PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

Submission on the Therapeutic Products Bill

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 2,000 pharmacists, from all sectors of pharmacy practice. We provide to pharmacists professional support and representation, training for continuing professional development, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines.

GENERAL OVERVIEW

The Society supports the development of a new legislative regime for therapeutic products in Aotearoa New Zealand (NZ). We acknowledge the large amount of work undertaken by the Ministry of Health as well as various parts of the sector, to develop the Bill currently before Committee.

The proposed Bill is significantly more enabling than the Medicines Act. The Society supports the core principles of the Bill and the intended direction. In our technical response, we provide detailed comments for consideration by the Committee and Ministry of Health. These are based on feedback from our members including pharmacists working directly with patients and our interpretation of the proposed legislation and its impact on day-to-day pharmacy practice.

The proposed Bill gives significantly more power to the Regulator, which may be appropriate. We are of the opinion that the Regulator's actions and approach must be transparent and open to public accountability.

We are also concerned that a large amount of decision making has moved to the lower instruments, specifically the rules rather than the regulations. This will allow for flexibility in approach, but rules do not currently require the same level of sector engagement when being established. We suggest that the Committee encourage the Regulator to engage with the sector around clear development of the rules to ensure appropriate support, practical applicability, and transparency if the Bill progress through all the stages of the House.

TECHNICAL RESPONSE

Therapeutic Products (Sections 15-24)

Meaning of therapeutic purpose (Section 15, page 28)

This definition includes pregnancy, but ovulation is omitted. Is there a reason for this? Please can this be added?

Activities (Sections 35-58)

Low concentration NHP (Section 31, page 36)

The Society is supportive of the appropriate regulation of Natural Health Products (NHPs). However, we recommend that the term low concentration NHP is reviewed. The definition includes criteria describing more than just the concentration (e.g., origin of the NHP).

Reportable products and critical needs products (Section 34, page 37)

The Society is fully supportive of the concept of reportable and critical needs products and requirements to notify the Regulator regarding potential shortages or cessation of import. This will support continued access for New Zealanders who require ongoing treatment. However, we would like to suggest that this requirement be applied to all products with a New Zealand market authorisation. This will save on resources required to determine if a product meets the requirements to be deemed a reportable product/critical needs product and be clearer to all.

Compound (Section 37, page 39)

The current definition of compounding appears to prevent it from being undertaken in advance of an identified patient as it refers to supply to a specific patient *in response to a request* for that supply. The ability to compound in advance is useful for preparing ward stock in a hospital environment and for paediatric formulations. Other examples would include where it is only possible to undertake compounding at one time of the day,

For items where there is a known constant demand (e.g., omeprazole suspension) a pharmacy should be allowed to compound ahead of an individual request to prevent delayed patient treatment. Good batch preparation records are a routinely part of pharmacy practice and products are not produced for wholesale supply without the appropriate licence.

Responsible manufacturer (Section 42, page 40) and manufacture of medicine (Section 43, page 41)

We note here the confirmation that dispensing is not considered part of the manufacturing process. Dispensing is defined elsewhere in the Bill as bringing a medicine to a state ready for immediate supply to a specific patient

in response to a request for that supply. This definition does not cover pharmacists repacking medicines into smaller quantity for supply as stock to a hospital ward or another pharmacy, so we would like to verify that this practice is covered Section 81 pharmacist: wholesale supply to transfer stock (page 62). Section 81(2) refers to supply to another pharmacist (presumably covering supply to another pharmacy), a health practitioner, or a veterinarian – is a hospital ward covered by this?

Off-label use (Section 49, page 45)

The Society is supportive of this proposed clause.

Pharmacy business and pharmacy activity (Section 50, page 45)

We recognise this legislation is designed to enable flexibility to grant licences and permits for innovative delivery of services in relation to supply of therapeutic products and this necessitates a move away from a single definition of operating a pharmacy. However, the Society questions the need for the word "business" and asks if it could be removed from the Bill. The concept of a business has a financial outcome focus that we feel is inconsistent with the purpose of this legislation i.e., ensuring the quality and safety of therapeutic products in use in NZ. We think that the previous terminology of 'operating a pharmacy' is appropriate and suggest that it remain. If an organisation or individual is undertaking specified controlled activities in relation to medicines, they could still be 'operating a pharmacy' although the new legislation enables a pharmacy to take different forms.

