Independent Community Pharmacy Group Inc.

Submission to the Health Select Committee on

Pharmacy ownership

As part of the select committee process for the Therapeutic Products Bill

March 2023

To Chair Tracey McLellan and the members of the Health Select Committee:

Thank you for the opportunity to comment on pharmacy ownership as part of the select committee process for the Therapeutic Products Bill. While pharmacy ownership is not included in the Bill, we note Hon Andrew Little, when introducing the Bill as then Minister for Health, invited submitters to comment on the topic of pharmacy ownership and sought recommendations from the select committee on the topic.

Of the three options outlined in the 2021 MoH Pharmacy Ownership and Licensing Regulatory Impact Statement:

- **We support Option 2: retaining and strengthening pharmacist ownership requirements as a criterion for gaining a pharmacy licence.**
- **We oppose Option 3: separating ownership of pharmacies from the regulation of the quality and safety of pharmacy services.**

Strengthening pharmacist ownership requirements is the best option to ensure equitable access of all New Zealanders to medicines and health care services; and protects quality control of vital health delivery and the professional independence of pharmacists from non-pharmacist interference and pressure.

Yours sincerely,

Clive Cannons on behalf of the ICPG

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The Independent Community Pharmacy Group (ICPG), est. 2021, is an Incorporated Society representing 115 independent pharmacy owners across Aotearoa New Zealand. Our purpose is to promote, protect and improve owner-operated community pharmacies in New Zealand. Many of our members prefer to remain anonymous to avoid any potential due to the real fear of repercussions from their local contracting bodies / Te Whatu Ora | Health New Zealand districts.

Executive Committee:

Clive Cannons, Wainuiomata
Shane Helms, Waitara
Sean Shivnan, Gisborne
David Holt, Carterton
Doug Fargher, Silverstream
Gemma Parry, Te Awamutu

EXECUTIVE SUMMARY

There are three proposed options for pharmacy ownership.[1]

- 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 current corporatisation of the sector. It would require that pharmacists have financial, governance and operational control of any given pharmacy business via (1) majority pharmacy ownership and (2) management and operational control over the pharmacy's systems and practices.
- Option 3 would remove ownership restrictions, separating ownership of pharmacies from the regulation of the quality and safety of pharmacy services.

Option 2 is the best option to ensure equitable access of all New Zealanders to medicines and health care services; and protects the professional independence of pharmacists from non-pharmacist interference and pressure. Option 2 is the ICPG's preference. It will safeguard the integrity of the profession – and our ability as pharmacists to serve New Zealanders by maintaining quality and effective control of pharmacies.

The long term outcome of Option 3 is not a mix of community and corporate pharmacies. Due to the aggressive competitive nature of corporate pharmacy businesses, it probably means New Zealand will have mainly corporate pharmacies serving its population in the future.

The difference between Option 2 and Option 3 highlighted

The different drivers between pharmacies controlled by pharmacists and corporate pharmacies are captured by the following example.

When Cyclone Gabrielle came and the power failed in Napier, independent pharmacy owner Susie Farquhar and her husband grabbed medicines that were ready and uncollected, and delivered them to those that needed them. They worked out ways to work without power. Using candlelight, paper records, and worrying about payment for medicines later.

> '"If people don't have medicines, some people will die, that's the fact of it ... Pharmacists just have to find a way to make it work," Susie Farquhar, owner and pharmacist at Napier's Unichem Pharmacy Greenmeadows, said.'[2]

Contrast that with the corporate pharmacy in Hastings. It was open for only two hours per day, did not deliver, didn't dispense any prescriptions, and made people pay cash (even though the ATM machines weren't functioning at the time).[3]

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[1] 2021 MoH Pharmacy Ownership and Licensing Regulatory Impact Statement, p13
[2] https://www.stuff.co.nz/national/health/131287674/pharmacists-worked-through-cyclone-by-candlelight-to-get-meds-to-patients accessed 25 February 2023.
[3] Facebook.com Chemist Warehouse New Zealand post 15 February 2023. Accessed 25 February 2023.

Pharmacists are still the health professionals New Zealanders see most often. Pharmacies are found in every city, town, and district. No appointments are necessary. Health advice is free.

The pharmacists who own and work in independent pharmacies are highly regarded and trusted members of their communities. They understand local health needs and work hard to meet those needs. In so doing they improve the health and wellbeing of their communities.

Are ownership restrictions and effective control of pharmacies necessary?

In the cabinet paper on Pharmacy Ownership, the Minister of Health eloquently explains why pharmacy ownership restrictions have remained since 1957[4]

> 'The historical rationale for pharmacy restrictions has been the maintenance of a strong community pharmacy sector where patient health interests are placed ahead of commercial interests.'

Public safety is not and cannot be protected if control is held by a non-pharmacist. Neither can public safety be protected if pharmacist control is jointly held with non-pharmacists.

Equitable access to pharmacy services

Equitable access to pharmacy services means ensuring that all New Zealanders, regardless of their ethnicity, socioeconomic status, location and severity of health conditions, can access appropriate pharmacy services, therapeutic products and advice when needed in a timely and reliable way.

Pharmacies effectively controlled by pharmacists have often built-up decades of trust with patients. This is important because to fully address inequity in any community, it is vital that health providers understand local issues and demographics. Evidence-based solutions must be formulated in partnership with communities, building on an existing community focus.

The commitment necessary to begin properly addressing inequity is only possible in pharmacies where the owner is a pharmacist with effective control, and communities and pharmacists work together to find solutions for identified needs.

Around the country equity issues have been addressed through visiting kaumatua, meeting iwi leaders, sourcing extra funding, and running outreach programmes in people's homes.

Concerned about the level of non-adherence with kaumatua, an ICPG pharmacy formed a partnership with a local marae. Hui were held and solutions discussed. Pharmacists spent time with kaumatua and their whānau to allow for comprehensive assessment of health needs. Innovative solutions and interventions were not just limited to pharmaceutical solutions. Referrals were often made to other health

[4] Cabinet Paper: Pharmacy Ownership and Licencing September 2022

professionals and community support agencies. The results were significant improvements in kaumatua's management of their long term health conditions.

A recent survey of New Zealand pharmacy services, which some ICPG members participated in[5], highlights that these largely unfunded services, comprise a significant share - i.e. 15%-50% - of pharmacist's daily activities, requiring cross-subsidisation using revenue from other activities (like dispensing or retail sales).

Innovation in pharmacy service delivery

The worth of any pharmacy "innovation" should be assessed by the benefit it brings to the patient, not the pharmacy business. Innovations can address inequity, aid medication adherence generally, free up pharmacist time, and meet the needs of isolated rural communities.

Pharmacist-controlled pharmacies are best positioned to contribute to the development of novel patient care approaches which improve health.

This is because innovations which work are only possible if health providers understand local issues and demographics. As with inequity, developing innovative pharmacy services relies on being 'on the ground'. Innovations are not made for the sake of it. They occur because a problem needs to be solved. Innovations are often impromptu and designed for the need of a particular patient.

An ICPG pharmacy heard from their patients about difficulties with reliable district nurse services in the area. The pharmacists completed wound care training, and now offer a wound care service in patients' homes. This service ran right through the period of Covid lockdowns.

Community pharmacists are highly motivated to do the best for their patients and therefore, will often absorb the costs of innovation where they can, in order to provide important enhancements for their community. Pharmacists in corporate pharmacies do not have the discretion to implement actions if they will bring an extra cost to the business.

Ensuring high quality pharmaceutical service delivery

The risk of reducing service quality is diminished when pharmacists are in effective control of pharmacies. There is no conflict between meeting the needs of patients and satisfying the business objectives of non-pharmacist owners.

The time needed to provide adequate patient care is considerably longer than what is funded through the ICPSA agreement[6].

[5] Aziz, Y., Heydon, S., Duffull, S. and C. Marra, 2021, "What free services do pharmacists offer - Investigating the provision of unfunded pharmacy services in community pharmacies", Research in Social and Administrative Pharmacy, 17, 588-594.
[6] Integrated Community Pharmacy Agreement. https://www.tewhatuora.govt.nz/assets/For-the-health-sector/Community-pharmacy/Community-pharmacy-agreement/ICPSA-variation-4-amendments-v2.pdf

Pharmacy services are not restricted to simply dispensing and selling medicines. Pharmacists provide a wide range of services and advice which are often integrated with a patient's other healthcare providers.

Because community pharmacy is underfunded, costs for these services are often cross-subsidised from other pharmacy services, such as basic dispensing or selling over-the-counter products. There is a temptation to reduce or 'shade' the quality of services in preference for more profitable endeavours.

