pharmacycouncil
Te Pou Whakamana Kaimatu o Aotearoa

SUBMISSION FOR THE PROPOSED THERAPEUTIC PRODUCTS REGULATORY SCHEME

Introduction

1. A once-in-a-generation change to a regulatory system, especially in the New Zealand health system, is an awesome responsibility and opportunity. The Pharmacy Council (the Council) appreciates and welcomes the opportunity to provide this submission to help the Ministry of Health finalise its proposals for the Government. The Council is conscious of:

    a. The sensitive and sensible way the Ministry has chosen to ensure effective stakeholder inputs into the process by developing the draft Therapeutic Products Bill (TPB) and the draft Therapeutic Products Regulatory Scheme (TPRS) as a first stage of the process; and that

    b. The Ministry is making it clear that its ideas are not set in stone, and that stakeholders have a role in shaping the final project outcomes.

2. The Council's submission on the TPRS and the TPB is based on three basic premises. They are:

    a. Patient safety is the primary focus, and it is through that lens that the Council makes its comments and recommendations;

    b. Pharmacists are health professionals who ensure safe and quality use of medicines and optimise health outcomes by contributing to patient assessment via the selection, prescribing, monitoring and evaluation of medicines; and

    c. The control by, and supervision of, a pharmacist is essential and non-negotiable for all controlled pharmacy operations.

3. As defined in the Health Practitioners Competence Assurance Act 2003 (HPCA), the Pharmacy Council exists to support the purpose of the Act i.e. the protection of the health and safety of members of the public through the provision of mechanisms ensuring that health practitioners are competent and fit to practice.

4. To achieve that outcome the Act:

    a. Provides a consistent accountability regime for health practitioners;

    b. Sets scopes of practices for health practitioners;

    c. Ensures that health practitioners do not practice outside their scopes of practice; and

    d. Is empowered to restrict specified activities of health practitioners to protect the public from the risk of serious or permanent harm.

Pharmacy Council's Position

5. The Council appreciates the Ministry's intention to set up a future proofed regulatory scheme, and the Council endorses:

   a. The application of innovative models of care for patient needs;

   b. The establishment of a regulator to control the manufacture, distribution, supply, prescribing, and dispensing of medicines and medical devices;

   c. Establishing an effective infringement and punishment system;

   d. Recognition of communication technology advances to enable consultation between pharmacists and inhabitants of remote areas;

   e. Regulation of cell and tissue products, medical devices, and radioactive medicines;

   f. Regulation of parallel imports;

   g. Regulating vending machines;

   h. The content of Part 5 – Sub-Part 3 as it ensures a robust supply chain and improves patient safety;

   i. The content of Part 5 – Sub-Part 4 as it recognises the importance of protecting active ingredient information;

   j. The increased flexibility in pharmacy licensing;

   k. The ability to apply for a permit to authorise controlled activities or the supply of unapproved products during emergencies;

   l. The inclusion of a review panel provision; and

   m. Information sharing between regulators.

6. However, the Council considers there are issues with the proposed TPRS and the TPB which this submission will discuss. They include:

   a. The expansive powers and undefined form of the proposed regulator;

   b. The operation of the proposed regulatory system which does not retain, upfront, the importance of professionalism and ethical behaviour as a primary principle:

   c. The potential for ambiguity of regulation, particularly in areas of conflict and overlap with the HPCA's purpose and processes for ensuring patient safety;

   d. Options for effective control of pharmacy activities;

e. The expansion of the scope of practice of health practitioners and their staff without adequate oversight, operating standards, and other safeguards;

f. Proposed definition and categorisation of “dispensing”, “manufacture” and “preparing for administration” with the potential to increase risks to patient safety;

g. The proposed mechanism for tightening the requirements for prescribing and supply of unapproved medicines;

h. Inconsistencies in regulation of health practitioners and relative overregulation of the pharmacy sector compared to other classes of health practitioners; and

i. The absence of a national integrated patient healthcare database which is an interdependency for the safe implementation of the TPRS.

7. The Council is concerned that a national integrated health information database, readily accessible and contributed to, by all health practitioners, is critical to the achievement of the TPRS objectives. The Council has not heard with certainty that this will occur before the implementation of the TPRS and therefore raise our concern that the fundamental principle of patient safety is likely to be adversely affected by provisions currently proposed in the draft TPB.

Structure of the Submission

8. The submission is in two parts. The first discusses a range of general observations and policy positions on the overall TPRS and the TPB and the second responds to the questions posed in the TPRS Consultation Document.

9. To aid the Ministry’s analysis the comments and observations are, in the main, standalone statements.

Part One – General Observations

Enabling Innovative and Futureproofed Regulatory Scheme through a Principled Approach and a Dedicated regulatory entity

10. The proposed TPRS and the TPB aim to empower a regulator and create a regulatory system to control the manufacture, distribution, supply, prescribing, and dispensing of medicines and medical devices.

11. The Council supports the main themes of this approach, but it has reservations about elements of the overall proposal which it considers inconsistent with the importance of patient safety and risks the outcomes of quality for patients and other health system stakeholders.

12. The TPRS also licenses and widens the current scopes of practice of health practitioners and increases access of medicine to non-health practitioners by enabling them to engage in actions which the Council believes breaches the patient safety purpose of the HPCA.

13. It does so by not ensuring consistent standards and accountability apply to health practitioners and through inadequate oversight provisions by enabling health practitioners and others under their control/supervision, or similar, to engage in potentially unsafe practices. It thus places patients at risk of serious or permanent harm through the ability to supply pharmacy medicines (Category 3) without effective safeguards.

14. Clause 4 of the TPB sets out the 'Principles guiding exercise of powers under this Act', and Part 5 of the TPB sets out licensing parameters and conditions. The Council is concerned to note that the TPB does not carry over the requirement of compliance with professional and ethical standards of pharmacy practice set out in Section 55C of the Medicines Act 1981.

15. In that section, pharmacy license holders cannot ask or make pharmacists act in a way inconsistent with the applicable professional or ethical standards of pharmacy practice. However, the TPB proposes to empower health practitioners and their staff to supply prescription medicines and supply pharmacy medicines and medical services without the safeguards within the current system, creating a two-tier approach and an inconsistent system which compromises patient safety.

16. The TPB proposes to amend the HPCA, but the Council considers that an enhanced amendment enabling full regulation of health practitioner staff/technicians via the HPCA makes for a more effective vehicle for regulating health practitioner staff and technicians rather than the TPB and its regulatory instruments. This approach would have three outcomes:

    a. A clear distinction between clinical and non-clinical activities i.e. the clinical decision making required to prescribe and supply medicines, and non-clinical activities such as manufacturing and delivery of medicines and medical devices to health practitioners;

b. The HPCA would govern the ethical foundation for safe prescribing and the supply of medicines and medical devices by health professionals within health practitioner scopes of practice;

c. The future TPB would focus its attentions entirely on the mechanisms and competencies necessary for the safe manufacture and provision of medicines and medical devices to health practitioners.

17. This approach recognises that it is the HPCA which creates the framework ensuring the competence of health practitioners and that it should also be the basis for a regulatory framework for regulating health practitioner workers, other relevant personnel, and service-delivery supervision. The HPCA would thus be the mechanism for ensuring overall competence by applying the HPCA's principles via augmented or new standards and by ensuring clarity about which legislation and related regulatory and compliance regime a health practitioner works.

18. The Council also favours copying the prosecution and enforcement powers set in the TPB to the HPCA to ensure consistency when applying those powers.

19. The Council also favours revisiting the proposed single regulator model, with an emphasis on determining whether more specialised regulatory entities would be better positioned to manage the split focus between licensing practitioners, premises, and modes of operation and the safe production and supply of medicines and medical devices the proposed regulator is expected to manage.

20. The Council commissioned the NZ Institute of Economic Research (NZIER) to examine regulator models. The NZIER applied two separate lenses to their analysis. It examined regulator models using a cost benefit analysis and a multi-criterion analysis against a range of metrics, advocated by NZ Treasury to assure good regulatory design principles. The metrics were:

a. **Proportionality** – noting that the key change is a model supporting earlier detection and of contribution of pharmacist competence to process errors and more effective corrective action;

b. **Certainty and predictability** – a model where the people and organisations understand and meet their professional standards;

c. **Durability and ability to evolve** – the ability to respond to change, e.g. changes to standards, scope of practice, patient expectations, and technology;

d. **Transparency to the public** – publicly accessible information about service quality provided by pharmacists/pharmacies and mechanisms to support and improve service levels; and

e. **Capable regulator** – the clarity or regulator purpose and role, its growth support and its scale economy and information use.

21. NZIER found that the information-sharing and single-regulator options scored more favourably than the two-regulator model but there were strong arguments for both so

the preferred option depends upon which criteria is given the highest weighting. We have provided the key points from the NZIER report[1] and table summarising the comparison of pharmacy regulation options in Appendix One.

22. To make an information-sharing approach work, each of the regulatory bodies would need to work within an overall framework that ensures regulatory entities work proactively and co-operatively and share information in a timely fashion to achieve safe patient outcomes, whilst avoiding regulatory gaps that generate risks for patients.

23. The Council recently (1 March 2019) signed a Memorandum of Understanding (MOU) with Medsafe (Medicines Control) endeavouring to optimise the duality of regulation of pharmacy practice in pharmacies. It is too early to establish whether the MOU alone will resolve the challenges both regulators have encountered delivering on their respective legislated functions in a space where, regulatory boundaries under three separate pieces of legislation are unclear.

