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THERAPEUTIC PRODUCTS BILL SUBMISSION

Pharmacy Council, Te Pou Whakamana Kaimatū o Aotearoa

Executive Summary

1. The Pharmacy Council (Council), a Responsible Authority under the Health Practitioners Competence Assurance Act 2003 (HPCA), welcomes the opportunity to make a submission on the Therapeutic Products Bill (the Bill). We endorse the development of a legislative framework that aims to be future-proofed and flexible, enabling further regulation to manage the innovations and changing health needs of New Zealand's citizens.

2. Council is concerned, however, that the Bill needs enhancements to ensure effective regulation between the new proposed Regulator (of the product and systems), with that of Council (the regulator of pharmacists). The provisions for a new Regulator to manage the supply chain via controlled activities, include activities that fall under health practitioners' scopes of practice. These provisions, rather than the authorisation of products, are Council's focus for this submission.

3. Notably for pharmacy licensing, the substantial interface between the Bill and the HPCA, limits the agility of future regulation of the sector, including Council's ability to hold pharmacists accountable for safe and professional pharmacy services.

4. Whilst the Bill includes new provisions to strengthen the interface between the Regulator and Council, our submission includes recommendations that the Bill should:

    - Address the two-regulator scheme for pharmacy. Pharmacy effectively currently operates with three regulators. The Bill reduces it to two but there are provision implications which will continue to constrain effective regulation in this space given the overlap between systems and people. How the two-regulators will work in practice, given the creation of new obligations and offences is unclear. The responsible person is undefined and critical to accountability under the HPCA.
    - Enhance information sharing provisions. Mandatory information sharing provisions are required to enable the Council and the Regulator to perform their functions properly and efficiently, including receiving timely information relevant to Council's role in monitoring the conduct, competence, and health of pharmacists.
    - Remove ministerial prescribing approval. The prescribing authorisation, as current provisions for secondary legislation (i.e., setting or amending a scope of practice) have adequate checks and balances. Additional ministerial approval is not required. This further provision creates unnecessary delays in getting scopes approved for publication.
    - Ensure adequate funding for the Regulator. The Bill significantly increases the Regulator's functions and obligations and must be adequately funded to fulfil those functions and obligations. This should include recovery of investigation costs to minimise cross-subsidisation.

5. We also recommend amendments to the HPCA to enable Council to take interim action whilst an investigation is in place and to clarify whether investigation can occur concurrently. (Pharmacists who are licensees or responsible persons (or both) may be the subject of investigation and prosecution under the Bill and HPCA in relation to the same conduct).

6. Even with our proposed recommendations we remain concerned that pharmacy practice will continue to be over-regulated, with a two-regulator approach remaining in place. The two-regulator approach is also less effective, due to the need to share information in acknowledging the overlap between systems and practitioners. One Regulator is possible, as we have previously advised, and should be considered for this once-in-a generation opportunity.

- **Diagram: Over Regulation of Pharmacy Practice and Implication of Therapeutic Products Bill proposals**

Proposed Regulatory Framework

Therapeutics Products Bill

- Market authorisation requirements for therapeutic products
- Controlled Activity and supply chain requirements

Further Regulations

Establish Regulator

- Issuing licences, permits and sets Rules

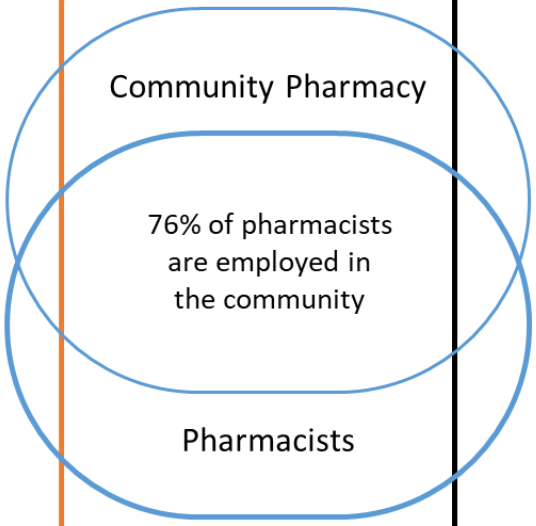
Controlled Activities including

- **Dispensing**
- **Prescribing**
- **Administration**
- **Supply**

Monitor compliance

Investigate and prosecute breaches

Conviction, civil penalties & infringement



Health Practitioners Competence Assurance Act

- Protect the health and safety of the public by ensuring health practitioners are competent and fit to practise

-Pharmacy Council (Established Responsible Authority)

Registration and Annual Recertification

Setting Scopes of Practice, qualifications and professional standards.