A pharmacy which is effectively controlled by a pharmacist must still be profitable. Breaches in the quality of services reflect directly on the pharmacist owner and the trust they have built up in their community. If there are too many breaches, patients will look for another pharmacist who can serve them. The resulting decrease in revenue and profit is a strong incentive against any temptation to 'shade quality'.

Contrast that with a non-pharmacist owner of a pharmacy business. If any quality shading they engage in prejudices their long-term ability to remain in the pharmacy sector, then they just revert to other profit-making activities (e.g. their supermarket).

The issue is not the quality of supply, but the pressure to diminish the quality of the services offered. This is not due to the lack of professionalism of the employee pharmacists in open ownership pharmacies. It is because those pharmacists are in conflict with non-pharmacist owners to pursue different objectives.

Evidence from the Canadian experience with deregulation highlighted similar concerns. These study authors defined role conflict as follows:[7]

"Role conflict items included being required to do things in one's job that are against professional judgment, receiving incompatible requests from 2 or more people, and having to choose between the business and professional aspects of pharmacy."Option 2, where the pharmacy is directly under the control of a pharmacist, has the effect of reducing the risk of introducing quality shading into the pharmacy to satisfy the business objectives of non-pharmacist owners.

Local Benefit

Effective control of a pharmacy company by a pharmacist allows for high quality services that fulfill the needs of local communities.

Corporates do not provide individualised solutions for individual communities or families. Strategy is determined directly from a head office, not from pharmacists who are in touch with the needs of their communities.

Corporate-owned pharmacies can only deliver one-size-fits-all solutions. In the ten years corporate pharmacies have been operating in New Zealand, the facts speak for

[7] Perepelkin, J. and R. Dobson 2010, "Influence of ownership type on role orientation, role affinity, and role conflict among community pharmacy managers and owners in Canada", Research in Social and Administrative Pharmacy, 6, 280-292, p. 285.

themselves. Profit is the goal and the quality of service received by patients is in decline.[8]

A suburban ICPG pharmacist was concerned about the wait time for GP appointments in their area. A lot of children were coming to the pharmacy with ear infections and no way of seeing a doctor in a timely manner. The pharmacist undertook extra training. Now her local GPs will take her referral for antibiotic prescriptions to treat ear infections.

At its core, the argument for strengthening the link between ownership and effective control, is about care and focus. Pharmacists in local pharmacies are invested in and understand their communities. They discover and nurture innovative equitable solutions for local needs in partnership with their communities.

In the words of an ICPG pharmacist,

> 'During Lockdowns we employed a staff member to call every patient we have who we were aware was isolated, anxious or would have issues with the lockdown situation. We had two staff members on full time driving doing deliveries of groceries, taking blood pressures, checking wounds, getting people stuck in their toilets out etc. None of these services were paid but we felt that our vulnerable patients needed support.'

[8] Compare Google reviews for Chemist Warehouse Wellington and Clive's Chemist, and ICPG member. Both pharmacies are in the same region.

INTRODUCTION

Government Standards for Good Regulatory Practice and the Objectives of the Pharmacy Action Plan

This submission is considering pharmacy ownership in terms of the government expectations for good regulatory practice [9], the Pharmacy Action Plan[10] and the changes proposed in the Therapeutic Products Bill.[11]

According to the expectations for good regulatory practice 'the government expects any regulatory system to be an asset for New Zealanders, not a liability.'

The government wants a regulatory system delivering a stream of benefits or positive outcomes in excess of its costs or negative outcomes over time. For pharmacy ownership, this is the statement against which all proposals should be measured.

Work is under way to refresh the Pharmacy Action Plan, 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.[12]

> '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.'[13]

The final consideration is to pass all conclusions through the lens of our patients and seek their input into what they want from their local pharmacy. One of the key themes of the Heather Simpson Report[14] was to ensure patients, whānau and communities are at the heart of any health system. In the executive summary she writes:

> '…The system must understand the needs of individuals, whānau and communities in much more detail and must design and deliver services to address the identified needs… Planning and funding these services must be driven by the needs of each community…'
>
> 'Patients, whānau and communities are not, however, only concerned with their immediate wellness. Communities need to have a part in the decision making about the design and delivery of treatment services at all levels.' [15]

Any change must be driven by the needs of each community, not policy makers.

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[9] Government Expectations for Good Regulatory Practice. https://www.treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf
[10] Ministry of Health. 2016. Pharmacy Action Plan: 2016 to 2020. Wellington: Ministry of Health.
[11] Therapeutic Products Bill 2022 [204-1]
[12] Ministry of Health. 2016. Pharmacy Action Plan 2016 to 2020. Wellington: Ministry of Health. Pg. iv.
[13] Ministry of Health. 2016. Pharmacy Action Plan 2016 to 2020. Wellington: Ministry of Health. Pg. iv.
[14] Health and Disability System Review. 2020. Health and Disability System Review – Final Report – Pūrongo Whakamutunga. Wellington: HDSR.
[15] https://www.health.govt.nz/system/files/documents/publications/health-disability-system-review-final-report-executive-overview.pdf Pg. 4 of report. accessed 27 February 2023

There are three proposed options for pharmacy ownership.[16]

- 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, separating ownership of pharmacies from the regulation of the quality and safety of pharmacy services

It is the considered opinion of the ICPG, that the only option and model of pharmacy ownership that can deliver a stream of benefits and positive health outcomes, aid the fulfilment of the objectives of the Pharmacy Action Plan, and keep patients, whānau, and communities at its heart is Option 2: 'A strengthened link between ownership and effective control of pharmacies, to limit the continued corporatisation of the sector'.[17]

Option 3 is the Ministry of Health's preferred option.[18] The Minister of Health has also stated that the current system ownership restrictions as defined by the Medicines Act 1981 s 55 (D)(2) [19]

> 'are no longer consistent with the Government's expectations for good regulation and do not fit well with the aims of the new therapeutic products regulatory scheme, such as enabling integrated and innovative models of patient care. They do not support the current objectives for the pharmacy sector, such as enhancing equitable access to medicines and pharmacy services, and fully utilising the unique skill set of pharmacists.'

In our opinion, Option 3 would not deliver benefits or positive outcomes in excess of its costs or negative outcomes over time for the people of New Zealand.

The submission will outline how this Option 2 ensures the equitable access of all New Zealanders to medicines and health care services and that the importance of the professional independence of pharmacists from non-pharmacist interference and pressure is protected.

[1616] RIS- Pharmacy ownership and licencing. Section A Summary of Preferred Option. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021. Summary and Proposed approach. Pg 1.
[17] RIS- Pharmacy ownership and licencing. Section A Summary of Preferred Option. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021. Summary and Proposed approach. Pg 1.
[18] RIS- Pharmacy ownership and licencing. Section A Summary of Preferred Option. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021. Section 5: Conclusion. Pg 51
[19] Cabinet Paper from the Office of the Minister of Health on Pharmacy Ownership, paragraph [6]. 6 Sep 2022

SECTION I: The history of pharmacy ownership in New Zealand, and why effective control was established

Current situation: not as intended

By the Ministry's own admission in the Regulatory Impact Statement (RIS) - Pharmacy Ownership and Licensing Policy Document,[20]

> 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).

There is widespread acknowledgement of issues with pharmacy ownership in New Zealand.

The Medicines Act 1981 s 55 (D) (2) restricts ownership of community pharmacy businesses. Currently 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, business arrangements have developed that comply with the letter of the law, but not the original intention of a maximum of five pharmacies, where the owner has effective control. In fact, some company and shareholder structures have seemingly been set up to knowingly avoid the ownership rules.

The result of this is an erosion of[21]

> '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 current pharmacy business arrangements have arisen because of regulatory problems, not the ownership legislation.

Legislative history of Pharmacy Ownership in New Zealand

An examination of the history of pharmacy ownership in New Zealand is essential to firstly understand why the current regulations are in place and the reason behind the effective control clause in the Medicines Act 1981. Then secondly, to answer the question whether the ownership restriction and effective control is still appropriate today and complies with good regulatory practice.

The legislative history and context of the "effective control" requirement show that the ownership and control restrictions exist to preserve the independence of pharmacists from non-pharmacist interference and pressures.

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[20] RIS- Pharmacy ownership and licencing. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021 Problem and Proposed Approach. Pg1

[21] RIS- Pharmacy ownership and licencing. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021 Section 2.2 What regulatory system(s) are already in place? Pg9

The relevant history is split into two main periods: first, the period after the 1954 and 1957 amendments and second, the period from the 2003 amendments onwards.

The 1954 and 1957 amendments: origins

The requirement that pharmacists have "effective control" over companies operating pharmacies originates in a 1957 amendment to the Pharmacy Amendment Act 1954.