24. Although early days, we remain concerned that the information-sharing option may not truly close the gaps in regulation and ensure the primary intent of optimising patient safety is consistently met.

25. The Council, therefore, recommends the Ministry explores the regulator options fully prior to the Bill being finalised to ensure optimised regulation in the pharmacy space.

26. Council also recommends the insertion of a clause requiring a review of the effectiveness of the operationalisation and implementation of information-sharing arrangements with regulatory agencies enabled in accordance with clause 209 via a report submitted to the Select Committee three years after the enactment of the TPRS. Council would expect MOUs established with regulatory authorities such as the Pharmacy Council to be included in this review.

Effective Control of Medicines and Other Therapeutic Products and Information Sharing – National Shared Health Record database

27. The Council is concerned at the intention of the TPB to extend the power to supply Category 3 medicines to health practitioners (subject to their scopes of practice) and their staff, subject to the health practitioner's scope of practice and the health practitioner's supervision.

28. The Council considers that this constitutes an effective liberalisation of the control of Category 3 medicines and medical devices and generates unnecessary risks to patient safety by creating opportunities for serious unintended health practitioner error and adverse outcomes for patients.

29. The Council is concerned that:

[1] Good Regulatory Design – Assessing the regulatory options for the Pharmacy Council and Medicines Control. NZIER 8 April 2019

a. A nationally accessible and shared electronic health record database detailing patient health conditions and prescribed patient medications does not exist;

b. Without a national shared electronic health record database, the TPB would enable health practitioners, and their staff, to supply Category 3 medicines without the clinical skills to understand and manage the potential/real impacts of medicines taken in conjunction with overall patient health conditions and medicines supplied or prescribed by other health practitioners; and

c. This approach risks further fragmenting information about the prescribed medicines patients receive even as the health sector works towards a national shared electronic health record database. The Council considers that it is vital that all health practitioners, including pharmacists have read/write access to patient's records to better ensure patient care and safety, and expects an operational national shared electronic health record database when the proposed legislation comes into effect.

30. The Council is also concerned about the patient well-being and safety risks resulting from health practitioner prescribers being able to prescribe and supply medicines. Although it is enabled for medical practitioners within the TPB there is potential for a reduction in patient autonomy and freedom of choice where health practitioners control the whole prescribing and supply process. There should be equivalent standards of safety, and monitoring, for this activity.

31. Presently, the Pharmacy Council *Standards and Guidance for Pharmacist Prescribers 2013* ethical principle 6.3 requires pharmacist prescribers to 'have robust procedures in place to ensure the separation of prescribing and dispensing'. This is currently interpreted by the Pharmacy Council to mean that pharmacist prescribers are not permitted to dispense medicines they have prescribed.

The Best Approach To Ensuring Pharmacy Activities Are Under The Control Of A Pharmacist

32. The Council's position will always be that the professional and ethical provision of pharmacy services to the public is paramount to ensure patient safety. Therefore, the best approach will be one where professional service prevails over commercial incentives and mitigates commercial tension, which compensates or rewards those with high quality service delivery and where mechanisms exist to ensure pharmacists can exert effective control over the delivery of safe, high quality pharmacy services to patients.

Option One

33. The current ownership model relies on the assumption that pharmacist owners more effectively manage quality control systems and practices than corporate entities can, but only within a limited number of pharmacies. The underlying concern is that increasing or removing the limit will dilute the effectiveness of quality control systems and practices because of reduced oversight by owner pharmacists.

34. A potential benefit of Option 1 is improved owner accountability by enforcing the current ownership model often flouted by innovative ownership structures. However, the arguments for keeping the ownership quota as it currently stands boil down to perceived improvements in service quality and improved patient safety because:

    a. The experience in the deregulated model in other jurisdictions emphasises the commercial interests of the company and sales targets and profit margins along with skewed product ranges and disenfranchised workforces inadequately invested in the business and their patients;

    b. Where the pharmacist is the owner or part-owner, there is potential to manage the risks, but where ownership of a pharmacy is through a corporation or an absentee licensee, there is greater probability the commercial/professional tension will affect the supervisory pharmacist's ability to ensure professional and ethical standards of practice. Incentives matter and it is more likely that incentives within a pharmacist owned business will see more of a balance between a focus on financial return and an emphasis on professional service; and

    c. Pharmacists are accountable to the Pharmacy Council for their conduct, whereas corporate license holders are not, and there is a risk that the removal of the current professional and ethical standards of pharmacy practice set out in Section 55C of the Medicines Act by the TPB will encourage future corporate owners to apply undue influence on their pharmacist staff, with a resulting risk to patient safety.

35. The Council also notes that the limited ownership model creates the risk of opportunity loss through limited commercial investment caused by reduced economies of scale, investment, and innovation. This runs counter to the Ministry's goals of improving access to medicines, increasing innovation in health service delivery, and improving affordability, while not compromising patient safety.

36. Owner-operator pharmacists are investing in technology and innovation, with some pharmacies delivering innovative services to their customers, such as robotic dispensing. And, economies of scale and increased affordability can and are occurring through pharmacy buying cooperatives (although this only affects Category 2 and 3 medicines, since the price of category 1 medicines is set by PHARMAC – aside from non-subsidised medicines and unapproved medicines).

37. The competitive business model can stifle the professional and the ethical frameworks required for pharmacy practices. While viability of a business is essential, pharmacists are often more motivated by their professional integrity and duty to the profession yet conflicted through the divergence of the ethos of retailing and the provision of a clinical service. The erosion of pharmacy ownership or control of business decisions heightens the difficulty in achieving the fine balance in the duality of interests.

38. The Council notes that the proposed licence system enhancement, coupled with enhanced auditing counters some of the issues associated with the Option 1 model. However, the Council does not believe that those measures address a fundamentally flawed model.

39. The Council doesn't consider there is a strong enough link between pharmacist ownership of pharmacies model and the delivery of effective quality control systems and practice. If anything, the current and proposed quota system will do nothing to ensure effective quality control beyond frustrating the efforts of many pharmacists who have worked hard to circumvent the current ownership model through imaginative pharmacy ownership schemes.

40. The practical problems flowing from imposing a new limited ownership model for existing pharmacy owners are considerable and promise significant regulator involvement through detection and enforcement processes.

41. The Council also considers that if the Ministry applies the limited ownership model, it should consider encouraging innovations such as the development of mixed ownership health centre models. These are health-care hubs that include GP, nurse, pharmacist, and other health professionals, where a pharmacist could offer clinical pharmacist and dispensing services from a site co-located with a medical centre without needing to sell other goods to support the business.

42. This approach would mean prescribers with a financial interest in a pharmacy just as a limited number of pharmacists currently have a financial interest in a medical centre. To make this work means devising a system to avoid unethical prescribing practices and overcome the obvious objections currently discouraging regulators from recognising the merits of this model.

Option Two

43. The Council considers the advantages of Option 2 are:

    a. The deregulated ownership model enables the opportunity for greater innovation and resource inputs from corporate owners and the rapid transfer of successful services, and service models to other communities; and it

    b. Promises to reduce the cost of medicines and medical devices through bulk buying by chains and franchises.

44. The Council also recognises some disadvantages. They include:

    a. The risk of the *supervisory pharmacist* role not being able to report or address safety concerns, a real risk if the role does not have 'teeth'. The issue is the practical enforceability of measures such as ensuring licensees name pharmacists as *responsible persons* and giving them the authority and resources to fulfil their obligations;

    b. Deregulation supports the establishment of new pharmacies in urban areas, where the population is high enough to support the business, while rural areas will continue to suffer for lack of pharmacy services;

    c. Non-pharmacist owners will only be bound by the TPRS rather than any Professional Standards or Code of Ethics and this gives rise to a two-tier model of patient centred care; while

d. health practitioner owners will be subject to dual regulation under both HPCA and TPRS for the same activity.

45. Option 2 mirrors the UK's Superintendent Pharmacist role and generates a level of safeguard. However, a criticism of the Superintendent Pharmacist role is that it is often nominal and under resourced. Assuming the NZ model is similar then there is a risk that the equivalent *supervisory pharmacist* controls do not deliver the accountability promised.

46. This corresponds to the Council's view that the most sensible regulatory approach is for a single regulator to regulate all activities relating to the sale, supply, and disposal of medicines and the provision of advice in relation to medicines. That means the Council is interested in pursuing models which ensure the Council has regulatory oversight over non–pharmacists engaging in pharmacy services.

Conclusion

47. Given the choice only between the two options, the Council favours Option Two. The reason for that choice is that patient safety is more likely in a model which ensures pharmacists control pharmacies rather than one focussing on ownership of pharmacy businesses.

48. In any future ownership/control model, the Council wants to ensure pharmacists have clear responsibility, accountability, and control of pharmacy operations, with regulatory authorities bearing responsibility for setting training and operational protocols and standards.

49. The Council's primary concern is that pharmacy systems must be under the effective control of a pharmacist (holding a current annual practising certificate relevant to the competence standards) who is sufficiently resourced, and that patients have access to and receive safe and effective services. From the Council's perspective, the issues are:

    a. Empowering early detection of problems;

    b. Giving protection to whistle blowers so they can meet their responsibilities;

    c. Significant penalties for pharmacists who don't honour their obligations;

    d. Significant penalties apply to directors, shareholders, and managers compromising their own professional standards and those applied to the operation of a pharmacy; and

    e. Strong enforcement of the fit and proper person test.