Prescription, complying prescription and prescribe (Section 53(1), page 47)

We appreciated the inclusion of the definition of prescribe in the proposed legislation, as this is not currently defined in the Medicines Act 1981. However, the proposed definition is very broad and will have unintended consequences for the hospital environment where "orders to supply and administer" are used instead of prescriptions. Regulations or Rules that define a "complying prescription" are critical and should not be solely developed in relation to the community setting.

Section 53(6)(b) discusses making a record to set out the rest of the medicine remaining to be supplied. It is not clear why this has been included in the Bill and is quite granular. This does not align with the broad principles approach for development of the Bill. We recommend that this clause is moved to the Regulations level.

Effect of complying standing order (Section 54, page 47)

Please can this definition be changed to include medicines that do not have New Zealand market authorisation? Due to the nature of the NZ supply chain, medicines that do not have an authorisation are often used in practice in a hospital and primary care environment. Ideally, these should be able to be included under a standing order to ensure ongoing patient care is achieved when there are no suitable authorised medicines available.

Wholesale supply and non-wholesale supply (Section 56, page 49)

The Society is supportive of the broad concepts proposed in this clause. However, we would like to verify/confirm that pharmacies are able to sell or supply medicines to health practitioner prescribers under the 'wholesale' category via ordinary pharmacy licence as part of the later section 81 Pharmacist: wholesale supply to transfer stock' (page 62). This form of procurement by health practitioner prescribers is currently enabled under Section 25 of the Medicines Act 1981 and underpins funded 'Practitioner Supply Orders' for emergency situations, teaching and where a prescription is not practicable, and also allows purchase of unfunded medicines for use in their practice.

Section (56)(2)(d) appears to imply that if specialist compounders (e.g., Baxter) are considered manufacturers, then this would mean that a hospital pharmacy could not supply medicines to them for compounding on their behalf. This would cause significant disruption to the supply chain and ultimately patient care. The clause should be reviewed.

Other Terms (Sections 59-66)

Health benefit claim, permitted health benefit claim, and substantiating claims (Section 61, page 52)

The Society understand the need for defining a health benefit claim and having a route for fair and robust regulation of NHPs. However, we are of the view that this high-level clause leaves many aspects of how this will operate in practice unclear which creates uncertainty for the sector especially as the final details and decisions will not be available until the development of the rules, a process which is also not open to the same degree of scrutiny and sector discussion as that for primary legislation and regulations. We find the terminology confusing and difficult to follow. We suggest that this section is reviewed for clarity and the processes for establishment of the rules be required to include further sector engagement.

Special case requirement (Section 65, page 54)

The Society is supportive of this clause but is not clear from the legislation how it links to "off-label (Section 49, page 45). In practice, awareness of the difference between off-label and special case will be important. For this reason, we recommend that the two clauses are linked in some way and/ or the text highlight the difference (an example may help).

Controlled activities and supply chain activities (Sections 69-75)

Controlled activities prohibited unless allowed by licence, permit or subpart 3 (Section 69, page 57)

Section 69(2) should include administering a pharmacy medicine for completeness and protecting those registered health professionals (e.g., nurses) directly caring for patents.

Persons in supply chain must comply with qualifications, training, and competency requirements (Section 73, page 59)

The Society supports the concept of appropriately trained people involved in the supply chain but raises concerns about the use of the term competency, especially in relation to workers without a defined process of certification/competency assurance (such as that in place for registered health practitioners). We understand the intent but consider that clarification is needed on the definition of competency and expectations for how a person would verify competence in this context.

When activities are allowed (Sections 76-116)

Qualified pharmacy worker (Section 82, page 63)

Section 82(2) (page 63) captures the requirements for a pharmacy worker working in a pharmacy business and includes qualification and activities. However, Section 92 (page 67) does not specify the same level of requirements for health practitioners' staff who are supplying medicines. There should be a consistent approach to all activities involving medicine provision across this Bill.

Section 82(3) is an example where the rules are defined, but the Regulator does not need to consult on their development. It gives significant and potentially inappropriate power to the Regulator if they are not held accountable.

Health practitioner: controlled activities (Page 63 to 67)

Section 85(3) states that a health practitioner may only administer a prescription medicine if they are the prescriber for that medicine. We have difficulty seeing how this will work in practice for other health practitioners (e.g., pharmacists, nursing staff) who are not the prescriber but are required to administer the medicine in their role as a registered health practitioner.

The Society supports the approach of clearly defining controlled activities with provision for allowing different groups to undertake certain controlled activities as this provides enhanced clarity for the sector. However, we note that this improved clarity has increased the visibility of dispensing as a controlled activity that could be carried out by all health practitioner prescribers creating potential for the practice to become more widespread.