The 1954 Amendment Act [22] introduced a partial consenting regime based on a "one pharmacist, one pharmacy" principle, whereby individual pharmacists could each operate one pharmacy without the consent of the Pharmacy Authority.[23] This was to: [24]

> '…recognise as desirable the principle of individual ownership and operation of pharmacies, limited to one pharmacy.'

To support individual ownership and operation of pharmacies, the 1954 amendment also permitted pharmacists to run a pharmacy through a company provided the pharmacist(s) owned at least 75% of the shares of the company. Although pharmacists were health professionals, they could not carry out their practice without an element of commerciality.

This requirement was set out in s 3(1), which provided:

> 3. (1) Except as otherwise provided by this Act, no company shall, except with the consent of the Pharmacy Authority …, establish or carry on business in a pharmacy:
>
> Provided that nothing in this section shall apply to a company of which at least seventy-five per cent of the share capital is owned by a chemist or by chemists…

However, there was a problem. A loophole was left open for pharmacists to circumvent the 'one owner, one pharmacy' model. Pharmacists could own shares in multiple companies each running pharmacies. The Pharmacy Amendment Act 1957 was passed to plug that gap.[25] The 75% ownership proviso in s 3(1) of the 1954 Amendment Act was deleted, and a new subs (1A) was inserted.[26] It provided:

> (1A) Notwithstanding the provisions of subsection one of this section, any company may establish and carry on business in a pharmacy without obtaining the consent of the Pharmacy Authority if at all times—
>
> (a) At least seventy-five per cent of the share capital of the company is owned by a chemist or by chemists *and effective control of the company is vested in that chemist or those chemists*; and
>
> (b) No member of the company is the proprietor or part proprietor of any other pharmacy; and
>
> (c) No member of the company is a member of any other company which is the proprietor or part proprietor of any other pharmacy…

This closed the loophole and introduced the effective control requirement.

[22] Pharmacy Amendment Act 1954, s 17(1), repealing the regulations referred to in Part 1 of Schedule 1.
[23] Pharmacy Amendment Act 1954, ss 3 and 4.
[24] (30 September 1954) 304 NZPD 2073.
[25] (23 October 1957) 314 NZPD 3008.
[26] Pharmacy Amendment Act 1957, s 3(1).

Why was effective control introduced?

The parliamentary record on this amendment shows that the "effective control" requirement was intended to support the purpose of the 75% ownership requirement; that is, to ensure that the company was there to serve independent pharmacists and not some outside interest.

During the second reading of the Pharmacy Amendment Bill 1957, the Minister of Health reiterated the Government's policy view that "a pharmacy business should, as far as possible, be conducted by a free and independent proprietor owning his [sic] own shop".[27] Pharmacists were intended to be "completely free and independent of any financial control by a wholesaler or anyone else".[28] It was on that basis that the 1954 amendments permitted a qualified pharmacist to "start one shop for himself, either under his own name or in the name of a company".[29]

The first draft of the 1957 Amendment Bill, however, did not contain the effective control requirement; it merely re-enacted the 75% ownership proviso. A Member of Parliament therefore raised concerns during the second reading that the proposed s 3(1A) would not achieve the intended purpose of "confin[ing] controlling interests in chemists' shops to genuine practising chemists" due to the multitude of ways a company could be structured to give control to a minority shareholder.[30]

Examples the Member gave included situations where pharmacists held shares that did not come with the controlling voting interest, or as a stand-in for outside interests.[31] Consequently, the Minister of Health added the "effective control" requirement to the Bill during committee stage.[32]

Thus s 3(1A) stood, until it was repealed and re-enacted as s 42(2)(a) of the Pharmacy Act 1970.

The purpose of 75% ownership and effective control by a pharmacist ensured that the freedom given to individual and independent pharmacists to operate pharmacies through companies, was not encroached by non-pharmacist interests which could negatively interfere with health delivery.

The 2003 amendments: change and continuity

The Pharmacy Act 1970 lasted until the passing of the Health Practitioners Competence Assurance (HPCA) Act 2003. This Act consolidated 11 regulatory regimes relating to health professionals (including pharmacists) into a single consistent framework to protect the public from the risk of harm by ensuring practitioner competence.[33] The Pharmacy Act 1970, under which pharmacists were previously registered, was repealed. The question was raised as to whether the previous pharmacy ownership requirements should be retained.[34]

[27] (23 October 1957) 314 NZPD 3251.
[28] (23 October 1957) 314 NZPD 3252.
[29] (23 October 1957) 314 NZPD 3251.
[30] (23 October 1957) 314 NZPD 3252.
[31] (23 October 1957) 314 NZPD 3252
[32] (23 October 1957) 314 NZPD 3256. 31
[33] Health Practitioners Competence Assurance Bill 2002 [230-1] [explanatory note] at 1-2
[34] See Office of the Minister of Health "Memorandum to Cabinet Social Policy and Health Committee: Amendments to the Medicines Act 1981" (27 March 2002) at Background, [3]–[4].

Parliament's response to this question contained elements of both change and continuity. In relation to change, Parliament re-introduced blanket licensing for the operation of all pharmacies.[35] On the other hand, it removed the "one pharmacist, one pharmacy" model, expanding the number of permitted pharmacies per pharmacist to five,[36] and reducing the pharmacist ownership requirement from at least 75% to more than 50%.[37] This is now reflected in s 55D(2)(a).

Alongside the now reduced ownership requirement, the effective control requirement was retained without change.

Based on Hansard, Parliament's rationale for retaining a majority ownership requirement was to protect the safety of the public. **Members noted that pharmacists, as health professionals, are driven by the needs of patients, and open ownership by non-pharmacists risked compromising those standards for the maximisation of revenue.[38]** This was seen as undermining the purpose of the HPCA Bill of protecting the health and safety of the public.[39]

The purpose of effective control has not changed since first introduced in 1957.

Effective control is evident when a majority pharmacist shareholder or group of pharmacists can proactively make decisions, thus having "effective control" over the company under the Medicines Act 1981 s 55D(2)(a).

<u>Are ownership restrictions and effective control still valid?</u>

In the cabinet paper on Pharmacy Ownership, the Minister of Health acknowledges this[40]

> 'The historical rationale for pharmacy restrictions has been the maintenance of a strong community pharmacy sector where patient health interests are placed ahead of commercial interests.'

Ownership and effective control are linked.

The amount of control that ordinarily comes with a greater than 50% shareholding in a company under the Companies Act 1993 is control over the decision-making of the company.

Notably, the Ministry's own website[41] describes "effective control" by reference to three indicators, two of which are:

- the ability to appoint directors; and
- the ability to control the board of directors.

[35] Medicines Amendment Act 2003, s 5.
[36] Medicines Amendment Act 2003, s 17 inserting s 55F
[37] Medicines Amendment Act 2003, s 17 inserting s 55D.
[38] See, for example, (15 October 2002) 603 NZPD (Martin Gallagher, Labour – First Reading of Health Practitioners Competence Assurance Bill).
[39] (15 October 2002) 603 NZPD (Sue Kedgley, Green – First Reading of Health Practitioners Competence Assurance Bill).
[40] Cabinet Paper: Pharmacy Ownership and Licencing September 2022
[41] https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/pharmacy-licensing/pharmacy-ownership-and-control accessed 24 February 2023.

This must mean the ability to control the number of directors required for directors' resolutions to be passed. That is what "effective control" over a company ought to require, at minimum, for the purposes of s 55D(2)(a) of the Medicines Act 1981.

It is parliament's clear intention to ensure pharmacist independence against commercial pressures, to promote public safety. This requires the ability to make decisions relating to governance and operational matters.

Public safety would not and could not be protected if the same control was held by a non-pharmacist. Neither could public safety be protected if pharmacist control was jointly held with non-pharmacists.

Ownership restrictions and effective control are still valid because there are many active decisions required to be made at Board (and not operational) level that can impact on the health and safety of pharmacy patients.

Pharmacist control over the bare minimum obligations of pharmacy companies required by legislation does not satisfy effective control, as legislation and regulations governing pharmacy only relate to operational decisions.