Other changes to pharmacy licensing requirements

Direct and Remote Supervision

50. The Council does not consider this as the best mechanism to ensure safe patient access to the provision of therapeutic products. However, remote supervision may be unavoidable for communities or populations lacking safe access to health services, such depot sites in areas of low access or providing methadone in remote areas where clinical supervision can be included, e.g. where a technician and PACT work in a dispensary with a pharmacist providing surveillance over clinical oversight.

51. Where these conditions exist, the proposed regulator should consider each circumstance on its own merits to ensure risk mitigators maximise patient safety. The Council's view is that applicants must meet specific licensing requirement before being granted licences involving remote supervision. The pharmacist must show how supervision will occur, with Council set standards applying to the protocols mitigating risks.

52. Currently, the supply of medicines or clinical medicines advice without a pharmacist's oversight is contrary to the Ministry's policy of having an integrated healthcare system which makes every contact count. For people living outside urban areas, poor access to professional medical and medicines advice has implications for both the safety of patients and the appropriateness of medicines use.

53. New communications technology or supply systems Improving access to medical and medicines services promises to help patients with restricted access to them. A good example is the in-the-field use of remote dispensing supervision by the UK Armed Forces where most dispensing occurs via Pharmacy Technicians (or Medical Assistants) without the direct supervision of a pharmacist. As such, a pharmacist available televisually can support pharmacy staff working in remote locations.

54. The downside of the use of televisual systems for patient interviews is the potential for patients unfamiliar with the medium to feel intimidated and the resolution quality of the system may affect results. The Council recognises that televisual supervision relies on the licence holder meeting the specific licensing requirements. This should include ensuring staff integrity and competence, and robust processes to fulfil all licensing requirements.

55. As already noted, the absence of a national shared electronic health record database available for pharmacists to use compromises the patient safety element of remote patient interviews.

Regulation of Cell and Tissue Products, Medical Devices, and Radioactive Medicines

56. Cell and tissue products, medical devices, and radioactive medicines regulation occurs for the first time in the TPB. These therapeutic products all impact on pharmacist practice, with cell and tissue products and radioactive medicines currently principally

affecting hospital pharmacists and medical devices affecting hospital and community pharmacists.

57. The UK constitutes a useful parallel for these classes of therapeutic products. There Hospital Chief Pharmacists bear responsibility for aspects of cell and gene therapy and radiopharmaceutical production and use within their organisations. That also applies for medical devices, particularly hybrid devices. Medical device regulation affects community pharmacists as well, and pharmacists are accountable for therapeutic and diagnostic products classified as medicines, as well as for certain medical devices.

58. While the Consultation Document discusses Advanced Therapy Medicinal Products (ATMPs), radiopharmaceuticals receive only a cursory mention and the Consultation Document does not reference the role of the pharmacist in the use of cell and tissue products, medical devices, and radioactive medicines, particularly relating to hospital pharmacy activities.

59. The lack of detail in the TPB hinders the Council's ability to comment further, and it welcomes the opportunity to comment in detail during consultation on the TPB's subordinate legislative instruments.

Natural Health Products and Māori Traditional Medicines

60. The Council notes the exclusion of natural health products and Māori traditional medicines from regulation under the TPB. It also notes that natural health products are the subject of ongoing Ministry of Health policy development.

61. The Council's view is that any future policy and legislation development programme encompassing the production and supply of natural health products, Māori, or other traditional medicines products and medicines, will place them under the future Therapeutic Products Act.

62. The Council also expects that the HPCA will apply to the prescription and supply of natural health products, Māori, or other traditional medicines products and medicines.

63. That will ensure health practitioners working with these products and medicines are able to give balanced clinical advice to patients on their efficacy and safety, and patients have the same level of protection in relation to those products and medicines that apply to the prescription and supply of Category 1 to 4 medicines and other products provided by the HPCA and the future Therapeutic Products Act.

Diagram F

64. The Council notes that Diagram F in the Consultation Document shows licence and qualification-based requirements. However, it incorrectly excludes prescribing and administering medicines from pharmacy activities. These should appear in their own box as they currently do but should also appear in the box labelled 'pharmacy activities' as it is possible now and in the future for a pharmacist to prescribe and/or administer a medicine or medicines either from a pharmacy or another practice base.

Part Two – Consultation Document Questions

Key Features of the New Regulatory Scheme

Question A1

Do you support the general design of the new regulatory scheme for therapeutic products?

1 Support
2 Partially support
3 Neutral
4 Partially don't support
5 Don't support.

65. Partially support. The Council's support relies on the assurance that the TPRS applies consistent standards to all health practitioners and workers to ensure patient safety and that the same checks and balances apply to all health practitioners.

66. The Council sees merit in aspects of the new regulatory scheme, particularly with improving the systems ensuring the safety, quality, efficacy, and performance of therapeutic products and medical devices over their lifecycle.

67. However, the Council is concerned that a common regulatory system for the manufacture and supply of therapeutic products and prescribing and dispensing of therapeutic products to patients is an inappropriate way to regulate a complex system. Regulatory mechanisms for therapeutic products and the supply system should be different from those applying to prescribers and suppliers of those products to patients.

68. The Council is concerned about the potential impact on patient safety. Driving this view is that the likelihood of errors increases in the absence of a national shared electronic health record database capable of supporting liberalised Category 3 medicine supply, as the TPB proposes, coupled with its inherent expectation that health practitioners and their staff can adhere to the same standards as pharmacists, despite their divergent training and experience.

69. In many respects the TPRS carries over the structure of the Medicines Act, which relies on a single regulator to undertake a wide range of functions relating to the licensing, permitting, and supply of therapeutic products and medical devices, as well as monitoring the licensing and qualifications of health practitioners, health practitioners support staff, their premises and other entities responsible for the prescription and supply of said items.

70. The Council prefers a regulatory system in which the TPRS focuses on the safe supply of medicines to the end user, stopping at the point of supply to patients, and the HPCA regulating the safe supply to patients by health practitioners, including HPCA coverage of health practitioners' staff.

71. The Council is also of the view that the HPCA would supply a framework for licensing health practitioner premises, enabling the application of the same ethical and

professional standards framework for premises currently applied to health practitioners.

72. As a result, the Council recommends the HPCA be amended through the TPB to enable it as the primary legislative mechanism to regulate and license all health practitioners and their staff holding and supplying Category 3 medicines and their premises, including health practitioners such as physiotherapists, podiatrists, and dentists.

Content of the Draft Therapeutic Products Bill

Question B1

Please provide any comments on the purpose or principles of the Bill (ss 3 and 4).

73. The Council agrees with and supports the intent of the TPB to ensure the safety, quality, efficacy, and performance of therapeutic products.

74. However, the Council opposes combining regulatory functions relating to the safe manufacture, import, and supply chain distribution of therapeutic products with the regulatory functions applicable to controlled activity restrictions.

75. Instead it prefers splitting the two regulatory functions and supports moving the regulatory functions applicable to controlled activity restrictions into the regulatory mechanisms of the HPCA, so the authorities created by that Act become responsible for regulating their specific scopes of controlled activities.

76. Should such a split go ahead, the Council would expect oversight of retailing activities does not separate from the oversight of other supply chain activities and does not end up operating under a different standard or being managed in a disjointed manner.

Question B2

Please provide any comments on the definitions or meanings set out in the TPB (ss 14–50).

Clause 14 – Interpretation - Definition of Health Practitioner

77. The Council wants the definitions used in the TPB standardised with the definitions in the HPCA.

Clause 15 – Meaning of Therapeutic Purpose

78. The Council notes that the definitions of *therapeutic purpose* carry over from the Medicines Act 1981, but the definitions are broad, and it is difficult to appreciate the

extent of cover based on them. The ambiguity creates uncertainty in determining what types of products the proposed system covers and does not cover, and the definitions need greater clarity.

79. The Council is also conscious that narrowing definitions would enable sponsors to position their products as non–therapeutic 'yet therapeutic'. Creating exploitable openings between definitions would decrease patient (and pharmacist) protection.

Clause 16 - Meaning of therapeutic product

80. The Council notes that the definition of *therapeutic product* is overly broad, and there is a heavy reliance on the proposed regulator making decisions on a product-by-product basis. The Council expects the proposed regulator to institute a process to ensure consistency, timeliness, and clear communication to the stakeholder with regards to their decisions.

81. This ambiguity creates uncertainty and the appearance that many products need exemptions or rulings by the proposed regulator to determine whether they fall within the scope of the Act. The Council would prefer advance clarification of the definitions of therapeutic products to ensure confidence and certainty for the products coming to market, especially during the transition phase. The Council is also concerned at the likelihood of medicines needing reclassification to ensure safety, and monitoring, e.g. more medicines classified from Category 3 to 2, in an environment without a robust national shared electronic health record database

82. An example of the effects of this overly broad approach is blood and tissue products including donated blood. The Council is interested to understand how the definition would cover procedures such as CAR T-cell therapy or HIVT where blood is drawn from, and reintroduced, to the same patient.

83. The same issue applies to products falling outside the scope of the four categories, such as sunscreen, toothpaste, mouthwash, and antiseptic washes. They, arguably, fall within the definitions of therapeutic products. The Council is interested to hear how drug eluting stents will be defined as arguably they likely fall within the definition of both therapeutic products and medical devices.

84. The Council's main interest in definitions is to ensure patient safety is optimised whilst not imposing additional layers of regulation to therapeutic products or medical devices at unnecessary cost or patient access.