Scope of Practices and standards for:

- **Dispensing**
- **Prescribing**
- **Administration**
- **Supply**

Consider complaint and notifications

Investigate Conduct/Review competence

Disciplining of misconduct (HPDT)

Implications & Concerns

Gaps in Regulatory Oversight = Regulatory failure - risk to public safety

Duplication in Regulatory Functions = **Higher Administrative Costs** and greater potential for administrative inefficiency

Needs proactive engagement and information sharing relevant to the other regulator's scope & mandate

Different mandate, expertise, drivers & understanding of information.

Further provisions for responsible persons and licensee- unclear

Overlap in Regulatory Scope
(not addressed in policy analysis or RIS)

Information Sharing

Regulation

Pharmacist as:
- Licensee
- Responsible person

Rules

Quality of regulatory intelligence

Poor Clinical Governance

Incomplete Accountability

Cost to regulated party

Introduction

1. This is the submission of the Pharmacy Council (Council), a responsible authority established under the Health Practitioners Competence Assurance Act 2003 (HPCA). (See also page 14; About the Pharmacy Council). It focuses on addressing the possible ineffectiveness of regulation due to two regulators in pharmacy and proposes enhancements, as a minimum, if the one-regulator option remains unpreferred.

Regulation of Pharmacy Practice

2. The Bill supports multi-disciplinary healthcare delivery by enabling broader access to therapeutic products, which enhances the capacity of the health system. This requires health professionals that maintain and enhance their competencies working within a support system that is adequately and effectively resourced to support the health practitioners.

3. With this enhancement comes the risk of fragmentation of care, requiring mitigation through robust clinical governance and mature patient data-sharing arrangements, e.g., a nationally accessible and shared electronic database, detailing health conditions, medication record, contra-indications, and allergies. The Pharmacy Council encourages a greater urgency to develop these prior to the enactment of the Bill. The Bill establishes a Regulator with a broad remit, requiring the capacity and capability to regulate products and people who manage the supply chain, via controlled activities, many of which are highly technical and specialised. The activities will mostly be carried out by, or under the supervision of health professionals regulated by the HPCA.

4. Health professionals must demonstrate the necessary competencies for these activities and are subject to statutory action under the HPCA if their practice may be a risk of harm to the public. The Bill enables health practitioners and their workers to carry out controlled activities, including dispensing, if this is within their scope of practice.

5. As the previous diagram illustrates, there is a significant overlap between the two pieces of legislation, which could detract from the desired agility and adaptability of the overall regulatory scheme if this is left unaddressed. (See page 8 for an example of the challenges presented by the overlap). Council's submission focusses on ensuring the foundational legislation provides a framework for safe, right-touch regulation[1].

6. Pharmacists working in community pharmacies (3037, 76%)[2] are registered with the Council and working in pharmacies licensed by Medicines Control (licensing authority within Medsafe). The Bill sets out a similar regime for the future. We question what residual risks requires mitigation through a licensing system, that could not be addressed through scope of practice requirements. If dispensing is to be expanded to non-pharmacists, why must pharmacists be subject to competence and licensing requirements, whilst other health practitioners are not?

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[1] Professional Standards Authority, UK, (2015): Right-touch Regulation, includes six principles:

- Proportionate
- Consistent
- Targeted
- Transparent
- Accountable
- Agile

[2] Pharmacy Council, 2022. Primary type of pharmacy practice from Workforce Demographic Report.