Practical examples of decisions needed to be made by pharmacists at a board level are:

- Contracting decisions. The board must agree to actively enter into a new contract. Many independent community pharmacists provide optional services for the safety and well-being of the public. A recent example is the Covid Care in the community contract. Under this contract pharmacies agree to provide RAT tests, vaccinations and anti-virals.
- Decisions relating to services offered. These decisions go directly to business strategy and cost and would require board approval. They may also involve contracts with external suppliers. Examples of services independent community pharmacists might offer that are patient- rather than profit-centred include the hiring of delivery services to ensure patients receive medication during lockdown or isolation.
- Staffing decisions. Maintaining enough staff is important for patient care and safety because being short-staffed increases wait times, increases the likelihood of dispensing error, and reduces the ability for pharmacists to give patients safety advice in relation to certain medicines. Ensuring adequate staffing requires (1) actively hiring at the right time and (2) deciding on the period of overlap needed for adequate handover training.
- Staff wages. For the same reasons as above, pharmacies might need to agree to increase the budget allowance for more pharmacists or for them to work more hours (resulting in greater wage costs).

Currently legislation allows for pseudo corporate ownership in as many pharmacies as a corporate shareholder would like to have. This was acknowledged in the RIS-Pharmacy Ownership and Licencing document:[42]

> 'Current ownership restrictions have… allowed de facto corporatisation of the sector: many pharmacies are part of chains, and pharmacies exist as part of supermarkets.'

Summary: pharmacist ownership and effective control complies with good regulatory practice

According to the expectations for good regulatory practice[43] 'the government expects any regulatory system to be an asset for New Zealanders, not a liability.'

The current regulations and the proposed regulations in Option 2 of the RIS[44] deliver a stream of benefits or positive outcomes in excess of its costs or negative outcomes. These benefits and positive outcomes in the health of all New Zealanders would be unattainable in pharmacies where the majority shareholding is held in the hands of non-pharmacists.

This will be fully explored in the next section.

[42] RIS- Pharmacy ownership and licencing. Section 2.2 What regulatory systems are already in place? Pg. 8 Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021. Summary and Proposed Approach Pg. 1

[43] Government Expectations for Good Regulatory Practice. https://www.treasury.govt.nz/sites/default/files/2015-09/good-reg-practice.pdf Pg 7

[4444] RIS- Pharmacy ownership and licencing. Section A Summary of Preferred Option. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021. Summary and Proposed Approach Pg. 1

SECTION II: What are the objectives sought in relation to reviewing Pharmacy Ownership?

2.1 Equitable access to pharmacy services

The RIS- Pharmacy Ownership and Licensing Policy Document states:[45]

> 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 patient, accurate and appropriate to patient needs.

Is this best delivered by Option 2 or Option 3?[46]

The best option to begin to tackle the inequity present in the delivery of pharmaceutical services in New Zealand is Option 2. Pharmacist owners with effective control of their pharmacies, who are given the right support from Te Whatu Ora | Health New Zealand, and who work closely with their communities, will reduce inequity far more effectively than corporate pharmacies whose main priority is seemingly their bottom line.

The Ministry of Health defines equity in the following way:[47]

> In Aotearoa New Zealand, people have differences in health that are not only avoidable but unfair and unjust. Equity recognises different people with different levels of advantage require different approaches and resources to get equitable health outcomes.

Recent New Zealand research reviewing studies on equitable access to medicines via primary healthcare distinguishes between equity of access and equality of access:[48]

> "'Equity' is often confused with 'equality', however, these words are not synonymous. 'Equality' is about 'sameness', uniformity and about fair distribution assuming everyone is at the same starting level. It ignores contextual differences between people such as ethnicity, socioeconomic status and disability as well as the barriers that some groups face even to get to the 'assumed' starting point.
>
> In contrast, 'equity' is an ethical construct acknowledging that different approaches may be required for different groups to achieve the same outcomes. Thus, equal approaches become inequitable if differences such as socio-economic status, or severity of health conditions are not taken into account. For example, in terms of populations that are known to have a greater burden of disease "equality of access is inequitable in the face of unequal need"."

[45] RIS- Pharmacy ownership and licencing. Section 2.5 What are the objectives sought in relation to the identified problem? Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021
[46] RIS- Pharmacy ownership and licencing. Section A Summary of Preferred Option. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021. Summary and Proposed Approach Pg. 1
[47] https://www.health.govt.nz/about-ministry/what-we-do/work-programme-2019-20/achieving-equity accessed 24 February 2023
[48] Carswell, S., Donovan, E. and F. Pimm, 2018, Equitable access to medicines via primary healthcare a review of the literature, report prepared for PHARMAC, September, p. 11.

This implies that equitable outcomes in health from pharmacy services will only be achieved if different approaches such as greater or superior access to health services are possible for people with a greater disease burden.

The outcome of equitable access to pharmacy services will ensure that all New Zealanders, regardless of their ethnicity, socioeconomic status and severity of health conditions, can access pharmacy services, therapeutic products and advice when needed in a timely, affordable, and reliable way.

The pharmacy Health Equity Statement 2013[49] identifies two issues:

> 1. To develop an understanding of health equity and health equality that enables pharmacists and their staff to deliver pharmacy services that ensure all people have a fair and equitable opportunity to achieve their full health potential irrespective of different levels of underlying social advantage or disadvantage.
>
> 2. To encourage all pharmacists / pharmacies to become more aware of equity issues within their immediate and extended communities and to advocate for more equitable outcomes.

This is made more explicit in s 7(2) of the Pae Ora Act,[50] which provides that: each health entity (defined to include Te Whatu Ora I Health New Zealand) "must", as far as reasonably practicable, "be guided by the health sector principles" when performing a function or exercising a power or duty under the Pae Ora Act. The "health sector principles" are set out in s 7(1). They include the principle that the health sector should be equitable, which includes ensuring that population groups have access to services in proportion to their health needs, receive equitable levels of services and achieve equitable health outcomes.

In the Pharmacy Council of New Zealand Code of Ethics[51] pharmacists are called to

> 'respond appropriately to the health needs of Māori including inequities in health and access to healthcare services.'

Pharmacies and pharmacists have to be very deliberate in their service offering, and the way they provide those services to ensure this happens.

<u>What is it about a strengthened link between ownership and effective control that will be better for equity (Option 2)?</u>

To fully address inequity in any community, it is vital that health providers understand local issues and demographics, before any solutions are proffered.[52] Then those solutions, based on evidence, must be formulated in partnership with communities to build on an existing community focus.

Given Māori health needs and known challenges for Māori to access pharmaceutical support, Māori community participation in decisions about pharmacy services is essential. Communities know best the types of services they need to respond to the

[49] Health Equity Statement 2013 (Pharmacy Reference Group for the Implementation of the Strategy for Māori Health (PRISM))

[50] Pae Ora (Healthy Futures) Act 2022

[51] Pharmacy Council of New Zealand Code of Ethics

[52] https://bpac.org.nz/bpj/2008/may/docs/bpj13_solutions_pages_10-14.pdf accessed 24 February 2023

issues facing them.[53]

Tackling inequity alongside communities is time consuming and expensive. The solutions are as complex as the issues and are not just about cost. Solutions are only found by talking and listening to those affected.

Such solutions involve considering access to the pharmacy, how consultations occur, liaising with prescribers, involving whānau in treatment decisions, forming partnerships with marae and other community providers and seeking funding for all costs relating to medicines (not just prescriptions). Receiving the medicine is only a small part of the medicine pathway.

After gaining feedback from communities, independent pharmacies have begun to address inequities through visiting kaumatua, meeting iwi leaders, sourcing extra funding, and running outreach programmes in people's homes.

Concerned about the level of non-adherence with kaumatua, an ICPG pharmacy formed a partnership with a local marae. Hui were held and solutions discussed. Pharmacists spent time with kaumatua and their whānau to allow for comprehensive assessment of health needs. Innovative solutions and interventions were not just limited to pharmaceutical solutions. Referrals were often made to other health professionals and community support agencies. The results was significant improvements in kaumatua's management of their long term health conditions.[54]

A recent survey of New Zealand pharmacy services, which some ICPG members participated in[55], highlights that unfunded customer services, such as the list above, comprise a significant share - i.e. 15%-50% - of pharmacist's daily activities, requiring cross-subsidisation using revenue from other activities (like dispensing or retail sales).

The commitment necessary to begin addressing inequity is only possible with pharmacies where the owner is a pharmacist who has effective control of the company. If each activity was looked at in isolation, they are a cost to the business. The solutions take time and occur over many visits or interactions with patients and whānau.

One of the arguments in the Pharmacy Licensing and Ownership RIS[56] is that tackling inequity and innovation would be stymied if effective pharmacist control of pharmacy companies had to be retained. An example was given where other healthcare service providers (such as iwi organisations) would be prevented from establishing pharmacies to serve particular areas or patient groups. [57]

However due to the current funding model, even if there was a will for such

[53] https://www.msd.govt.nz/about-msd-and-our-work/publications-resources/corporate/annual-report/2009-10/communities-are-better-able-to-support-themselves.html accessed 3 February 2023
[54] Email reference available on request.
[55] Aziz, Y., Heydon, S., Duffull, S. and C. Marra, 2021, "What free services do pharmacists offer - Investigating the provision of unfunded pharmacy services in community pharmacies", Research in Social and Administrative Pharmacy, 17, 588-594.
[56] RIS- Pharmacy ownership and licencing. Section 2.3 What is the policy problem or opportunity? Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021
[57] Therapeutic Products Bill 2022 [204-1] s152

arrangements, the cost of establishing, running and staffing small pharmacies to service such areas or patient groups would make the schemes unfeasible.