Clause 18 - Meaning of Medicine

85. The Council notes that the definition of *medicine* is overly broad, and there is a heavy reliance on the proposed regulator making decisions on a product by product basis.

86. This approach generates uncertainty. A great many medicines require exemptions or rulings by the proposed regulator to determine whether they fall within the scope of the Act. It is vital that pharmacists are aware of the classification for existing products to ensure confidence and certainty for the products, especially during the transition phase.

87. The Council requests consistency with the standards regulating the location or environment of sale, supply, administration, and disposal of therapeutic products irrespective of the health practitioner involved.

Clause 20 - Meaning of AMI (Active Medicinal Ingredient)

88. The Council notes that the international norm for active ingredients in medicines is *Active Pharmaceutical Ingredient* or API. The Council supports harmonising the definition with the international norm. This would also be consistent with the general principle of co–operation with overseas regulators set out in Clause 4 (d) of the TPB.

Clause 21 - Meaning of Medical Device

89. The Council notes that the definition of *medical device* is overly broad, and there is a heavy reliance on the proposed regulator making decisions on a product by product basis.

90. This approach generates uncertainty by creating the appearance that many medical devices need exemptions or rulings by the proposed regulator to determine whether they fall within the scope of the Act. Pharmacists supply patients with many types of medical devices, and an understanding of the increased control over medical devices will be essential for regime compliance. For example, would this meaning apply to genetic test kits and bowel screening test kits?

Clause 22 - Supply-Restricted Devices and Use-Restricted Devices

91. Pharmacists supply patients with many types of medical devices, and an understanding of the increased control over medical devices will be essential for regulatory compliance.

Clause 26 - Meanings of Administer and Prepare for Administration

92. The Council supports the extension of requirements relating to the supply and administration of medicines and raising the standards needed to ensure patient safety. However, it is concerned at the potential for inconsistent application of standards across health practitioners. The Council expects standards and controls implemented which ensure health practitioners meet medicines safety, quality, and efficacy and consistent standards.

93. For example, it would be inappropriate to hold pharmacists to a requirement to reconstitute palliative care injections for specific patients in pharmacies using aseptic standards but enable palliative care nurses to reconstitute the same injection in a non-aseptic environment.

Clause 28 - Meaning of Compound

94. The definition introduces subtle changes to the understanding of pharmacist practice and the legal requirements pharmacists must satisfy with respect to innovations in dispensing service delivery.

95. The Council wishes to see the production of special (one-off) compounded products occurring according to standards that protect patient safety whilst not applying those required for large scale manufacturing facilities.

Clause 29 - Meaning of Dispense

96. The Council disagrees with the proposed definition of *dispense*. There are two principle issues with the definition. They are:

    a. The current definition incorporates a clinical assessment of the patient by a pharmacist ensuring the appropriateness of the medicine, within the bounds of information available, and patient counselling around the safe and optimal use of the medicine. The proposed definition refers only to the technical element of the process and defines it as manufacturing which degrades patient protection.

    b. Of further concern are the potential patient safety consequences of allowing other health practitioners under the proposed definition of *dispense*, to dispense without being subject to the same inspection/licensing/audit requirements provided under GMP rules.

97. The Council expects greater clarity and consistency on the control of these activities via the standards and rules maintaining GMP and any auditing requirements for dispensing and administering medicines.

Clause 32 - Meaning of Manufacture, for Medicine

98. The definition of *manufacture* should not include dispensing. The Council takes the view that this definition defines the boundaries for medicine preparation practice and creates a more complex practice environment than presently supported.

Clause 36 - Meanings of Pharmacy Business and Pharmacy Activity

99. The Council recommends that the definition clarify what constitutes a *pharmacy business* and *pharmacy activity*, such as information on protocols, standards, and the protection of patient safety in the course of pharmacy activities.

100. The Council supports a more flexible definition as an essential precursor to practice evolution and considers that this changed definition widens the definition of what constitutes a pharmacy business and institutes a more flexible approach to practice structure and allows for a wider range of practice types. Whilst not desirable on grounds of patient safety, in exigent circumstances Council acknowledges the need for *retail licences*.

Clause 37 - Meanings of Pharmacy Worker and Qualified

101. The Council recommends removing *pharmacy worker and qualified* definitions from the TPB and placing them within the HPCA. The proposed definitions support the differentiation of people undertaking the same activities, but in different environments. That is inconsistent with the lack of qualification, training, and competence requirements in the proposed meanings of *work and worker* (viz Clause 49).

102. The Council considers that this definition empowers the extension of regulatory oversight to non-pharmacist staff but also has the potential to alter the dynamics of pharmacy business models, such as product placement and where sales occur.

103. The supply of Category 3 medicines requires general supervision by a pharmacist, while all other activities require direct supervision of a pharmacist (unless rules allow a lower level of supervision). While the TPB references rules specifying the level of qualification necessary for the performance of activities by pharmacy workers it is unclear which regulator will have oversight of the qualifications and the competence requirements.

Clause 38 - Meanings of Prescription, Complying Prescription, and Prescribe

104. The Council notes that the form of *prescriptions* allows a wide variety of prescription formats, but it is unclear who bears the responsibility for ensuring that the prescription complies.

105. In the current Medicines Regulations, the prescriber bears the responsibility of compliance with the requirements of a prescription (MR40A). This requirement needs carrying over into the TPB's subordinate legislative instruments, without negating the pharmacist's obligation to meet all necessary requirements, or the pharmacist's obligation not to dispense if the necessary requirements are unmet.

106. The Council's preference is that prescribing standards are the same across all prescribing professions because consistency is essential for patient safety.

Clause 39 - Meanings of Special Clinical Needs Supply Authority and Complying Special Clinical Needs Supply Authority

107. The Council is concerned that while this definition tightens the requirements around prescribing and supplying unapproved products for compassionate access, it has the potential to significantly complicate practice in this area by limiting patient access to needed medicines.

108. To ensure the new regime can work efficiently, pharmacists need ready access to information about authorities integrated into their practice management systems.

Clause 40 - Meanings of Standing Order and Complying Standing Order

109. This definition has the potential to expand the types of practice and medicines prescribed by various health practitioners which will make the need for a national patient database even more critical to ensure patient safety. Whilst Council recognises there are circumstances where the use of standing orders enables safe patient access to medicines in a timely manner there are concerns were this mechanism to be used to circumvent other more robust options to facilitate safe supply to patients.

110. The Council also believes this has the potential to complicate dispensing medicines prescribed under standing orders if supply becomes separated from prescribing and creates the potential for inadequately skilled people prescribing medicines.

Clause 42- Meaning of Supply

111. The Council believes the definition needs to explicitly cover the delegation of supply, so health practitioners know what activities to delegate to non-health practitioner workers. For example, not giving advice to patients but just accepting payment for a Category 3 medicine.

Question B3

Please provide any comments on the product approval controls (ss 51 and 52).

Clause 51 – Product approval required to import or supply medicine, medical device, or type-4 product

112. The Council supports the connection of product sponsors to manufacturers as it ensures product safety and supports pharmacist confidence in imported medicines.

Question B4

Please provide any comments on the controlled activities and supply chain activity controls (ss 53–55).

Clause 54 - Non-Wholesale Supply Of Category 1 Medicine: Prescription Required

113. The Council is concerned that the TPRS describes circumstances where a licence, permit, or regulation(s) could authorise supply without a prescription, such as the supply of trimethoprim by health practitioners in specified circumstances. The Council considers it necessary to ensure consistency of standards across all health practitioners in this regard.

Question B5

Please provide any comments on the authorisations for pharmacists (ss 57–59).

Clause 57 - Pharmacists: Approved and Approval-Exempt Medicines

114. The Council supports the intent of Clause 57(2)(b), whereby a pharmacist only supplies a Category 2 medicine after a determination of its clinical appropriateness.

115. The Council also notes the provision of authority for pharmacists and qualified pharmacy workers to perform controlled activities without the need for a licence, including *compounding* and *dispensing*, that occur within the dispensary.

116. There are several issues with the use of the terms *dispensing* and *dispensary*. Given the emphasis on increasing flexibility in pharmacy licencing to move away from the 'bricks and mortar' model, there may be no dispensary to speak of. For example, dispensing and/or compounding occurring in hospitals may not take place in a dispensary but in an aseptic unit or other location with an isolator such as a ward.

117. The use of the term *dispensary* may have an unintended consequence of excluding certain legitimate areas within which controlled activities take place either now or in the future. Accordingly, the Council encourages the use of a definition of *dispensary* that

is expansive, so it covers all the areas where services controlled by a pharmacy licence may occur.

Clause 58 - Pharmacists: Unapproved Products

118. The Council supports tightening the controls around medicines that are repacked (dispensed) in different quantities to the approved pack.

Clause 59 - Pharmacists: wholesale supply (approved, approval-exempt, and unapproved products)

119. The Council notes that this provision covers the situation of pharmacists supplying medicines to other pharmacies to resolve out of stock situations and is unable to comment further without sighting the detail in subordinate legislative instruments.

Question B6

Please provide any comments on the authorisations for pharmacy workers (s 60).

Clause 60- Qualified Pharmacy Workers

120. The Council recommends amending the HPCA to include this definition. However, the Council supports the intent of subclause 3 which states that pharmacists cannot delegate their clinical judgements.

121. The Council also notes that this clause differentiates 'general supervision' needed for supply of Category 3 medicines with other activities needing 'direct supervision'. The clause does not define 'general' or 'direct' and the assumption is that the level of qualification to perform an activity appears in rules.