In certain situations, this activity (prescriber dispensing) is important to facilitate access to medicines (e.g., after hours, rural areas). However, it should be the exception rather than the rule. It may therefore be prudent to set restrictions around a maximum volume that may be dispensed outside a pharmacy licence.

Processes for dispensing medicines should be systematic and covered by 'standard operating procedures' to limit the risk of error and resulting harm, irrespective of location. This is more, not less, important in circumstances of infrequent or 'low volume' activity where lack of familiarity by staff increases the chance of unintended errors with resulting patient harm. There are operational and technical aspects related to safe medicines management and supply that pharmacists and their staff are specifically trained in. There should be provision for any personnel enabled to undertake controlled activities under the proposed legislation (such as dispensing by health practitioners and supply of pharmacy medicines by their staff) to be required to demonstrate the same level of training if that activity is undertaken.

Another aspect to consider is that the separation of prescribing and dispensing provides an important mechanism for additional clinical and safety checks. Avoiding self-checking where possible was advised in a Health and Disability Commission report about medication errors as a way to reduce dispensing errors.

We understand the policy intent to develop a regulatory regime for therapeutic products that is safe and cost-effective. We are concerned that any inconsistencies in relation to those allowed activities could undermine the ability of the regime to provide the necessary assurance that New Zealanders will receive consistently safe provision of medicines regardless of point of contact. All health practitioners allowed to undertake a particular controlled activity (e.g., dispensing) should be governed by the same quality assurance/regulatory processes.

If health practitioners are undertaking the same activities as a pharmacy (e.g., dispensing, non-wholesale supply, medical devices, and wholesale supply) they should also be licensed and regulated using the same tools as a pharmacy undertaking these tasks. If this is not possible then the regulatory aspects applied to a pharmacy delivering these activities should be reviewed.

The safety and quality of medicines management is not location specific. It does not matter whether insulin is stored in a licensed pharmacy premises or a doctors' surgery, if the cold chain is broken because of a poorly maintained fridge, then doses taken from the vial will not be of the appropriate quality and diabetic control will be affected. All areas where medication is stored and from where supplies are made should be expected to conform to the same standards and be auditable according to the same criteria. As a member of the public, we would expect the same standards from any health professional providing similar aspects of care.

A prescriber may dispense a medicine that has been stored in the boot of their car for many weeks over summer. This is clearly wrong, but only a pharmacist could be penalised under the proposed Bill. This may be in the existing legislation, but there is opportunity now to address this rather than perpetuate the problem.

Permitting any health practitioner to prescribe medicines (either from a restricted list or within a defined scope of practice) at present could perpetuate problems of fragmented care as there is currently no shared record of

supply of prescription medicines that can be seen by all other potential prescribers. This creates the risk of duplicated therapy or drug interactions with resulting adverse effects for the patient. We recommend this risk be addressed in the regulations and/or rules with requirements related to documenting supply in the planned future national electronic health record.

In practice, Sections 83, 84, 85 and 86 will potentially run the risk of 'cherry picking' of services being provided to patients. This needs to be mitigated in the future regulations and rules.

Health practitioner's staff: non-wholesale supply (Section 92, page 67)

Recognising the benefits of timely access to medicines, we are supportive of the proposed authorisations for health practitioners' staff in relation to pharmacy medicines. However, requirements for this supply must provide the same safeguards as those available in a pharmacy environment, such the overall supervision by, and ready access to, a registered health professional.

In relation to health practitioner's staff supplying pharmacy medicines, Section 92(3)(c)(ii) uses the terminology "general supervision". This is very vague and open to significant interpretation. A definition would ensure consistency of approach for all staff involved in the process.

From a wider perspective the ability of health professionals to recommend and supply medicines in line with their health care models would seem to provide a positive resource for patients and potentially save the costs of visits to the doctor etc. Allowing health practitioners to supply pharmacy medicines may provide convenience for patients but there is a risk of harm from increased medicines in circulation.

Personal or carer importing medicines for personal use (Section 105, page 72)

Section 105(6)(a) lists all classes medicines are available for personal importation, except prescription medicines. We recommend that pharmacist medicines are also excluded. These medicines have been placed in this category with the intent that treatment will be provided after consultation with a pharmacist. They should not be imported through this route.