These arrangements are already happening in numerous sites around the motu through contractual partnerships with pharmacies that have trusting relationships with local whānau or other groups.

It is highly unlikely that large corporate organisations will provide bespoke solutions to equity issues that vary from community to community and whānau to whānau. That is just not the way they operate. Corporates usually operate on a 'turnkey' operation. They are unable to fashion individual solutions, nor take the time and care required to understand the structural inequities in the communities in which they operate.

The best option to begin to tackle the inequity present in the delivery of pharmaceutical services in New Zealand is Option 2. Pharmacist owners with effective control of their pharmacies, who are given the right support from Te Whatu Ora | Health New Zealand, and who work closely with their communities, will reduce inequity far more effectively than corporate pharmacies whose main priority is their bottom line.

2.2 Innovation in pharmacy service delivery

Pharmacy services are evolving. This is due to technological advancements, changing patient expectations, and innovation in meeting differing levels of need.

The Pharmacy Ownership and Licensing Policy RIS states[58]

> Patients 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.

To adequately assess, recognise, and prioritise which option of pharmacy ownership delivers the most innovative models of patient care, and will enhance equitable access to medicines and pharmacy services, pharmaceutical innovation needs to be defined.

> Pharmaceutical innovations create value to society by making it possible to generate improvements in patient health (net of treatment risks) that were previously unattainable. It is the uniqueness of such health improvements that defines pharmaceutical innovations.[59]

[58] RIS- Pharmacy ownership and licencing. Section 2.5 What are the objectives sought in relation to the identified problem? Pg 14. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021

[59] Morgan S, Lopert R, Greyson D. Toward a definition of pharmaceutical innovation. Open Med. 2008;2(1):e4-7. Epub 2008 Jan 30. PMID: 21602949; PMCID: PMC3091590.

The value of patient care, equitable access, and pharmacy services is not in their commercial value, as assessed by their profitability. Their value lies in the health outcomes they generate. Innovation in pharmacy must only be assessed by the benefit it brings to the patient, not the pharmacy business.

Doucette et al. described pharmaceutical innovation as,

> 'A tendency to perform activities that develop and bring new services into markets.' [60]

So, to describe a pharmacy service as innovative, **it must be new and deliver measurable positive health outcomes.**

Some innovations in pharmacy originate with central government. An example is the waiver of the co-payment to children under the age of 13 introduced in 2015.[61] It was introduced to remove the cost barrier for children's medicines.

> Health Minister Jonathan Coleman says more kids are getting the prescriptions they need following the introduction of the free under-13 policy.
>
> "We want to ensure young Kiwis get the best possible start in life. Removing the cost barrier of prescription charges and doctor visits is having a really positive impact on many families," says Dr Coleman.[62]

Some innovations have arisen due to a specific need in a community. The most recent example is Te Whatu Ora | Health New Zealand 's response helping people impacted by Cyclone Gabrielle to get easier access to healthcare by funding a range of primary care initiatives across pharmacies, clinical telehealth and general practice.[63]

These innovations are actioned by all pharmacies. They were new at the time of implementation and benefited patients. The ownership model had no effect on their implementation.

However, at a local level, innovation in pharmacy is very different. Whether addressing inequity, aiding adherence generally, freeing up pharmacist time with technology, or meeting the needs of isolated rural communities; pharmacists with effective control of pharmacy companies, and those who work in such companies, are the best positioned to contribute to the development of novel patient care approaches which improve health.

Why is that the case?

Firstly, because **innovations which work are only possible if health providers understand local issues and demographics before any solutions are proffered.**[64] As with inequity, developing innovative pharmacy services relies on being 'on the

[60] Doucette WR, Rippe JJ, Gaither CA, Kreling DH, Mott DA, Schommer JC. Influences on the frequency and type of community pharmacy services. *J Am Pharm*. 2017;57:72-76.
[61] https://www.beehive.govt.nz/release/under-13s-benefiting-free-prescriptions accessed 25 February 2023
[62] https://www.beehive.govt.nz/release/under-13s-benefiting-free-prescriptions accessed 25 February 2023
[63] https://www.tewhatuora.govt.nz/about-us/news-and-updates/te-whatu-ora-funding-primary-healthcare-delivery-in-affected-regions accessed 25 February 2023
[64] https://bpac.org.nz/bpj/2008/may/docs/bpj13_solutions_pages_10-14.pdf accessed 24 February 2023

ground'. Innovations are not made for the sake of it. They occur because a problem needs to be solved. Innovations are often impromptu and designed for the need of a particular patient.

Secondly it takes commitment and hard work for a pharmacy owner or manager to cultivate an innovative mindset amongst their staff. That mindset is evident in a work culture which welcomes change and new ideas. It is a culture where employees feel safe and supported to express their creativity, offer solutions and provide effective feedback. [65]

Thirdly innovation requires a focus on meeting the patient's need by whatever means are at your disposal. If nothing is available or appropriate, then a new innovative solution must be found for that patient.

An ICPG pharmacy heard from their patients about difficulties with reliable district nurse services in the area. The pharmacists completed wound care training, and now offer a wound care service in patients' homes. This service ran right through the period of Covid lockdowns.[66]

Another suburban ICPG pharmacist was concerned about the wait time for GP appointments in their area. A lot of children were coming to the pharmacy with ear infections and no way of seeing a doctor in a timely manner. The pharmacist undertook extra training. Now her local GPs will take her referral for antibiotic prescriptions to treat ear infections.[67]

<u>Which ownership model is most likely to bring innovation in pharmacy service delivery?</u>

Often innovative interventions run at a loss or are initially cross subsidised by other pharmacy services. There can be a lot of experimentation and change before a workable innovative solution is successful.

The most common barriers to innovation are the staff to provide it, and the money to pay for it. Community pharmacists are highly motivated to do the best for their patients, often at a cost to themselves and their business.

Pharmacists in corporate pharmacies do not have the discretion to implement actions if they will bring an extra cost to the business.

The difference in innovation between the two ownership models is highlighted by the recent response of pharmacists in Hawke's Bay to the aftermath of Cyclone Gabrielle. The difference is stark.

When the cyclone came and the power failed in Napier, pharmacist Susie Farquhar and her husband grabbed medicines that were ready and uncollected and delivered them to those that needed them. They worked out ways to work without power;

[65] https://www.pharmacytimes.com/view/tip-of-the-week-innovation-influences-new-pharmacy-services accessed 8 February 2023.
[66] Email reference available on request.
[67] Email reference available on request.

using candlelight, paper records, and worrying about payment for medicines later.

> '"If people don't have medicines, some people will die, that's the fact of it ... Pharmacists just have to find a way to make it work," Susie Farquhar, owner and pharmacist at Napier's Unichem Pharmacy Greenmeadows, said.'[68]

The corporate pharmacy in town was open for only two hours per day, did not deliver, didn't dispense any prescriptions, and made people pay cash (even though the ATM machines weren't functioning at the time).[69]

The best model of pharmacy ownership which will deliver innovative solutions which are new, and benefit patients with measurable positive health outcomes is Option 2.[70] This is because pharmacists who are in effective control of their pharmacies are embedded in their communities, motivated to meet the needs of those communities, and driven by the ethical responsibilities as a pharmacist. Quite simply, we care.

<u>Examples of innovation</u>

a. Innovation, Technology and Capital Investment

The Ministry of Health states that[71]

> 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.

It is possible to bring technological innovations into pharmacy businesses under the current ownership model. The most common technological innovation in New Zealand pharmacies is the use of dispensing robotics. These free up pharmacist's time from the 'count and pour' of dispensing to spend more time with patients delivering clinical services.

There are currently many examples of pharmacists in the ICPG who have committed strongly to investment in technology. The capital for such investments is readily available through current funding channels.

It is not the current ownership provisions which impede and restrict innovation in the sector. It is the legislation on which Medsafe relies. Some innovations such as hub and spoke models for dispensing may not be legally available. Current legislation impedes scaling these innovations up to a national level. The Therapeutic Products Bill goes someway to addressing this, but not far enough.