Right touch Regulatory principles and relevance to Pharmacy Practice Regulation

7. We are concerned that the proposed Regulator and the overlap with the pharmacist, regulated under the HPCA, has not been considered against international best-practice regulatory principles. As briefly demonstrated below:

Proportionate	Intervene when necessary, and remedy should be appropriate to the risk posed. The Regulator and Council will need clear information sharing arrangements in place to ensure information is sufficient to understand the risk. This requires clarity on which regulator is best placed to address any given risk, and that both regulators are kept informed on ongoing management of risk and new information.
Consistent	Regulation, Rules and Standards should be joined up and implemented fairly. This will require a mature understanding of respective mandates (which is potentially constrained with entities holding different resourcing priorities), active consultation on development of legislative instruments, and ongoing case management meetings.
Targeted	Regulation should be focused on the problem and minimise side effects. Again, this requires good regulatory intelligence to understand the risk, and is reliant on the information sharing provisions.
Transparent	Regulators should be open and keep regulations simple and user friendly. This will be challenging and may require joint communication strategies to keep regulated parties informed about the joint approach to regulation.
Accountable	Regulators must be able to justify decisions and be subject to public scrutiny. There are currently challenges in determining which regulator is responsible for holding a pharmacist accountable for a given risk, e.g., quality management system. For areas of overlap, the regulators must have a robust framework to identify who is accountable.
Agile	Regulation must look forward and be able to adapt to anticipated change. This requires a mature strategic planning relationship between both regulators.

8. The Council's compliance cases demonstrate the public risk from the lack of professional oversight and systems-focus in pharmacies, i.e., clinical governance. This is illustrated by:

    - An example of failure through incomplete processes to identify multiple presentations of fraudulent copies of a prescription in 20 pharmacies, resulting in a medicine of abuse being dispensed inappropriately 61 times in a five-month period. Whilst Council investigated individual pharmacists (37), there was evidence of under-resourcing and poor systems management. The overlap of mandate of two-regulator made it difficult to hold those responsible for the systems failure to account.
    - Dispensing errors reported by the Health and Disability Commissioner indicating systems and resourcing problems as root cause rather than competence.

- Notifications from Medicines Control about pharmacists who are responsible persons on a licence. The information in the notification about a pharmacist's competence or conduct relates to failure to meet audited standards, (Health and disability services Standards - Pharmacy services Standards). Conversely, results from Pharmacy Quality Audits show a low rate of full compliance, with persistent non-compliance rates, including around 20% associated with moderate to critical risk of harm to the public. Despite this level of non-compliance, the number of notifications forwarded to the Council are low. As we do not have easy access to the broader data, we do not have sufficient regulatory information to analyse the level of competence of clinical governance, and what proactive regulation may be required to address the risk to the public.

9. We have concerns that pharmacy practice is over-regulated, and that a two-regulator approach perpetuates an ineffective and inefficient regulatory system for pharmacy practice creating barriers to enforcement and maintenance of quality and potentially leaving risks of harm unaddressed.

10. In Council's submission on the exposure draft of the Bill we indicated a preference for considering a one-regulator solution and encouraged the Ministry to use this once-in-a generation opportunity to examine all options for pharmacy regulation.

Current Regulation of Pharmacy

- Medicines Act 1981 and the Health Practitioners Competence Assurance Act 2003

11. The introduction of the Health Practitioners Competence Assurance Bill 2002 brought all regulated health practitioners under one legislation. The bill included amendments to the Medicines Act 1981, introducing pharmacy licensing requirements for pharmacies and pharmacy ownership.

12. Under the Pharmacy Act 1971, the Pharmaceutical Society of New Zealand (PSNZ) was responsible for regulating pharmacists and pharmacies, and PSNZ submitted that the Pharmacy Council should also licence pharmacies.

13. The Bill maintained pharmacists' control of pharmacies through restrictions on companies operating pharmacies, requiring that pharmacist or pharmacists owns more than 50% of the share capital, and that effective control is vested in that pharmacist or pharmacists. The number of pharmacies a company could hold (or a pharmacist hold more than 50% share capital) increased from one to five. The Health Committee noted '*the concept behind the one pharmacy restriction was that a pharmacist must be in a position to actively oversee that pharmacy. We believe that a pharmacist will be able to actively oversee five pharmacies'.*

14. In practice, these provisions enabled workarounds deviating from the stated intention, resulting in large pharmacy groups emerging, (40+ pharmacy licences) such that the same two or more pharmacists are named on most of the licences for a group. Each licence (issued to a legal entity) names the responsible persons[3].

[3] In relation to a licensee corporation, means an agent or employee of that corporation who is a pharmacist, or a person approved by the licensing authority as a responsible person for the purposes of the licence.

15. The Medicines Act 1981 does not define effective control and there are no provisions to ensure there is effective system-level control and appropriate clinical governance of pharmacy services.