122. While the intention is for those rules to reflect the status quo, there are several issues. Firstly, without sight of those rules it is impossible to know how faithfully they will reflect the status quo. Secondly, the status quo may not be adequate. In the UK there is a debate taking place about levels of supervision, principally to enable pharmacists to undertake the growing range of clinical activities both on and off-site of the pharmacy, thus enabling both in the sense of 'freeing up' and 'allowing' from a legal and ethical perspective.

123. The clause also needs to avoid creating a loophole that allows a pharmacy worker to release a prescription medicine to a patient without a pharmacist being present to undertake a clinical appropriateness check.

Question B7

Please provide any comments on the authorisations for health practitioners (ss 61–64).

Clause 61- Health Practitioners: Approved And Approval-Exempt Medicines

124. The Council is concerned about increasing risks to patient safety by putting patients in a situation where obtaining a medicine from a non–pharmacy practice may result in a lower standard of care and protection than applies to medicines obtained through pharmacists. Other practice types must show how they would achieve pharmacy level protection before the proposed regulator grants a licence. The Council considers this essential and that it falls within the purpose of right–touch licensing. Driving this view is that the section authorises health practitioners to prescribe within their scopes of practice.

125. At the behest of other regulatory authorities, the Council currently does not allow pharmacist prescribers to dispense prescriptions they have written. The TPB proposes to remove those boundaries for all health practitioners who are prescribers, removing a step in the prescribing to dispensing process that helps safeguard patient safety. The Council recommends further discussion with regulatory authorities to assess whether patient safety concerns can be mitigated before this provision is written into the Bill.

126. The proposed dispensing power heightens the risk to patient safety. Medicines are not ordinary articles of commerce and as such, *Pharmacist Standards* mandate advice on the safe use of medicines. The concern is that there is no safety mechanism defined in the TPB which ensures the standards applicable to pharmacists apply to other health practitioners supplying medicines by non-wholesale supply.

127. In the UK, nurse dispensing is clearly described in nursing professional guidance (UK Nursing and Midwifery Council, *Standards for Medicines Management*) as an extension to professional practice, reminding nursing registrants that ‘a patient has the legal right to expect that the dispensing will be carried out with the same reasonable skill and care that would be expected from a pharmacist’.

128. The Council is also concerned that while the TPB limits health practitioners to prescribing within their scopes of practice, a major consideration in healthcare is the separation of the prescribing and medicine review/dispensing/supply/disposal activities irrespective of the profession of the prescriber; this is required to remove perceived and actual conflicts of interest and to ensure patient safety.

129. The Council recommends that *dispensing* requires consistent standards and licensing. Therefore, the Council takes the view that all prescribers are subject to the same requirements on the grounds of patient safety. A further issue is how prescribers would handle the non-prescribing components of supply — would the level of supervision of other staff reach the level achieved in pharmacies and if not does this pose a risk to patients?

130. The clause also allows health practitioners and health workers to prescribe, supply, administer and dispense medicines without the requisite requirements of a pharmacy licence. The Council expects the same standards and licensing requirements to apply to the dispensing, supply, and administration of medicines to all practices involved in such activities. The Council would need confirmation by the Ministry that pharmacists can continue to accept prescriptions on ‘their face’ i.e. they do not have to police the

scopes of practice of prescribers. Pharmacists are part of the checks and balances protecting patient against prescribers exceeding their scopes of practice and pharmacists must raise concerns if it is obvious a prescriber is not prescribing within their scope of practice e.g. a dentist prescribing sumatriptan for migraine.

131. The Medical Council's *Good Prescribing Practice* states that doctors should not dispense pharmaceuticals or other therapeutic products unless there is no reasonable alternative. Any model for prescribing where the assessment and sale of a product is inextricably linked, especially where there is a power imbalance as is the case in the patient-healthcare practitioner relationship, introduces an element of actual or perceived conflict of interest and has the potential to compromise patient care and undermine quality use of medicines.

132. Finally, the definition of *administer* under Clause 26 of the TPB includes to dissolve, disperse, dilute, or mix the medicine with another medicine. While the TPB states that compounding or dispensing of a medicine is part of manufacturing the medicine, the supply and administration of medicines is not. This allows health practitioners to supply and administer medicines without the controls needed for a pharmacy licence.

133. The Council expects all health practitioners to deliver services to a consistent standard to ensure patients receive an acceptable level of protection. The Council believes that one approach to doing so is through the application of a right touch licence approach that ensures meeting benchmark standards for reconstitution and dilution.

Clause 62 - Health Practitioners: Unapproved Products

134. The Council's fundamental concern is that the responsibility for these authorities will lie with the dispensing pharmacist who may not have ready access to, or enough information about, the authority to dispense the medicine to the patient promptly. It will require access to a database fully integrated into the dispensary patient management systems for verification by pharmacists.

135. The Council is concerned that Clause 62 states that authorisations for unapproved medicines need the completion of a special clinical needs supply authority (SCNSA). In the consultation document paragraph 72 states:

> 'Section 62 would provide the same authorisations for unapproved medicines but would include the additional requirement for a complying special clinical needs supply authority (SCNSA). Note, that a product approval only approves the product for the purposes specified in the approval (s 99(2)). This means that whenever a medicine is prescribed for off-label use it is an unapproved medicine and would require a SCNSA".

136. There are clinical situations where an approved medicine is used as a standard treatment for an unapproved indication. The requirement to complete a SCNSA for each prescribing that is off-label generates an enormous administrative burden.

137. The proposed system needs to take into consideration the practical operational aspects of an approval system to ensure patients can receive medicines promptly that doesn't burden them with administrative delays or the costs of administrative compliance.

138. An example is a medicine falling under section 29 of the Medicines Act and prescribers prescribing it without knowing its status has changed, e.g. propranolol. A specific example occurs in primary care for ex-smokers with severe infected COPD exacerbations. The internationally recommended antibiotic is unregistered for that use in New Zealand, but specialist respiratory physicians continue to initiate and recommend GPs prescribe it.

Clause 63 - Health Practitioners: Wholesale Supply (Approved, Approval- Exempt, and Unapproved Products)

139. The Council notes that this clause has the potential to authorise health practitioner prescribers to supply 'small' amounts of medicine to each other as well as medical devices, if considered necessary. The clause has issues of definition, i.e. what does 'small' and 'appropriate' mean, and the Council is concerned about regulating the system. The Council appreciates that the Ministry aims to regularise existing practice but if such terms are in legislation then they need definition.

Question B8

Please provide any comments on the authorisations for health practitioners' staff (s 65).

Clause 65 - Health Practitioner's Staff: Non-Wholesale Supply Of Category 3 Medicine

140. The Council notes that this clause broadens access to pharmacy medicines by allowing the supply by a registered health practitioner's staff working under supervision. Any attempt to broaden access to medicines classified primarily for supply under the authority and supervision of a pharmacist needs critical assessment against a range of professional scenarios. One approach to resolving this issue is to set professional standards for all staff and licencing all practices supplying Category 3 medicines.

141. The Council expects audits of all practices supplying Category 3 medicines at least once every five years. For practices supplying Category 1 and 2 medicines the Council expects different licences needing annual APC declarations and contracting/DHB's and regulatory authorities auditing those health practitioners. The Council also expects:

    a. Licences listed on a publicly available register;

    b. Licences have quantity limits;

    c. Regulators able to access practices electronic records to check orders reflect the limits of licences; and

    d. An effective complaints/notifications and investigative system.

142. A scenario illustrating an absence of an effective regulatory regime is a physiotherapist telling a patient to collect Voltaren®, a non-steroidal anti-inflammatory (NSAID)

medicine, from the clinic receptionist before departure. While the physiotherapist attends another patient, the patient collects the Voltaren® and asks the receptionist if it is safe to take with warfarin. Voltaren® can increase the risk of over anticoagulation with warfarin, reducing platelet aggregation and can therefore prolong bleeding if it occurs, increasing patient risk. The clause assumes the receptionist is competent to answer that question while the physiotherapist is busy with the next patient.

143. The Council is concerned about how health practitioners will exercise control over the medicines supply process given their potential frequent physical separation from their staff. To address this the Council proposes holding the health practitioner accountable for the clinical appropriateness and safety of the supply of medicines to patients.

144. Pharmacies are licenced with trained personnel capable of dealing with these issues, with routinely audited regulator protocols, including as a minimum that during pharmacy audits dispensary staff qualifications, direct supervision of non-pharmacist staff, and storage and security and cleanliness of premises, and procedures for storage are all checked. The Council is concerned that the TPB has no comparable requirement for non-pharmacy sites supplying pharmacy only medicines (Category 3 medicines).

145. The Council is also concerned about limits to patient autonomy and choice through the range of pharmacy only products carried by health practitioners. Patient treatment should not be artificially restricted through limited choice of products. This is enabled by current practice.

Question B10

Please provide any comments on the approach for the personal importation of medicines or medical devices (ss 76 and 77).

Clause 76 - Patient or Carer Importing Medicine For Personal Use

146. The Council endorses the Ministry's concerns about imports of counterfeit and substandard products and notes that where there is a clinical need for an unapproved product, a medical practitioner could issue a special clinical needs supply authority, and a licensed wholesaler could source the medicine.

147. The administrative burden and costs associated with safely sourcing medicines by pharmacists' risks making access to unapproved medicines more difficult.

148. It is unclear whether pharmacists will be willing/able to source these products and against what standards they would be measuring the supplier or the quality of the product without access to information about both. Often there is no assurance that manufacture of the medicines is to an acceptable level of safety or quality and patients need to be aware and involved in the decision to source and take these medicines.