One of the ICPG members who has invested considerably in technology writes about potential cooperation for mutual benefit between pharmacies:[72]

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[68] https://www.stuff.co.nz/national/health/131287674/pharmacists-worked-through-cyclone-by-candlelight-to-get-meds-to-patients accessed 25 February 2023.
[69] Facebook.com Chemist Warehouse New Zealand post 15 February 2023. Accessed 25 February 2023.
[70] RIS- Pharmacy ownership and licencing. Section A Summary of Preferred Option. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021. Summary and Proposed approach. Pg 1.
[71] RIS- Pharmacy ownership and licencing. Section 6.2 What are the implementation risks? Pg 24. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021
[72] Email reference available on request.

> 'If, for example, there was allowed to be a 'halfway house' for doing rest home and blister packs, then I would open up the robot facility to other players. If we were allowed to lease the robot room to a pharmacy for a time period - and for the time period of the lease, the robot room was subject to the SOPs of the lessor , and the SOPs of the lessee also applied to the lessor - then this would cure the problem [of requiring economies of scale]. This would spread expertise across a number of outlets and produce a high quality result.'

b. Innovation and Rural Pharmacy

Speaking of open ownership and rural innovation, the Ministry of Health states:[73]

> '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.'

Such a statement is surprising as it does not reflect the reality of the challenges faced in rural areas.

New Zealand supermarket pharmacies have trouble staffing their city pharmacies with pharmacists. Currently rural owner-operated pharmacies also struggle with the same issue, so it could be expected that rural supermarkets would have even more difficulty, facing both rural and corporate challenges.

The difference between urban supermarkets and rural pharmacies effectively controlled by a pharmacist, is that the rural pharmacists have the ongoing motivation to enhance the health and wellbeing of their communities. That drive, combined with the staffing needs of the business, is driving innovation in staff recruitment.

One of the ICPG members who has a pharmacy in a rural area writes:[74]

> 'In rural, the struggle is real to attract staff. An innovation that this business has implemented is to confer scholarships annually to year 3 Pharmacy students at Otago University to help with costs for students coming to work at our pharmacy. Once here, the students are shown the possibilities of working in our rural work environment and what it would be like to be a part of our wider community.
>
> We have recently partnered with local iwi to create a career pathway (in pharmacy) for the younger generation. In rural, especially areas with a high percentage of Māori population, young people are often expected by their families to stay within the area.'

As with the staff issue, rural innovation in service delivery is only possible by pharmacists from pharmacies effectively controlled by pharmacists. Because

[73] RIS- Pharmacy ownership and licencing. Section 6.2 What are the implementation risks? Pg 25. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021

[74] Email reference available on request.

innovations which work are only possible if health providers understand local issues and demographics before any solutions are proffered.[75]

An example was provided by another rural ICPG member. In Northland the overwhelming number of Covid-19 vaccinations were delivered by pharmacies effectively controlled by a pharmacist, as opposed to the corporate pharmacies. She writes:[76]

> The Covid Vaccination summary from March 2022 in Northland[77] shows that Chemist Warehouse Okara park in Whangarei delivered only 2261 vaccinations. My little independent pharmacy in Mangawhai did 5819 (Kaipara district)'

Why is this? Because she understands her community, how to deliver the services they need, and is personally committed to her community along with her ethical obligations as a pharmacist.

Corporate pharmacies are poorly represented in rural New Zealand. This is not because there is a lack of need. It is because it is harder to make those pharmacies profitable.

2.3 Ensuring high quality pharmaceutical service delivery

The Pharmacy Ownership and Licensing Policy RIS[78] states that to 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.'

Because of the public health and safety implications associated with the provision of prescription medicines to members of the public, a high level of quality is essential in pharmacies.

The ICPG believes this quality assurance is better delivered by pharmacies effectively controlled by a pharmacist owner than by pharmacies that are corporately owned.

Pharmacy services are not restricted to simply dispensing and selling medicines. Pharmacists provide a wide range of services and advice which are often integrated with a patient's other healthcare providers. These include, but not limited to:[79]

- Long Term Conditions Service – optimising use and adherence of prescribed medication
- Medicines Use Review and Optimisation - optimising use and adherence of prescribed medication for patients with more complex needs
- Community Pharmacy Anticoagulation Management Service – managing doses of patients' anticoagulation therapy in collaboration with their GP.
- Immunisation Services

[75] https://bpac.org.nz/bpj/2008/may/docs/bpj13_solutions_pages_10-14.pdf accessed 24 February 2023
[76] Email reference available on request.
[77] Northland DHB Covid-19 Vaccination Programme. Weekly report 2 March 2022
[78] RIS- Pharmacy ownership and licencing. Section 2.5 What are the objectives sought in relation to the identified problem? Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021
[79] Pharmaceutical Society of New Zealand, 2014, *New Zealand National Pharmacist Services Framework 2014.*

- Pharmacist Only Medicines – medicines sold without a prescription, but which require pharmacist intervention
- Health Education
- Medicines Information and Counselling
- Screening and Intervention – for cardiovascular disease, diabetes, gout
- Local initiatives funded by different Te Whatu Ora | Health New Zealand districts

Quality in pharmacy is not just about the safety aspects of dispensing, but also about the attention, care and skill, with which the above pharmacy services above are provided.

Compared with the quality audits undertaken by Medicines Control which measure the quality of premises, equipment, and adherence to regulations[80], the quality of services is harder to measure. The time spent with a patient can be measured, but that does not correlate with the quality of advice given.

Therefore, patients must place a great deal of faith in their pharmacist to apply the appropriate care and skill when delivering their products and services. A patient will often build relationships with trusted pharmacists, and pharmacies in their communities. In pharmacies that are effectively controlled by an owner pharmacist who works in the business, this relationship can span decades. The trust in pharmacist owners will often transfer to their staff as well. This is not always the case in corporate pharmacies where the pharmacists are often in specific pharmacies for relatively short periods of time.

Trust lies at the heart of the relationship between pharmacists and their patients and communities.

The time needed to provide adequate patient care is considerable and longer than what is funded through the ICPSA agreement.[81] Each pharmacy also has to employ enough pharmacists to ensure each patient has quality care.

Because community pharmacy is underfunded, counselling and service costs are often cross subsidised from other pharmacy services. This means pharmacists may have to spend more of their time in more profitable endeavours such as basic dispensing or selling over-the-counter products.

What is the result of that? Either less time advising patients, having to choose which patients to give priority to, or reducing the number or quality of services offered. The result is overall reduced service quality, otherwise known as “quality shading”.

Like many industries in New Zealand, pharmacies are struggling finding qualified staff. In pharmacies that are effectively controlled by pharmacist owners, those owners often work extended hours unpaid to compensate for low staffing during the day. This allows for ‘catch-up’ on dispensing backlogs and administrative tasks so that they have more time during opening hours to give quality service to their consumers.

[80] https://www.medsafe.govt.nz/profs/PUArticles/September2019/Pharmacy-quality-audits.htm accessed 14 February 2023
[81] https://www.tewhatuora.govt.nz/assets/For-the-health-sector/Community-pharmacy/Community-pharmacy-agreement/ICPSA-variation-4-amendments-v2.pdf accessed 26 February 2023

Contrast that with the availability of trained pharmacists to work corporate pharmacies' extended trading hours.

If pharmacists working at corporate pharmacies are already under time pressure due to a lower staff to prescription volume ratio, then service quality may deteriorate if additional pressures are placed on those pharmacists. Their time would have to be reprioritised towards meeting financial and business goals rather than serving consumers.

Corporate pharmacies in New Zealand are weakening and/or driving their competition their competition out of business, while increasing their profits by undercharging for one product (i.e. prescriptions). The resulting loss in revenue is recouped from the profit of patients buying unanticipated add-on products which they had not intended to buy when initially induced by 'free prescriptions'.[82] It also means that those pharmacies are likely to shade quality in other areas to make up for the lack of revenue.

Because the quality of the service of an organisation is affected by the objectives of the owners of that organisation, how pharmacies are owned will influence the services offered. Quality shading can in fact be an explicit element of a pharmacy's strategy if it is seeking to maximise its profits.

Although on paper the corporate pharmacies are majority-owned by pharmacists,[83] the pharmacists who work in them are more likely to be employee pharmacists than in other types of community pharmacy (where owner-pharmacists are more likely to also work in their pharmacies).

Moreover, employee-pharmacists in corporate pharmacies may face being governed and managed by non-pharmacists as well as pharmacists (e.g. Countdown Pharmacy combines pharmacy and supermarket activities). Business and financial priorities can create a tension between a pharmacist making profits and delivering quality healthcare.

The non-pharmacist owner simply does not understand the importance of specific types of services which have to be sacrificed in the pursuit of profit.