In practice, under the Section 105(6)(a) dextromethorphan, which has been restricted due to misuse could be imported with no issues at all. Also, importation of the emergency contraceptive pill could result in repeat use with no discussion with health professionals about other more appropriate contraception, or potential for sexually transmitted infections. We suggest that this clause is reviewed to prevent unintentional harm through the potential to import pharmacist medicines.

Section 106 refers to a person importing "a" medical device – does this mean that only one medical device may be imported at a time, or does there need to be some form of quantity and/or period of time restriction for medical devices as there is for medicines?

In practice, personal importation must be discouraged. Under the proposed legislation there will be no controls in place to prevent the personal importation of counterfeit products and substances of abuse that are classified

as "non-prescription" medicines in NZ. Patient safety is paramount and NZ residents should be able to access the medicines they require within NZ.

Emergency arrangements (Section 116, page 78)

The Society support the concept of an emergency arrangement notice. However, we would like to recommend that an expiry clause requiring review at a regular interval is included under Section 116(6) to ensure appropriate review and transparency.

Market Authorisations (Sections 117-150)

Sponsor must have surveillance and response system (Section 142, page 92)

The Society is supportive of this requirement. However, we would like to suggest that it is also linked to the Regulator's requirement to have a post-market surveillance and response system (Section 203, page 117) to ensure effective collaboration and communications between all parties.

Sponsor of reportable product must notify the Regulator of likely shortage (Section 145, page 94)

The Society is supportive of this clause but would suggest that it includes all medicines, not just those currently determined as a reportable product, to ensure consistent access across the whole supply chain. Currently, over 600 medicines are used by patients in NZ without a market authorisation due to lack of suitable approved products or supply issues of approved products. We therefore recommend medicines without market authorisation are also captured under this clause if they are being used regularly to treat New Zealanders.

Licenses (Sections 151-159)

What licence may allow (Section 151, page 96)

Section 151(2) states that "a licence may also authorise the licensees to do anything else specified in the licence that would otherwise contravene a provision of this Act." Our interpretation of this Section is that it enables the Regulator to allow a person (via provision of a licence) to undertake anything specified in the licence even if it contravenes the Act. We are concerned about how this will be managed to ensure transparency inappropriate governance. We recommend that a contingency or accountability clause is added.

Content of licence (Section 152, page 96)

The example given for Section 152 on page 97 includes the word 'shop.' We recommend this be replaced with the word 'premise.' A pharmacy is a location of health service provision which the word "shop" does not suitably reflect.

In practice, applying for a license for the separate services that a given pharmacy would provide would allow some practitioners to 'cherry pick' services which would not be in the interests of the public (e.g., if they didn't want to do any compounding, they wouldn't apply for this service on their licence). On the other hand, we can see some benefit in having this possibility (e.g., a pharmacy that is not open to the public that provides clinical trials supplies). We suggest that this is managed in the regulations in a way that ensures that the public is not disadvantaged.

Effect of pharmacy licence: additional provisions (Section 154, page 98)

The Society is supportive of the flexible approach proposed for the granting of licences and permits. Given the range of options enabled by this legislation, a high degree of transparency around the granting of licences and permits will be important to ensure confidence in the governance and consistency of regulatory processes. Some form of publicly visible online database or register for all permits and licences may be beneficial in achieving this.

Under the proposed legislation, when undertaking controlled activities such as dispensing, pharmacists (working in a pharmacy) are required to obtain a licence (or permit) and comply with the associated regulatory processes. However, when the same activities are undertaken by a health practitioner, there is no such requirement to secure a licence and meet the requirements of that licence. There is a risk that variation in requirements will result in different standards and introduce potential for inconsistency in safe provision of medicines. The Society considers that standards or requirements and their monitoring should be consistent for all controlled activities.

We are more than happy to work with the Ministry to achieve regulatory process surrounding controlled activities in relation to medicines and licence and permit requirements that are consistent and work in practice for patients and practitioners across the health sector.

Criteria for granting licence (Section 158, page 100)

Section 158(1)(c) states "relevant resources are adequate and suitable". The definition of "adequate and suitable" is required to ensure consistency.

Criteria for responsible person (Section 159, page 101)

The Society supports the concept of a responsible person but raises concerns about the use of the term competency, especially in relation to workers without a defined process of certification/ competency assurance (such as that in place for registered health practitioners). We understand the intent but consider that clarification is needed on the definition of competency and expectations for how a responsible person would verify competence in this context.