Question B11

Please provide any comments on the authorisations created in sections 71–75 and sections 78–80.

Clause 71 - Person Authorised By Standing Order

149. The Council notes concerns about the use of standing orders. The Consultation Document notes stakeholder engagement will address them and the requirements for use during regulation development. The Council wants to know how the Ministry will resolve issues such as the impact on pharmacists working under standing orders in their various roles (as a prescriber and/or service provider to a prescriber), and whether patients being supplied with a medicine by a person with standing order authority will receive the same level of labelling, counselling, and medicine suitability oversight consistent with appropriate standards.

Clause 72 - Downstream Supply or Administration of Medicine to Patient

150. The Council requires clarification on the responsibility of pharmacists and any boundaries to practice imposed by this section.

Clause 78 - Authorisation for Unapproved Product Stock in Supply Chain

151. The Council agrees that the emphasis on current stock is important. Pharmacists must not be able to build up stocks of a product that becomes unauthorised after its status changes and then continue to supply that stock due to patient safety concerns.

Clause 80 - Vending Machines For Medicine To Be Expressly Authorised

152. The Council supports the intent of this clause. The ability to obtain medicines from an automated cabinet delivers out-of-hours access or better access in remote locations, so long as the use of the machine meets the licence conditions. The corollary is that the licence also needs to ensure users get the necessary advice and oversight when obtaining the medicine.

153. The Council also notes that future technology may enable linking the vending machine to remote access to a pharmacist's input to support diagnosis, product choice, and counselling or to accredited technological systems that provide this level of support. Flexible and evolving approaches to licensing give options enabling technological advances to go with careful analysis of patient risk and proposed mitigations.

Question B12

Please provide any comments on the offences created in sections 81–94.

Clause 83 - Advertising

154. The Council is only concerned about direct-to-consumer advertising by pharmacists where they breach their ethical and professional obligations or the Advertising

Standards Authority Therapeutic Products Advertising Code. The Council expects that the proposed regulator will take responsibility for standards and breaches of any standards relating to advertising of therapeutic products.

Clause 84 – Meaning of tamper with and create a risk of harm

155. The Council highlights the definition of "tamper with" currently correlates with processes undertaken by pharmacists and pharmacy workers during dispensing. For example, when tablets are packed down into an amount less than an original pack, a label generated by the pharmacy is affixed to the quantity dispensed to the patient in appropriate packaging. This amounts to "tampering" under the proposed regulatory scheme which Council would consider is offset by special permissions for pharmacists to undertake this as a controlled activity.

Clause 86 - Supply Of Tampered-With Therapeutic Products

156. The Council expects an efficient notification system to alert pharmacists and other health practitioners to the existence of tampered-with therapeutic products in the medicine supply chain will be essential to pharmacists meeting their legal obligations as set out in clause 86.

Clause 91 - Obtaining Therapeutic Product When Supply Is Unlawful

157. The Council is concerned that the clause does not cover the situation of transcribing prescriptions generated by an overseas registered prescriber which is then dispensed by the New Zealand pharmacist knowing it is a transcribed prescription. As such, it needs including in the next version of Clause 91 as an unlawful activity.

Clause 93 - Health Practitioner Prescriber Must Not Hold Interest In Pharmacy Business

158. The Council recognises the advantages of a mixed model of ownership and is aware of the principle to protect patient safety and freedom to choose the provider of their health services.

159. It recommends that the proposed regulator develops clear and enforceable guidelines to protect patient autonomy without inhibiting the development of innovative service models.

Question B13

Please provide any comments on the sections covering product approval requirements (ss 94–104).

Clause 95 - Criteria for Product Approval

160. The proposed regulator must have the necessary capability to reliably assure health practitioner prescribers and pharmacists that it has applied the necessary standards and other requirements employed in application evaluation so they can reassure patients about the safety of products they supply.

Clause 98 - Content of Approval

161. Health practitioner prescribers and pharmacists need to be able to access information about individual approvals. The Council would define 'easy access' as being the provision of systems that allow pharmacy practice management systems to access and display this information in real time without needing direct pharmacist input.

Clause 99 - Scope of approval

162. Health practitioner prescribers and pharmacists need to be able to access information about individual approvals.

Clause 102 - Change of sponsor

163. Health practitioner prescribers and pharmacists need to be able to access information about individual approvals.

Question B14

Please provide any comments on the sections covering conditions on approvals and cancellation of approvals (ss 105–113).

Clause 111 - Regulator May Cancel Approval On Application

164. Health practitioner prescribers and pharmacists need to be able to access information about individual approvals and changes to them.

Clause 113 - Therapeutic Products Register

165. Health practitioner prescribers and pharmacists need to be able to access the information live on line for use where necessary in day–to–day operational procedures.

Question B15

Please provide any comments on the sections covering approval-exempt products and their sponsors (ss 114–115).

Clause 114 - Approval-Exempt Products

166. The proposed regulator must ensure this information is readily accessible by health practitioner prescribers and pharmacists and that standards supporting declarations of approval exempt status are clear and easy to understand so health practitioner prescribers and pharmacists can ascertain the product is fit for purpose.

> **Question B16**
>
> Please provide any comments on the sections covering sponsor obligations (ss 116–119).

167. The Council endorses the content of Part 5 – Sub-Part 3 as it ensures a robust supply chain and improves patient safety.

> **Question B17**
>
> Please provide any comments on the protection of active ingredient information about innovative medicines (ss 120–122).

168. The Council endorses the content of Part 5 – Sub-Part 4 as it recognises the importance of protecting active ingredient information.

> **Question B18**
>
> Please provide any comments on the sections covering the scope, content, effect and grant of licences (ss 123–127).

Clause 124 - Content of Licence

169. The Council endorses the increased flexibility in pharmacy licensing, allowing for different distribution and supply arrangements and not mandating pharmacy businesses to be capable of conducting all pharmacy activities.

170. However, the Council expects the proposed regulator to understand that while this could improve provision of on-line pharmacist services it also implicitly liberalises the market and could also generate unintended consequences such as the quality issues seen internationally where the quality of the services has come under scrutiny.

Clause 126 - Effect of Pharmacy Licence: Additional Provisions

171. Pharmacy licence holders must have pharmacists in effective control of pharmacy premises and controlled activities.

Question B19

Please provide any comments on the criteria for: granting a licence; licensees; and responsible persons (ss 128–130).

Clause 127 - Grant of Licence

172. The Council notes current issues with granting of licences in good time and expects that the proposed regulator will be adequately resourced to ensure licences are not held up when sought.

Clause 128 – Criteria for Granting Licence

173. Council agrees with the concept, but it needs more detail to understand how the licensing regime works, how it affects pharmacists, and how to apply for licences.

Clause 130 – Criteria for Responsible persons

174. While the proposed regulator decides if a person is 'fit and proper' via Clause 47, the Council recommends that regulators jointly agree on persons who fit the criteria through a set of standards and information sharing arrangements.

175. An alternative approach, taking account of the extent of information they may hold about applicants, including investigations that may be currently pending, is providing HPCA regulators with a veto power.

Question B20

Please provide any comments on the sections covering the scope, content, effect and grant of a permit (ss 131–135).

Clause 131 – What Permit May Authorise

176. The Council recognises this power is directly applicable to emergency situations and use of the equivalent power under the Medicines Act occurred most recently in the aftermath of the Kaikoura earthquake. The Council endorses the ability to apply for a permit to authorise controlled activities or the supply of unapproved products so long as the circumstances of the situation support it.

Clause 132 – Content of Permit

177. Pharmacists need to be able to access relevant permit details when necessary.

Clause 135 - Criteria for Granting Permit

178. The Council requests clarity on whether an independent pharmacist, contracted to work across unrelated sites, will need to have a permit to carry out a controlled activity e.g. possession of unwanted patient medicines following a home visit.

Question B21

Please provide any comments on the sections applying to licences and permits (e.g. those relating to duration, conditions, variations, suspensions and cancellations) (ss 136–149).

Clause 136 - Regulator May Split Application

179. The Council supports the view that licences and permits should be enabled to cover multiple activities. There are UK examples of diversification in practice (for example in the provision of medication use reviews) where pharmacists are torn between a variety of activities needing full attention and for which they are fully accountable.

180. The Council's view is that there are scenarios with potentially damaging consequences for professionals and patient safety resulting from these split arrangements, if they are not appropriately managed. The proposed regulator should also ensure that practice capabilities support future split arrangements and do not stifle the innovation of new services.

Clause 140 – Variation Suspension and Cancellation of Licence or Permit

181. The Council is concerned about the power for the proposed regulator to vary a licence or permit. It is unclear whether, in circumstances where the variation has resulted from poor practice or poor standards, that consultation would occur with the professional regulator (in the case of pharmacists, the Council) and that there must be an obligation on the proposed regulator to ensure that this happens routinely and reliably.

Question B22

Please provide any comments on the sections covering the transfer of licences and permits (ss 150 and 151).

Clause 151 – Death, bankruptcy, or insolvency of licensee or permit holder

182. The Council expects that license or permit transfer conditions should include temporary or permanent incapability, such as medical event incapacity or death, leaving the licence holder unable to exercise their obligations under the licence. Under those conditions, the Council is concerned that the license or permit may transfer to the licence holder's agent or estate executor or administrator. This may be inappropriate for controlled activities such as clinical trials.