16. In other jurisdictions, pharmacy and pharmacists are regulated by one regulator. This facilitates a regulator response that is proportionate to risk to the public. For example, pharmacy inspectors in the United Kingdom can respond to early signs of unacceptable practice through education and escalate to more formal action if a problem continues to increase. Each pharmacy owner organisation nominates a superintendent pharmacist, such *that the business of the body corporate, limited liability partnership or NHS trust, so far as it concerns the keeping, preparing, dispensing and supplying of medicinal products, other than medicinal products on the general sale list,* is under the superintendent pharmacist's management.

- **Concerns resulting from current regime**

17. Pharmacy Council mostly relies on notifications and complaints to address concerns about pharmacists' competence, conduct or fitness to practise. Complaints about dispensing errors occurring in pharmacies, show a pattern of system-management deficiencies, poor reporting, limited evidence for root-cause analysis, or the organisation learning from the dispensing errors.

18. The Licensing Authority (Medicines Control) conducts audits of pharmacy premises, including standards inspection audits (short and unannounced audit focussing on ten risk-related audit criteria). The standard inspection audits have been in place since 2017, using the same ten standards. The levels of full attainment of audit criteria for quarterly audits have remained stubbornly at a low level of around 40% with around 20% or non-compliance with a criteria risk of moderate, high or critical.

19. A recent research article[4] reports that suboptimal practice within community pharmacies has increased in the last five years. The authors raise concerns about organisational leadership, under-resourced workplaces, work-related stress, and unprofessional practice. Another article[5] on pharmacists' Satisfaction with Work and Working Conditions (73% practising in community pharmacies) reported that work dissatisfaction and psychological distress are high.

20. Council relies on notification from Medicines Control to act on concerns about a pharmacist's competence. We have a Memorandum of Understanding with Medicines Control for sharing information, and this has improved the flow of data between both regulators. Data sharing options between separate organisations, however, are invariably limited because of legal thresholds and differing interpretation of legislation and respective mandates. The threshold for competence notification is relatively low, although in practice, Medicines Control has tended to adopt a more conservative approach than is required by the HPCA.

- **Pharmacy Ownership, licensing regime and effective control**

21. Pharmacy ownership will continue to be based on current legislative requirements, as the new Pharmacy Ownership Act 1981 (clauses 396-422) retains the relevant part of

[4] Wong, L.S.; Ram, S.; Scahill, S. Community Pharmacists' Beliefs about Suboptimal Practice during the Times of COVID-19. *Pharmacy* **2022***, 10, 140*. (Available here*).*

[5] Lam, S.J; Lynd L.D.; Marra, C.A. Pharmacists' Satisfaction with Work and Working Conditions in New Zealand—An Updated Survey and a Comparison to Canada. *Pharmacy* **2023***, 11, 21.* (Available here*).*

the Medicines Act 1981. Therefore, the risks associated with pharmacy ownership and pharmacy activities will continue to be managed through a licensing regime akin to the current regime.

22. A 2022 regulatory impact statement setting out options for pharmacy ownership, confirms that based on decisions made by previous cabinets, other non-licensing options were not included in the analysis, nor consulted on in the exposure draft. The statement does not acknowledge that Pharmacy Council's submission on the exposure draft called for consideration of a single regulator for pharmacy, nor does it recognise the significant overlap between the two current regulators.

23. Future changes to effective control of pharmacies through ownership arrangements may help address the gap in systems management across pharmacies within a group.

24. Some of the detail about the licensing regime will be determined by regulation or set out in Rules created by the Regulator. We do not have full visibility of how the licensing regime will be structured and managed until Regulations and rules have been published.

Therapeutic Products Bill and Pharmacy Council

25. The Therapeutic Products Bill is an important development to regulate therapeutic products, including medicines, medical devices, biological components, and natural products. The Bill also regulates 'the supply chain' through controlled activities.

26. The Bill makes provisions for the Regulator to set qualification, training, and competency requirements for persons in the supply chain who carry out controlled activities or qualifying activities. For pharmacy practice this includes pharmacists who must meet qualifications, training, and competencies to register in the pharmacist scope of practice.

27. The Bill sets out a similar regime for the future, and there are further requirements in place for a 'responsible person' and for licensees. For pharmacy licences, we expect all responsible persons and most licensees to be pharmacists, at least initially. Pharmacy Council will want to be sure that pharmacists in these roles meet their professional obligations and deliver safe professional pharmacy services, not letting business interests compromise the standards expected.