The Pharmacy Ownership and Licensing Policy RIS[84] states that under Option 3, a de-regulated pharmacy ownership environment,

> 'there is no evidence that safety or medicines quality would reduce.'

The ICPG begs to differ.

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[82] https://thespinoff.co.nz/business/18-05-2022/the-chemist-warehouse-effect accessed 3 February 2023

[83] https://app.companiesoffice.govt.nz/companies/app/ui/pages/companies/7551936?backurl=H4sIAAAAAAAAAEXLMQ7CMAyF4dtkYQAGRguxwEAHJHoBk5jWUhMH2wX19hRRxPa%2FT3rrih3ZOkquWHguI9TY7x9wQ%2B2Qyyr2lNk8UHH2qZ0qGRyaZtlXRx%2FtpDLWL3OJovWokmHpViBgSkpm%2F%2FcCZ5peogmCOarDJgyc2WG7C3afMX2eTyyR0gULDeA6UsiSCH7%2BBsiOQKbBAAAA accessed 14 February 2023
https://app.companiesoffice.govt.nz/companies/app/ui/pages/companies/7990676 accessed 14 February 2023
https://app.companiesoffice.govt.nz/companies/app/ui/pages/companies/8217763/shareholdings accessed 14 February 2023
https://app.companiesoffice.govt.nz/companies/app/ui/pages/companies/6467294/shareholdings accessed 14 February 2023

[84] RIS- Pharmacy ownership and licencing. Section 6.2 What are the implementation risks? Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021

Evidence from deregulated pharmacy sectors overseas shows that concerns of "quality shading" are right to be heeded in New Zealand. For example, research into pharmacy deregulation in the UK found that:

> "Pharmacists working most regularly in supermarkets … and multiple pharmacy chains … considered conflicts with commercial interests to be a more significant barrier than their colleagues working within small chains … and independents ….[85]
>
> "This provides an example of the potential conflicts that can arise between operation in a commercial environment and the provision of professional services and adds weight to … criticism that the commercial interests of pharmacists are inconsistent with the altruistic attitude of the service ideal of professions. "[86]
>
> "The results of this study indicate that the provision of pharmacy-based public health services varies based on pharmacy ownership. The decreased levels of provision of certain services in certain types of pharmacy highlights potential conflicts between patient care and commercial interests."[87]

Research on the Swedish experience with deregulation specifically pointed to perceived reductions in pharmacist skills and services:[88]

> "Less positive assessments of the deregulation in Sweden are found in the evaluations of … the Patients Agency, another state authority, which confirmed increased accessibility of pharmacies and other dispensaries but highlighted a deterioration in pharmacy staff skills and information services according patients' perception."

Indeed, a review of the deregulation experience in nine European countries pointed to a loss of professional independence and change of commercial focus as being a major concern in countries with regulated pharmacy sectors:[89]

> "The loss of professional independency in the case of liberalisation of ownership was raised as a major concern by pharmacy representatives from regulated countries. "An increased focus on profit and sales was observed in all countries …"

Evidence from the Canadian experience with deregulation highlighted similar concerns. These study authors defined role conflict as follows:[90]

> "Role conflict items included being required to do things in one's job that are against professional judgment, receiving incompatible requests from 2 or more people, and having to choose between the business and professional aspects of pharmacy."

[85] Bush, J., Langley, C. and K. Wilson, 2009, "The corporatization of community pharmacy: Implications for service provision, the public health function, and pharmacy's claims to professional status in in the United Kingdom", Research in Social and Administrative Pharmacy, 5, 305-318, p. 313.
[86] Bush, J., Langley, C. and K. Wilson, 2009, "The corporatization of community pharmacy: Implications for service provision, the public health function, and pharmacy's claims to professional status in the United Kingdom", Research in Social and Administrative Pharmacy, 5, 305-318, p. 314.
[87] Bush, J., Langley, C. and K. Wilson, 2009, "The corporatization of community pharmacy: Implications for service provision, the public health function, and pharmacy's claims to professional status in the United Kingdom", Research in Social and Administrative Pharmacy, 5, 305-318, p. 313.
[88] Vogler, S., Habimanaa, K. and D. Artsa, 2014, "Does deregulation in community pharmacy impact accessibility of medicines, quality of pharmacy services and costs? Evidence from nine European countries", Health Policy, 117, 311-327, p. 312.
[89] Vogler, S., Habimanaa, K. and D. Artsa, 2014, "Does deregulation in community pharmacy impact accessibility of medicines, quality of pharmacy services and costs? Evidence from nine European countries", Health Policy, 117, 311-327, p. 324.
[90] Perepelkin, J. and R. Dobson 2010, "Influence of ownership type on role orientation, role affinity, and role conflict among community pharmacy managers and owners in Canada", Research in Social and Administrative Pharmacy, 6, 280-292, p. 285.

Likewise, experience from Poland also pointed to an increase in commercial focus and decrease in public health focus (i.e. a possible reduction in service quality):[91]

> "Deregulation of the pharmacy market usually leads to … the emergence of economic pressure to increase pharmacy turnover by selling over-the-counter and non-drug products .
>
> "The rapid development of the pharmacy chains led to a situation in which pharmacies mainly deal with sales. Excluding health promotion … "

This highlights how commercially focused corporate pharmacies overseas can exacerbate quality shading issues in medicines supply.

Which ownership model is most likely to ensure high quality pharmaceutical service delivery and pharmacy ownership?

To reduce the risk of introducing quality shading into the pharmacy to satisfy the business objectives of non-pharmacist owners, and eliminate the tension between a pharmacist making profits and delivering quality healthcare, ICPG believes the best model of pharmacy ownership which will deliver high quality pharmaceutical service delivery is Option 2.[92] This is the option where the pharmacy is directly under the control of a pharmacist.

When the Health Practitioners Competence Assurance (HPCA) Act 2003 was passed, members of parliament noted that pharmacists, as health professionals, are driven by the needs of patients, and open ownership by non-pharmacists risked compromising those standards for the maximisation of revenue.[93] That is still true today.

The issue in Option 3 is not the quality of supply, but the pressure to diminish the quality and variety of the services offered. This is not due to the lack of professionalism of the employee pharmacists in open ownership pharmacies. It is because those pharmacists are in conflict with non-pharmacist owners to pursue different objectives.

2.4 Local Benefit

The Pharmacy Ownership and Licensing Policy RIS [94] rightly states that

> '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.'

[91] Wisniewski, M., Religioni, U. and P. Merks, 2020, "Community Pharmacies in Poland The Journey from a Deregulated to a Strictly Regulated Market", International Journal of Environmental Research and Public Health, 17, 8751, p. 3.
[92] RIS- Pharmacy ownership and licencing. Section A Summary of Preferred Option. Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021. Summary and Proposed approach. Pg 1.
[93] See, for example, (15 October 2002) 603 NZPD (Martin Gallagher, Labour – First Reading of Health Practitioners Competence Assurance Bill).
[94] RIS- Pharmacy ownership and licencing. Section 2.5 What are the objectives sought in relation to the identified problem? Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021

However, it wrongly draws the conclusion that open ownership [95]

> '…would best enable some of the innovative patient care models envisaged in the Bill to be implemented.'

The most innovative patient care models envisaged in the Therapeutics Products Bill delivered at a local level, are best enabled through the status quo or Option 2.

The current Pharmacy Action Plan[96] 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.

In the Action Plan legislation is sought that[97]

> '…enables innovative pharmacy practice and drives improvement across the sector. '

Only pharmacies with a link between ownership and effective control of pharmacies by pharmacists can do this.

The Pharmacy Action Plan also states that[98]

> 'Demands on health care are changing, as long-term conditions such as diabetes, cardiovascular disease, cancer, asthma, arthritis, mental ill health and musculoskeletal conditions are becoming increasingly significant. Because New Zealanders are living longer, they are more likely to spend some of their later years with one or more long-term conditions. This trend has the potential to worsen their health and wellbeing, as well as placing additional demands on our health and disability system.
>
> Because pharmacists are accessible to many New Zealanders and have relevant professional knowledge, they can benefit health promotion and prevention services for individuals and/or populations by improving each person's understanding of medicines and contributing to public health programmes and/or targets. Population-based initiatives help people live healthy and productive lives, achieve education and employment goals and reduce the impact of long-term conditions.'

Pharmacies effectively controlled by pharmacists, and the pharmacists that work in them are embedded in their communities. They have often built-up decades of trust with patients. They are also very aware of the health issues affecting their area.