183. The Council favours an interim arrangement approach allowing a temporary permit for a suitable replacement for the licence or permit holder to ensure safely and continuity of patient care occurs until the licence or permit holder's they are fit to resume their role or their affairs are settled.

Question B23

Please provide any comments on the obligations of licensees and responsible persons (ss 153–159).

Clause 153 – Licensee must ensure responsible person has authority and resources

184. The Council supports the purpose of this clause and recommends that where licences enable multiple activities and sites within the scope of practice of the responsible person, there must be effective control mechanisms mitigating variations in the physical presence of the responsible persons.

Clause 156 – Responsible Person Must Report Non-Compliance

185. The Council is concerned that locum pharmacists (as a group) struggle in reporting non-compliance, especially when working in franchise-type pharmacies. While not named as responsible persons on the pharmacy licence, many pharmacies rely on locums to ensure maintenance of pharmacist oversight or supervision of pharmacy activities.

186. The TPB does not appear to supply adequate protection for them. For example, a locum pharmacist may accept a day or week's work and despite confirming the provision of support staff they arrive to find themselves working solo. Who do they report this to, and how are they protected from the consequences such as being black-listed from other locum jobs?

187. Locums may also be expected to work at short notice, without adequate time to ensure they are familiar with pharmacy systems and operating procedures, increasing risks to both the locum pharmacist and patients. Council recommends the pharmacist locum role become part of the proposed licencing systems for reporting by responsible persons.

188. The proposed regulator needs to make it easy and safe for locums to report concerns as they are most likely to discover poor practice standards as they practice in a variety of pharmacy business and are likely to be a rich conduit for sharing of best practice systems.

Clause 157 – Protection of Responsible Person From Retaliation

189. The Council believes it will be difficult to find a protective mechanism that will afford the degree of protection required for responsible persons reporting non-compliance. The pharmacy profession in New Zealand is small and especially in areas of monopolistic ownership, finding future employment may be difficult for those reporting to the proposed regulator.

190. The Council believes it is critical for that the proposed regulator has the power to enforce this requirement and protect responsible persons from the consequences of reporting non-compliance. The final model must have safeguards against inappropriate owner or management behaviour and the Council expects the proposed

regulator to ensure that whistle blowing is encouraged and that the incentive to whistle blow is stronger than the disincentives.

191. It recommends the proposed regulator set up a fund to financially support whistle blowers until they find alternative employment. Funding could come from licencing charges held in trust to support responsible persons reporting non-compliance.

192. The Council notes there are issues with this approach, such as:

    a. The duration and amount of financial support whistle blowers are eligible for e.g. they might not be able to find employment at a similar level (e.g. managerial status) leaving them with permanent career and financial damage; and

    b. how the proposed regulator would administer such a programme.

Clause 159 - Licensee must ensure only authorised persons carry on pharmacy Activities

193. While the Council endorses the purpose of this clause, it is concerned about the practicality of the 159 (2)(b) provision under certain circumstances e.g. if a prescription delivery service is part of the licence/permit, are prescriptions delivered by persons other than pharmacists breaching this provision? Subordinate legislative instruments should address this issue.

Question B24

Please provide any comments on the regulator's powers and functions in relation to safety monitoring, public safety announcements and regulatory orders (ss 160–182).

Clause 170 – Product Prohibition Order

194. The Council considers, for the purposes of completeness the inclusion of a prohibition on dispensing a prohibited product should be part of this provision, even if covered by the prohibition on supplying it. The Council also considers that the proposed regulator will need to respond quickly to individual cases to prevent further harm once a problem is identified.

Clause 172 – Regulator's Powers In Relation To Oversupplied Persons

195. The Council considers that the description in Clause 172(2) is an unusual description and considers it does not effectively convey the nature of the problem. The Council requests an alternative description which would help intuitive analysis of the patient's situation to ensure rapid reaction when an order is issued.

Clause 173 – Medicine Access Limitation Order

196. The Council notes that the application of *Medicine Access Limitation Orders* relies on suppliers and prescribers of medicine knowing about the orders. The proposed regulator must have an immediate notification process to support the process.

Currently, primary care health practitioners and pharmacists hunt this information down themselves, which is an undesirable situation. Pharmacists are currently not informed about restrictions of medicine supply to certain persons and often only become aware once a problem has occurred or an annotated prescription informs them of controls on supply of medicines with potential for abuse or misuse to particular patients.

197. In terms of patient safety, the Council strongly believes that robust information sharing with health practitioners will improve this system.

198. The Council notes that notifications of these orders would readily fall within the scope of any future shared electronic health record database.

Clause 175 – Statement about oversupplied person

199. Clause 175 (3) empowers the proposed regulator to disclose a statement to one or more notifiable persons. The Council is concerned if other notifiable persons and other health practitioners and pharmacists do not receive the statement, they may unwittingly contravene the order.

200. The effectiveness of the proposed disclosure relies on the oversupplied person actively notifying other health practitioner prescribers and pharmacies of the statement's existence, something the Council considers unlikely.

201. Accordingly, the Council recommends the inclusion of information about oversupplied persons and medicine access limitation orders linked to patient NHI in a national shared electronic health record database readily accessible by all health practitioners.

Clause 176 – Information in Statement to be Kept Confidential

202. While the Council acknowledges the importance of protecting personal information, it is also acutely aware of the risks of privacy constraints keeping relevant health practitioners ignorant of individual patient's health issues. Perceived privacy concerns are already inhibiting sharing of essential information about high–risk patients. The Council wants a system encouraging practitioners to exchange information to protect patients and communities while ensuring privacy is respected.

203. Under the current code applicable to health practitioners, they must behave professionally when handling personal information. Health practitioner prescribers and pharmacists must be able to brief staff about the statement. The Council looks forward to further information from the Ministry on how the proposed regulator will manage the statement notification process and the associated privacy issues.

Question B25

Please provide any comments on the regulator's investigative powers (ss 183–196).

Clause 184 – How Powers Are Exercised

204. The Council acknowledges the need for regulator investigative powers and notes their similarity to current investigative powers. However, it is concerned that the application of those powers must not erode the civil or legal rights of health practitioners or pharmacists and requires assurance that protections for patient personal information apply.

205. However, as one of the authorities responsible for the professional conduct of health practitioners, the Council believes that it also has a role in participating in these investigations, with particular reference to those health practitioners engaging in pharmacy activities, including, but not limited to the manufacture, supply, and dispensing of Category 1-4 medicines and medical devices. The Council believes this is essential to ensure patient safety.

Clause 189 – Entry and Inspection Without Warrant

206. The Council acknowledges the need for regulator investigative powers and notes their similarity to current investigative powers. However, it is concerned that the application of those powers must not erode the civil or legal rights of health practitioners or pharmacists and requires assurance that protections for patient personal information apply.

207. The Council notes a need for further work on this proposal, and cites the example occurring in the UK, where there is a role in all organisations which hold or handle controlled drugs (Accountable Officer for Controlled Drugs), typically a senior pharmacist, who is accountable for the use of controlled drugs within an organisation (and to share intelligence with colleagues in other organisations and wider networks). This role aims to encourage best practice with controlled drugs, reduce and/or remove diversion and overuse/dependence at a variety of levels.

Clause 193 – Destruction of seized things

208. While the Council supports the destruction of seized therapeutic products for which there is a risk through their safety, quality, efficacy, or performance the Council wants to know what happens to personal and other information seized during an investigation, such as patient records. The Council is concerned about legal actions arising from the retention of such information after the completion of the investigation.

Question B26

Please provide any comments on the offences relating to the regulator (ss 197–199).

209. The Council notes that the similarity of these offences to those described in current legislation.

Question B27

Please provide any comments on the review of the regulator's decisions (ss 200–204).

Clause 200 – Application For Review Of Regulator's Decision

210. The Council considers there is a need to ensure Schedule 2 includes pharmacist related decisions.

Clause 201 – Regulator to convene review panel

211. The Council endorses the inclusion of a review panel provision in the TPB. However, it requests the process occur using right touch regulatory principles. That means the process must be transparent and ensure the people selected are independent and have the necessary knowledge, skills, and experience.

212. The Council recommends the Ministry consider complainant input on panel selection to ensure process fairness.

Clause 203 – Decision On Review

213. The Council recommends review process rules specify timeframes. That will avoid the potential for denial of justice through delays. Otherwise, even if a review finds in favour of the applicant the negative effects of delay may adversely affect the applicant.

Clause 204 – Appeal to District Court

214. The Council recommends that since a confirmed decision may be subject to a District Court appeal, it would be useful, given the number of agencies with input into most activities under the proposed legislation, to have an independent review panel as an interim step before the District Court.

215. It might also be an alternative to the District Court, equivalent to the process provided in the Medicines Act. This would ensure transparency and an independent review process and enable an alternative approach for dispute resolution that both parties may prefer.

Question B28

Please provide any comments on the administrative matters relating to the regulator (ss 205–222).

Clause 207 – Regulator May Rely On Recognised Authorities

216. While the Council recognises the merit of this provision, the Council proposes that the proposed regulator should rely on recognised authorities representing the whole body of knowledge on a given subject.

Clause 208 – Notice and Reasons for Decision by Regulator

217. The Council supports this provision's intent to ensure the proposed regulator is transparent in its process.

Clause 209 - Sharing of Information With Regulatory Agencies, Etc

218. The Council supports the clause's purpose. It notes that information sharing relies on good faith and commitment by all parties in the information sharing agreement. It also notes that information shared must be confidential, reliable, and time sensitive.

