New Zealand to commission pharmacy services to meet local and national needs, to enable delivery of the New Zealand Health Strategy. The ICPSA came into effect in late 2018, and there is a nationally-agreed annual review of the agreement.
- 148. Some parts of the pharmacy audits use provisions of the ICPSA as references.

System-level monitoring and evaluation

- 149. The Pharmacy Council 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.
- 150. Non-pharmacist prescribers are regulated by other authorities under the HPCA Act, such as the Medical Council. If the prescriber ownership restriction is removed, we would expect the Medical Council and other relevant authorities to issue guidance on managing conflicts of interest for prescriber owners. Prescribing audits and other monitoring tools would also be used to detect any inappropriate prescribing.
- 151. The Ministry of Health is currently reviewing the HPCA Act, and will ensure that the Medical Products Bill aligns with any changes.
- 152. The Health and Disability Commissioner's role includes improving quality within the health sector, and holding providers to account.

Review of legislation

153. The Medical Products Bill may include a provision requiring a general review of the policy and operation of the Medical Products Bill at some point after implementation, along the lines of section 397 of the Therapeutic Products Act.