Permits (Section 160-165)

What permit may permit (Section 160, page 101)

Section 160(1)(d) states that "a permit may also authorise the licences to do anything else specified in the licence that would otherwise contravene a provision of this Act". Similar to section 150 regarding licences, we are concerned about how this will be managed to ensure transparency and governance, and prevent inappropriate regulation. We ask that this be addressed and clarified.

Criteria for granting permit (Section 165, page 103)

Section 165(h) states "any other criteria specified in the rules". In practice, under the proposed legislation we are not clear how the rules can be allowed to override the Act and recommend more appropriate transparency around when a permit may be granted.

In practice, the permit process would support flexibility if the pharmacy team were providing medicines at festivals or other areas where patients are difficult to reach, and therapy is beneficial. It would also be useful for short term needs such as emergency situations like natural disasters, pandemics, and attacks.

Other examples include mobile pharmacy services, such as an educational mobile service, a mobile point of care service to measure blood pressure, measure uric acid level and ascertain when to start allopurinol or do throat swabs.

There are some concerns from the pharmacy sector that the provision of a permit could potentially be applied as a permanent solution to bypass the restrictions on pharmacies. Appropriate transparency around their use and application is required.

Obligations of licensees, permit holders and responsible persons (179-186)

Licence or permit holder must ensure health practitioners or veterinarian has authority and resources (Section 180, page 109)

The Society supports the proposal that a licensee or permit holder must ensure their staff have sufficient authority and resources to act professionally. However, we are not sure if this will work in practice, as the definition of sufficient authority and professionalism is open to interpretation at a personal level.

Licence or permit holder must comply with qualifications, training and competency requirements (Section 182, page 109)

Qualifications and training can be easily established because they are definitive requirements. However, as mentioned in Section 73 and Section 159, we consider that clarification is needed on the definition of

competency and expectations for how a person would verify competence in this context and who would be responsible for that assessment.

Other prohibited conduct (Sections 187-201)

Supply chain activity with tampered-with products (Section 188, page 113)

The Society recommends that the Ministry of Health consider adopting the EU Falsified Medicines Directive for Aotearoa New Zealand, especially in relation to Section 188. The EU directive contains a robust process to reduce the potential risk of fraudulent and subtherapeutic medicines.

Advertisement, communication and distribute (Section 193, page 114)

It would be beneficial if a definition of "promoting" was included in the legislation. Communications and educational material are often developed by health professionals to help patients understand and improve their health literacy in relation to their medicines. We do not want this health professional group to be found in breach of the legislation, and subject to an advertising remediation order (Section 218), due to perceived promotion when education is being undertaken.

Improper inducement to health practitioner or veterinarian (Section 195, page 116)

The Society is supportive of this clause if it is appropriately managed and enforced with transparency.

Post-marketing surveillance and response and compliance monitoring (203-204)

Post-marketing surveillance and response (Section 203, page 117)

The Society is supportive of a post-marketing surveillance and response system. However, we are of the view that it should include all medicines prescribed in NZ and not just those with Regulator market authorisation. Currently a significant number of medicines used in NZ do not have market authorisation (600 at 26/1/23). These medicines may be captured by the wording "or that are otherwise lawfully in the supply chain" but this needs greater clarification. We are also of the view that the Regulator's post-marketing surveillance and response should be closely aligned with the sponsor's surveillance and response system, as mentioned above and referenced in Section 142.

Regulatory Powers (Section 205-213)

The Society is supportive of the powers given to the Regulator, provide a high level of public transparency and sound governance systems are in place. We also highlight that regulation is just one component of ensuring safe effective use of medicines and draw attention to the need for cohesive policy direction and coordination between stakeholders in this area.

Power to require person to give information (Section 206, page 119)

Section 206(1) requires a person to give the Regulator any specified relevant information. Please can the Ministry clarify in the legislation how this aligns with the requirements of the Privacy Act and Code of Rights? Can we assume these rights take precedence over the Therapeutic Products Bill when the request relates to personal information?

Regulatory Orders (Sections 214-235)

Medicines access limitation order (Section 227, page 128)

Medicines Access Limitation Order (Limited access patient) appears to be the drug abuse containment section from the Medicines Act 1981. This is now contained in the proposed legislation in considerable detail. However, we would like to suggest that Sections 226 to 229 be moved to the Regulations and out of the Bill. This will the intent is achieved but also enable future flexibility of approach for individuals who may fall into the classification of an oversupplied person.

Infringement Offences (Sections 276-283)

How infringement notice may be served (Section 282, page 154)

Section 282(1)(b) discusses the serving of documentations to individuals who appear to be at least 14 years of age. We are not sure how this age was determined and how it links across to other statute.