- Obligations for Licensees and Responsible Person

28. The Bill sets out obligations for licensees and responsible persons which strengthen the current provisions.

29. Licensees must ensure there are sufficient resources in place for each pharmacy, that the pharmacy operates safely and does not interfere with professional obligations; (clauses 179 and 180). The Bill creates specific offences for failing to comply with these obligations. We welcome these additions to the regulatory regime.

30. Licensees must also ensure that pharmacy activities are carried out by a pharmacist, or a pharmacy worker under the supervision of a pharmacist, (clause 186). A licensee may be too far removed from day-to-day operation, and this responsibility should sit with the responsible pharmacist.

31. The responsible person has responsibility for the day-to-day operation of a pharmacy, must comply with rules (set by the future regulator), including rules about quality control and assurance requirements and oversight of the day-to-day operation of the activities of the licensee. The responsible person must meet any qualification, training, and competency requirement in the regulations.

Example of practical implications of overlapping regulatory responsibilities: - Dispensing

The Bill includes the following definition for Dispensing (clause 38 (1)): *To dispense a medicine means to bring it to a state ready for immediate supply to a specific patient in response to a request for that supply.*

The Competence Standards for the Pharmacy Profession describes the expectation for pharmacists when dispensing medicines. In addition to supplying the medicine as prescribed, pharmacists are trained and expected (amongst other requirements) to assess the prescription to ensure it is pharmaceutically and therapeutically appropriate, review available patient medical history and medication record, determine whether changes are warranted and advice the prescriber accordingly. Further obligations for counselling individuals on the medicine prescribed, improve compliance with medicines, and provide a further opportunity to validate the safety and appropriateness of the medicine for the individual.

Medication error is the attributed cause of an estimated 2,247 deaths per year in New Zealand. It is also reported in a study that medication-related events prolonged hospital admissions by a mean of 7.8 days; that 43.9% of cases were preventable; and 12.3% resulted in permanent disability or death.

In a report by the Health and Disability Commissioner about medication error complaints, the proportion of errors attributed to different stages of the medication process were, Prescribing, 33%; Dispensing, 39%; and Administration, 28%.

Pharmacists are responsible for more than a per functionary supply of medicine but must ensure safe dispensing processes and identify prescribing errors (improvable with better access to health information) or address unsuitable prescribing. The pharmacy must be well resourced and have robust processes to deliver professional pharmacy services. The individual responsible for the pharmacy must be accountable. The overlapping regulatory responsibilities makes this challenging.

- ## Therapeutic Products Regulator

32. The Bill establishes an independent, self-funded Regulator with a wide remit. We note the Bill (e.g., clause 7) should recognise the relationship between the Regulator and Responsible Authorities (RA) and especially Pharmacy Council given the unique nature of the dual regulator model. The Bill should allow Council to have greater input in relation to Regulations and Rules, including consultation rights in relation to their drafting.

33. Setting competencies for regulated health professionals falls under RAs mandate, and it is unclear how the potential overlap will be managed. The Regulator may set qualification, training, and competency requirements, (e.g., clause 182). Whilst this provision may be appropriate for unregulated workers, the Regulator should defer to the RA for regulated health professionals.

34. The Bill does not specify that the responsible person must be a pharmacist, but must meet any qualification, training, and competency requirement in the regulations. We are unclear how a non-pharmacist responsible person would be able to oversee day-to-day clinical governance of a pharmacy, or a group of pharmacies, properly and effectively. Whilst further regulations may require a responsible person to be a pharmacist for a pharmacy licence, we consider that pharmacists must be the responsible person on a pharmacy licence to ensure effective control of professional pharmacy services, and to avoid future ambiguity this should be stipulated in the primary legislation.

- ## Monitoring Compliance

35. The Regulator must have in place a system for monitoring compliance (clause 204) by licensees and responsible pharmacists. To manage the overlap with Council's mandate and facilitate Council exercising its powers, we recommend further guidance for the Regulator to document behaviour that relates to questions about competence or conduct of pharmacists with these responsibilities. There is a risk that the involvement of two regulators will not adequately address risk of harm to the public arising from pharmacy services, as each regulator has differing focus, expertise, and mandate.

36. Similarly, we consider that a decision by the Regulator to suspend or cancel a licence (clauses 169-176) is very relevant to Council's mandate and further clarification is needed in the legislation to require the Regulator to inform Council of such decisions.