Te Whatu Ora | Health New Zealand districts, commission local projects through service contracts. This ensures that services are available to meet the needs of local communities. This is working well, although different districts have different means of commissioning.[99]

[95] RIS- Pharmacy ownership and licencing. Section 3.1 What options are available to address the problem? Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021
[96] Ministry of Health. 2016. Pharmacy Action Plan 2016 to 2020. Wellington: Ministry of Health.
[97] Ministry of Health. 2016. Pharmacy Action Plan 2016 to 2020. Wellington: Ministry of Health. Tool 4:Regulation, p.31
[98] Ministry of Health. 2016. Pharmacy Action Plan 2016 to 2020. Wellington: Ministry of Health. Focus Area 1: Population and Personal Health, p.11
[99] Waikato district commissions via MidCentral Pharmacy Group. Hutt Valley district commissions directly to pharmacies.

Local needs give rise to local solutions. Examples of solutions bring local benefit from pharmacies in the ICPG which fulfil this aspect of the Pharmacy Action Plan are:[100]

- Talking to every pregnant patient about the importance of whooping cough vaccinations. An ICPG pharmacy found a lot of expectant mothers had not been told about the importance of these vaccinations by their midwife. After talking to women, and taking advantage of changes in government policy, whooping cough vaccinations are now given in the pharmacy.
- An ICPG pharmacy noticed that mental health patients in their area were falling through the cracks. Home visits to mental health patients who are struggling were initiated. Time was made available to help with the issues patients were struggling with – referral to housing services, food assistance, WINZ assistance, social engagement.
- In one area, the owner pharmacist wanted to proactively encourage conversations about health, rather than waiting for people to come into the pharmacy. Outreach pharmacists went into community talking to community support groups about managing conditions – Parkinsons, Asthma, COPD, Diabetes, Arthritis. The outreach then expanded to schools, sports clubs, and service groups. This became an important part of the pharmacy's strategy to promote community wide uptake of the Covid-19 vaccine.
- An ICPG pharmacy in a medium-sized rural town initiated after hours, weekend and public holiday care to their local community. The drive to offer after hours care was a direct result of assessing the needs of their community. It involved collaboration with local prescribers.
- A suburban ICPG pharmacist was concerned about the wait time for GP appointments in their area. A lot of children were coming to the pharmacy with ear infections and no way of seeing a doctor in a timely manner. The pharmacist undertook extra training, and now her local GPs will take her referral for antibiotic prescriptions to treat ear infections.

As in the last example, many of these initiatives are followed up with referrals to other health and social providers in the area. These referrals are only possible because of good relationships.

The Heather Simpson report[101] highlighted a need for greater integration, with a recommendation for better connection between community healthcare services. This connection, or integration, is not the same as co-location with other health practitioners. Innovations that join pharmacy services with other local providers come out of the relationships built between these providers at a grass roots level.

The best examples can be seen in pharmacies where a pharmacist owner with effective control has prioritised the relationships which are required for innovation to flourish. The result is better integration with primary care teams and alignment of resourcing and

[100] References are available on request to icpg2021inc@gmail.com
[101] Health and Disability System Review. 2020. Health and Disability System Review – Final Report – Pūrongo Whakamutunga. Wellington: HDSR.

patient outcome goals. Indeed, if such key relationships are not present, innovations in integrated models of care would be impeded.

Examples of integration which result in local benefit from ICPG member pharmacies are:[102]

- A provincial member has a partnership with the local hospice. This has resulted in services such as medication reconciliation on admission and patient education on discharge. Due to more hospice patients being managed in the community, medicine education has become crucially important and very complex.
- A rural ICPG pharmacist liaises with a mobile community district nurse, to help patients in an isolated community one hour's drive from the pharmacy. The district nurse collects medicines on behalf of patients and delivers the medicine directly to the patient. Prescriptions charges are often received late for these medicines. This innovation occurred as courier companies and rural post are no longer reliable, and there is no suitable depot for drop off.
- An ICPG member in the South Island has set up and chairs a Medicine Advisory Committee for a local rest home provider.
- A rural ICPG member now has digital integration with a primary care practice. 'This partnership has allowed the true potential of integrated care to be enjoyed by all parties – patient, prescriber and primary care team, and pharmacist.'

These innovations are often expensive to initiate and do not usually provide the return on investment that the owners of corporate pharmacies require. Similar innovations arising from health needs in communities have not been reported in Pharmacy Today[103] as being delivered by corporate pharmacies.

The many innovations, interventions, and services in independent pharmacies which are often unfunded and unseen by the general public, are what Option 2 would protect and encourage.

<u>Which ownership model is most likely to deliver the most local benefit?</u>

The Pharmacy Ownership and Licensing Policy RIS states that open ownership [104]

> '…would best enable some of the innovative patient care models envisaged in the Bill to be implemented.'

But ICPG believes the most innovative patient care models envisaged in the Therapeutics Products Bill delivered at a local level, are best enabled through the status quo or Option 2.

There is no evidence that separating ownership from providing pharmacy services would support the shift to more tailored commissioning of pharmacy services. Neither would also allow more innovative approaches to service delivery, including to remote or disadvantaged communities.

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[102] References are available on request to icpg2021inc@gmail.com

[103] https://www.pharmacytoday.co.nz News, opinion, jobs and education for pharmacy. Independent news and education for those working in the pharmacy sector. Accessed 25 February 2023

[104] RIS- Pharmacy ownership and licencing. Section 3.1 What options are available to address the problem? Fiona Ryan Manager, Therapeutics System Strategy and Policy Ministry of Health 21 May 2021

The current ownership legislation allows for high quality services that fulfill the needs of local communities.

Corporates cannot provide individualised solutions for individual communities or families. Strategy is determined directly from a head office, not from pharmacists who are in touch with the needs of their communities.

CONCLUSION

Pharmacists are still the health professionals New Zealanders see most often. Pharmacies are found in every city, town and district. No appointments are necessary. Health advice is free.

The pharmacists who own and work in independent pharmacies are highly regarded and trusted members of their communities. They understand local health needs, and work hard to meet those needs. In so doing they improve the health and wellbeing of their communities.

It is the opinion of the ICPG that to maintain and improve the health of New Zealanders through a vibrant innovative community pharmacy sector, pharmacy ownership must be held in the hands of pharmacists. This can only happen with effective control.

The need to safeguard the integrity of the profession and its ability to serve New Zealanders by maintaining the effective control of pharmacies by pharmacists is greater than ever.

In proposing changes to the ownership of pharmacies, the government wants to ensure equitable access to pharmacy services, high quality service, support innovation, and support local benefit.

In all these areas the best outcomes are achieved with pharmacies that are effectively controlled by pharmacists, not through open ownership and corporatisation of the sector:

- To fully address inequity in any community, it is vital that health providers understand local issues and demographics, before any solutions are proffered.[105] Then those solutions, based on evidence, must be formulated in partnership with communities to build on an existing community focus.
- Developing innovative pharmacy services relies on being 'on the ground'. Innovations are not made for the sake of it. They occur because a problem needs to be solved by pharmacists who are embedded in their communities, motivated to meet the needs of those communities, and driven by the ethical responsibilities as a pharmacist.
- The risk of reducing service quality is diminished when pharmacists are in effective control of pharmacies. There is then no conflict between meeting the needs of patients and satisfying the business objectives of non-pharmacist owners.
- Pharmacies effectively controlled by pharmacists, have often built-up decades of trust with patients. They are also very aware of the health issues affecting their area. Because of this, local needs are easily identified, and met with innovative solutions.

Corporately owned pharmacies can only deliver one-size-fits-all solutions. In the ten years corporate pharmacies have been operating in New Zealand the goal has been growth and profit.

[105] https://bpac.org.nz/bpj/2008/may/docs/bpj13_solutions_pages_10-14.pdf accessed 24 February 2023

At its core, the argument for strengthening the link between ownership and effective control is prioritisation. Local pharmacists care. They are invested in and understand our communities. Innovative equitable solutions to local needs are discovered and nurtured in partnership with those communities.

Perhaps this is best summed up from a Google review of an ICPG pharmacy:[106]

> 'A wonderful hardworking team who have a heart for the people they serve. They're all knowledgeable in their own roles, from the back to the front. Their advise [sic] I can trust, because they understand our community. This takes great leadership, thank you.'

There are other issues which need to be addressed in the pharmacy sector, though their resolution is outside the scope of this submission. One is the underfunding of pharmacy services. The second is the haphazard awarding of ICPSA agreements by Te Whatu Ora | Health New Zealand districts.

Resolution of those issues would do more to achieve government aspirations for the sector than opening the ownership to non-pharmacists.

The ICPG would like the opportunity to address the Select Committee on issues raised in this submission.

[106] Google review of Clive's Chemist, Wainuiomata