Section 282(2)(a) discusses provision of notice on the 5th working day after it was posted. We are not sure how date was determined and how it link across to other statute? Can the use of "post" be reviewed, considering current and future methods of communication?

Review of Regulator decisions (Sections 357-362)

Application for review of Regulator's decision (Section 357)

Section 357(2)(a) discusses timeframes for applicants. It would be beneficial for the legislation to include a defined timeline for response back from the Regulator, to ensure consistency in requirements for both parties.

Please can the Ministry explain how the legislation will manage any potential unintended consequences where sponsor/pharmaceutical company prolong decisions with high legal costs then associated with appeals to district courts, which could have potential downstream effects of higher medicines expenditure for NZ? This may need addressing in the legislation.

Repeals, revocations and amendments - Medicines Act (Sections 396-422)

Health practitioner prescribers an interest in a pharmacy business

The Society has no concerns with prescribers taking a financial interest in pharmacy providing that the Regulator was confident the associated risks could be managed. We would suggest that the Regulator enable this activity to occur through granting an appropriate licence or permit for all prescribers.

In practice, the restriction of pharmacist prescribers not holding an interest in a pharmacy is inconsistent with pharmacist owners who prescribe funded NRT, emergency contraception and other emerging services.

If pharmacists are going to continue to expand professional services such as funded hay fever treatments for example (to cope with capacity issues in primary care) then the financial interest restriction must be removed.

If it is to remain, then to be consistent, GP prescribers, veterinarians and nurse prescribers must have the same restriction upon them if they are to stock and supply medicines.

Any process needs to be clear and transparent and appropriately regulated to avoid the risk of placing financial interests above ethical/professionalism to ensure public safety and confidence.

Pharmacist majority ownership

The Bill does not propose to make any changes to current pharmacy ownership requirements for a pharmacist to hold a majority shareholding. However, at the time of the first reading in the House of Parliament the Minister of Health invited submitters to Health Select Committee to comment on this issue.

The Society produced a comprehensive review paper and position statement on pharmacy ownership in March 2017 that considered various aspects including international evidence around deregulation of pharmacy ownership, potential effects on the NZ public, community pharmacy, rural pharmacies and communities, pharmacy services, professional practice, quality of care and patient safety.

We support a pharmacy ownership model that retains a requirement for pharmacist ownership. The term pharmacy is synonymous with the professional practice of pharmacists. Pharmacy practice inherently deals with aspects of medicines such as processes for safe manufacture and supply together with clinical aspects such as application of information and evidence to inform the patient-centred care and optimal use of medicines to achieve the best outcomes for patients. Pharmacies are recognised in government policy as a location for the provision of health services such as management of minor ailments and provision of other public health services (e.g., COVID-19 vaccination). Pharmacies in NZ currently have a variety of different models of investment but still have a pharmacist with majority ownership to maintain a professional influence on overall service provision and development as well as quality processes related to medicines supply.

We understand that the therapeutic product legislation is primarily focused manufacture and safe supply of medicines as products. However, separation of these aspects from broader pharmacy practice can be problematic. Pharmacist ownership retains professional governance over areas of pharmacy practice that are not covered by the therapeutic products legislation but are vital to optimal use of medicines and provision of high-quality pharmacy health services as part of primary care.

Enabling legislation as well as continued system investment in current and new pharmacy services is essential to ensure all patients in NZ have access to high quality medicines and pharmacy services. Any pharmacy ownership model should allow for integrated care models to develop that contribute to pharmacists being appropriately positioned to work as part of the multidisciplinary team and use their unique skill set to deliver effective health outcomes for New Zealanders.

While it is possible that allowing majority non-pharmacist ownership could mean greater financial resources were available, there is also a risk that this resource would be focused on products considered profitable rather than provision of health services. This may have a particularly negative impact on rural and small towns where the establishment or continuation of a pharmacy may not be considered a 'good investment' but is needed by the population.

A number of our members have practiced in jurisdictions where pharmacy ownership is deregulated. They describe evident tension between pharmacists as employees and non-healthcare business owners. Providing high quality healthcare is rarely the most cost-efficient practice, and adequate staffing levels that enable professionals to provide such care can be seen as less attractive than approaches that focus on sales targets to boost turnover. Some members expressed concern that commercial pressures such as this would negatively affect patients, public health, and cause moral injury resulting in reduced job satisfaction and poor staff retention in the sector due to the prospect of not being able to provide and tailor services to the meet the patient's needs.