37. Clause 180 prohibits conduct by a licensee that induces a practitioner to act unprofessionally. It is not clear whether Council and the Regulator can, or should, undertake concurrent investigations and in what circumstances information about investigations should be shared between Council and the Regulator.

38. We would appreciate greater clarity on regulatory boundaries to ensure poor practice or misconduct is not missed by either or both regulators.

- ## Information sharing provisions (Clauses 343-345)

39. The key information sharing provision states that the Regulator may give 'a regulatory entity' (includes Pharmacy Council) any information that it holds, (relating to its function or exercise of powers), that may assist the entity in performing its functions or exercising its power. Likewise, the entity can share information with the Regulator.

40. These further provisions enable a greater flow of information between the Regulator and Pharmacy Council, but we note the following qualifiers:

- Regulator can exercise discretion in deciding whether to share the information and provide information subject to condition, e.g., restrict Council's use of the information. We are concerned that a Regulator focussed on breaches of rules will not appreciate that questions about a pharmacist's competence or conduct may arise from collated information, and that reliance on a threshold (legislative or subjective) reduces the flow of relevant information between the two regulators.

- There is no timeframe provision for disclosing information, which may impact on Council's ability to mitigate associated risks.

41. We are concerned with the discretionary powers given in relation to activities that indicate that a health practitioner may be contributing to a risk of serious harm, and that the Regulator may frustrate Council's ability to take interim action to mitigate the risks. The Bill must therefore contain mandatory information sharing provisions to enable the Council and the Regulator to perform their functions properly and efficiently, including timely information relevant to Council's role in monitoring the conduct, competence, and health of pharmacists.

42. There will be non-compliance activity that may not reach the threshold of a breach of legislation but is relevant to consideration of the registrant's professional competence or conduct. This requires a low threshold for sharing information (e.g., from monitoring) with the Council to optimise regulatory intelligence that enables the Council and Regulator to manage the risk effectively and efficiently.

43. The Bill also includes information sharing provisions for notifications of convictions and civil penalties, but not infringements (Part 8, subpart 5). The Council is also likely to be interested in being notified of infringement offences, as whilst these are likely to arise from low level non-compliance, repeated infringements could point to concerns relating to a pharmacist's practice.

44. In the absence of a single regulator approach, it is vital that the threshold for sharing of information relevant to pharmacy practice is kept low. These further provisions have the potential to improve the quality of regulatory intelligence, but we note that their application is subject to the Regulator interpretation of information that is pertinent to Council and could be strengthened further by addressing the above qualifiers.

Enabling prescribing via the scope of practice (Clauses 386-395)

45. The Bill amends the HPCA to include provisions for prescribing to be authorised via the scope of practice. We welcome the flexibility afforded for Responsible Authorities (RA) to set and modify prescribing rights. However, the amendment includes giving the Minister further power to overrule the changes proposed. We question the need for further requirements over and above the current checks and balances that are consistent with established mechanisms for secondary legislation.

46. The Council's development of the pharmacist prescribers scope required parallel work at the Ministry of Health on regulation for designated[6] prescribing rights, and consultation on the list of medicines associated with the regulation. Medicines Regulation sits with the Ministry of Health although this was updated recently through Council's joint work with the Ministry. The multiple agency responsibility for prescribing has created confusion and it has been unclear who is responsible for updating the list.

47. The new regime removes authorised and designated prescriber categories, enabling RA, through changes to the HPCA, to list the medicines (or group of medicines) that a practitioner with that scope can prescribe. In the United Kingdom, 22.3% of registered pharmacists are qualified to prescribe[7] medicines, compared to 1.2% of New Zealand practising pharmacists. We therefore welcome any changes that can help increase the number of pharmacist prescribers in New Zealand.

48. The Bill includes a further clause however, requiring the scope to comply with any requirements relating to the form and content of the prescribing provisions prescribed by the regulations; and the Minister has approved the prescribing provisions. There is also a provision for the Minister to delegate this power to the Regulator. Is it realistic that the Regulator will also have the necessary capacity and capability to effectively consider applications for prescribing?

49. We note that ordinarily, an RA must consult with persons who represent the views of health practitioners and with organisations that will be affected, or whose members, will be affected by the proposal (Section 14 of HPCA, paraphrased).

50. It is unclear why further measures are included requiring Ministerial authorisation when the RA sets the requirements for prescribing and the list of medication. We consider that the safeguards for secondary legislation (i.e., setting a scope of practice) should be adequate as the Regulator and the Ministry can actively engage in the consultation process, especially if there are concerns. If an RA fails to heed reasonable concerns and cannot be persuaded to withdraw or amend the proposed scope, the Legislation Act 2019 enables the House to disallow secondary legislation.

51. We support the Regulator (in consultation with key experts with the necessary skills and competencies) setting provisions to support safe and consistent prescribing across health practitioners. However, the further power given to the Minister has the potential to cause inefficiencies, uncertainties and delays to the greater flexibility introduced by empowering RA to set prescribing requirements. There is also risk of political influence being used to disrupt an otherwise transparent process.

Investigations and Cost recovery

52. Pharmacists who are licensees or responsible persons (or both) may be the subject of investigation and prosecution under the Bill and HPCA in relation to the same conduct. We recommend amendments to section 69 of the HPCA to enable Council to take interim action whilst an investigation is in place and further amendments to the HPCA to clarify whether investigation can occur concurrently, or whether either the Regulator

[6] Designated prescribing rights- rights to prescribe medicines listed as per relevant Medicines Regulations. This similar process first enabled Nurse Practitioners to prescribe but are now authorised prescribers.
[7] Legally authorised to issue prescription for medicines, including prescription-only medicines. (This differs from 'over the counter prescribing' by pharmacist of pharmacist only medicines, which do not include issuing a prescription).

or Council should refrain from taking any action until the other has completed its investigation.

53. This amendment will allow the Council to take interim action based on information disclosed by the Regulator as part of its investigation before it can refer the conduct to a Professional Conduct Committee for investigation under the HPCA.

54. More broadly, the investigation and prosecution of breaches of therapeutic legislation may also be related to unprofessional conduct, that should be investigated by a Professional Conduct Committee.

55. The Regulator must be adequately funded. The Bill significantly increases the Regulator's functions and obligations, and the Government will need to fund any shortfall in cost-recovery to ensure the Regulator is able to fulfil those functions and obligations.

56. The cost recovery mechanisms are relevant to ensuring that the Regulator investigates and prosecutes serious breaches, and so that further professional conduct proceedings costs are kept to a minimum. We note that unlike the HPCA there is no provision for the Regulator to recover costs for investigation. The Regulator will need to set out the fees and levies for different activities and can recover costs *from the user or beneficiaries of the function or power* such that it will not be subsidised by other activities. It follows that the costs of successful prosecution and the prior investigation should be apportioned to the party in breach of the legislation.

About the Pharmacy Council

The Pharmacy Council (Council) is a Responsible Authority established under the Health Practitioners Competence Assurance Act 2003 (HPCA).

The Pharmacy Council regulates pharmacist practice by setting scopes of practice, qualification requirements, competence standards and ethical standards (Code of Ethics), and recertification requirements. The Council has three scopes of practice: pharmacist, intern pharmacist and pharmacist prescriber.

The pharmacist's scope of practice includes:

- the custody, preparation and dispensing of medicines and pharmaceutical products,
- the selection and provision of non-prescription medicine therapies and therapeutic aids,
- administration of medicines, including injectable medicines,
- manufacturing.

New graduates register in the intern pharmacist scope to work under supervision and prepare to register in the pharmacist's scope.

The Pharmacist Prescribers' scope is an additional scope for pharmacists with specialised clinical, pharmacological and pharmaceutical knowledge, skills and understanding relevant to their area of practice, who have completed further training to gain prescribing rights. These pharmacists work in a collaborative health team environment with other health professionals.

The Council's Strategic Plan has two key objectives:

- Minimise the risk of harm to the public from pharmacists' practice, and
- Maximise pharmacists' competence and fitness to practise.

We aim to achieve these by:

- ***Understanding***: Use available data to better understand risk and inform the proactive steps required to address risk and enhance pharmacists' competence.
- ***Using Proactive Regulatory Tools*** including setting new standards, scopes of practice, statements to manage risk, and setting qualifications, education programmes, recertification requirements to assure pharmacists' competence.
- ***Using Reactive Regulatory Tools*** to quantify and manage the risks of a pharmacist's practice evident from a notification or complaint and remedy competence deficits where applicable.