219. The Council looks forward to the opportunity to discuss developing an information sharing agreement with the proposed regulator. The Council also looks forward to the establishment of an expert committee made up of all the HPCA regulatory authorities and recommends that the proposed regulator create a robust mechanism to manage communication with the regulatory authorities and ensure there are no disruptions to information flows.

220. Council recommends the insertion of a clause to require a review of the effectiveness of the operationalisation and implementation of information sharing arrangements with regulatory agencies enabled in accordance with clause 209 via a report submitted to Select Committee three years after the enactment of the TPRS. Council would expect MOUs established with regulatory authorities such as the Pharmacy Council to be included in this review.

Question B29

Please provide any comments on the sections covering enforceable undertakings and a court's ability to grant injunctions (ss 223–232).

221. The Council supports the intent of Part 7, Sub-part 1 and 2 of the TPB.

Question B30

Please provide any comments on the sections covering penalties, court orders, liability, defences, and evidentiary matters for criminal offences (ss 233–248).

222. Overall, the Council supports the approach taken by Part 7, Sub-part 3, Sub-part 4, and Sub-part 5 of the TPB. The Council recommends the Ministry include reference to the *Protected Disclosures Act*, which is an existing protection for corporate whistle blowers, particularly in relation to reporting inappropriate conduct by colleagues and managers.

Clause 233 – Penalties for Offences

223. The Council supports the introduction of significant penalties to incentivise compliance. It also supports the proposed intention to adjust penalties over time through the tiered penalty approach.

Clause 238 – Notice of Court Orders

224. The Council notes that following the conviction of a health practitioner for an offence against the proposed Act, this provision has the court registrar notifying the proposed regulator. As one of the authorities responsible for dealing with competence, complaints, and discipline matters of health practitioners the Council insists the District Court supply copies of relevant court orders to the Council, or any other relevant authority for any actions considered necessary under Part 4 of the HPCA.

> **Question B31**
>
> Please provide any comments on the sections covering infringement offences and the related penalties and processes (ss 249–255).

225. The Council notes an issue with the approach taken with the scope of Part 4 Sub-part 6 of the TPB.

226. The Council, along with the other HPCA authorities, expects effective involvement in the prosecution and punishment of infringement offences against relevant health practitioners and persons working in relevant activities.

Clause 249 -Meaning of Infringement Circumstances and Infringement Offence

227. The Council expects the proposed regulator to notify the relevant regulatory authorities when an infringement is issued. The Council would also need to consider what this would mean in a 'fitness to practice' context to ensure tight governance.

> **Question B32**
>
> Please provide any comments on the sections covering administrative matters; such as cost recovery, requirements for the development of regulatory instruments, review of the Act, and relationships with other Acts (ss 256–274).

228. The Council notes that the proposed regulator may set fees and charges to cover funding shortfalls for direct and indirect administration costs of the Therapeutic Products Regulatory Schemes and the enforcement of the Act.

229. The Council is concerned there is potentially no limit to what amounts the proposed regulator may recover through fees and charges. While it appreciates that fee and charge setting occurs in subordinate legislation, the Council expects to see a process in legislation enabling a challenge to fee and charge setting if the entities paying them consider them excessive. The Council is also concerned that there is no clear indicator of the persons or entities liable for the fees and charges.

Clause 267– Consultation

230. The Council notes that sub-clause 3 seems inappropriate unless a good reason for not consulting is available. The Ministry may wish to consider what would constitute a good reason.

Question B33

Please provide any comments on the amendments to the Health Practitioners Competence Assurance Act 2003 (ss 276–285).

Section 276 - Amendments to Health Practitioners Competence Assurance Act 2003

231. The Council notes that the regulations for pharmacist prescribers are set for repeal. This change raise issues for the Council. Pharmacist prescribers are not diagnosticians and as such, Council will need to consider whether issuing standing orders is correct and should be within their scope of practice.

232. It might be practical to issue standing orders in some circumstances i.e. to improve access to medicines as per the Ministry's goal, but how that occurs is unresolved, as the authority to issue a standing order would need to be explicit in a scope of practice. As it stands:

    a. The Minister will have the power to amend or revoke prescribing provisions in a scope of practice, which potentially leaves a Minister open to undue influence from a group not wishing to see another group being able to prescribe.

    b. It is not clear why there needs to be provision for a responsible authority to be able to update a scope i.e. alter the wording but not the actual scope itself, without consultation.

Question B34

Please provide any comments on the amendments to the Search and Surveillance Act 2012 and the Customs and Excise Act 2018 (ss 286–289).

Clause 286 -Amendment to Search and Surveillance Act 2012

233. The Council notes the proposed changes to the Schedule of the Search and Surveillance Act 2012.

Question B35

Please provide any comments on the list of decisions that would be reviewable and who can apply (Schedule 2).

234. The Council notes the list of reviewable decisions listed in Schedule 2 of the TPB and expects to be involved in any decisions relating to pharmacists, controlled activities, or pharmacy business.

Question B36

Please provide any comments on the use of regulations, rules or regulator's notices for particular matters (Schedule 3).

235. The Council considers several items should appear in Schedule 3 of the TPB. They are:

a. Legal requirements of a prescription and specifying responsibility for ensuring it complies, i.e. the prescriber or the pharmacist;

b. 1 (6) – requirements and expiry events for complying prescriptions are primarily a prescriber responsibility since the prescriber has legal requirements to meet when issuing a prescription;

c. The Schedule must include reference to GMP current legislation and regulation in rules and regulations or must be specifically detailed;

d. Reference to *Pharmacy Standards* principles, as they relate to (e); and

e. Include audit rules and audit tools so they are publicly available and easy to access.

Question B37

Are there any other Acts or regulations containing an interface with the Medicines Act 1981 that are not identified in the list in Schedule 4?

236. The Council has nothing to add here.

Therapeutic Products Regulatory Scheme

Question C1

Please provide any comments on the approach to regulating changes to approved products (s 100 and 101).

237. The Council supports the tenets of this approach to regulating major and minor changes to approved (new) products, particularly to ensuring health practitioner prescribers and pharmacists receive proper and prompt notification of the changes.

238. The Council also notes that the TPB creates a product register and the proposed regulator must support that register and make it publicly available. The Council considers it is essential to include the approved indications for the registered products in the publicly available therapeutics products register.

239. Where changes occur relevant health practitioners and pharmacists must receive notifications of product changes from the register. Up to date information must be available from the register in real time and in a form both importable and usable by pharmacists' practice management systems.

240. The Council supports the intention to increase clarity about approved products and expects regulatory measures managing product approval will be sufficiently robust to allow pharmacists to reassure patients about the safety of the products they dispense.

241. The Council also advocates machine readable product labelling and barcoding to enable stock management record keeping among all health practitioner dispensers and pharmacists, and through that support the development and operation of a national shared electronic health record database. This will also aid pharmacovigilance and recall activities.

Question C2

Please provide any comments on the approach for medicines categorisation (classification).

242. The Council approves the classification approach taken by the Ministry. The use of regulations as the classification medium means that changes will occur faster than is possible through legislation.

243. The Council also supports using the classification system to restrict supplied medicines to specific scopes of practice. The Council does not currently support the notion of health practitioners apart from pharmacists dispensing medicines of any category. That approach has the potential to increase risks of medication harm to patients because of the absence of a national shared electronic health record

database capable of tracking and recording dispensing by all health practitioners, and a Ministry funded backup pharmacy helpline service to reduce the incidence of prescription errors.

244. The Council is also concerned the TPB will allow health practitioners and health practitioner workers to supply Category 3 medicines without ensuring the necessary clinical skills exist to understand and manage the potential risks to patients.

245. Supplying medicines should occur with relevant information about a patient's medical condition/s and medication history. Without a national shared electronic health record database, the appropriateness of supply would be difficult to determine, and the supply of any category of medicine (except Category 4) by any other health practitioner or their worker should be subject to the same scrutiny and requirements applying to pharmacists and pharmacy workers.

246. The Council expects a standardised approach to the dispensing of medicines by all health practitioners on grounds of patient safety.

Question C3

Please provide any comments on the transition arrangements for existing medicine product approvals.

Schedule 1 - Clause 1 - Outline Of Transitional Regime

247. The Council supports the use of temporary licences and authorisations, in principle, to support patient access to therapeutic products. The Council expects clarification of the circumstances under which they will be utilised.

Schedule 1 - Clause 11 - Medicines Grandfathered Under Food And Drugs Act 1947

248. The Council considers that this approach may affect continuity of care if consideration of a full approval application is not completed before the temporary application expires. Although it is unlikely to be a significant issue, handling it on a case by case basis when it arises should prove adequate. The Council expects that:

    a. In the overall operation of the therapeutic products system it should not be a major issue as it is likely to happen infrequently;

    b. For each occurrence it would be a major issue for the affected patients if there was no suitable substitute for medicines relied on to control their condition; and

    c. It should be possible to handle each event pragmatically on its unique characteristics rather than setting up a general procedure for it.

Schedule 1 - Clause 27 - Treatment of Existing Licences

249. The Council does not believe that the proposed process should create problems. Applicants renewing an existing pharmacy licences will have to manage timelines, allowing the maximum time needed for granting licences in their planning.

Schedule 1 - Clause 30 - Three-Month Temporary Authorisation For Medical Practitioners

250. The Council is concerned that this may interrupt continuity of care for patients receiving unapproved medicines. Prescribers will need to familiarise themselves with the SCNSA process and issue authorisations within the available period. Pharmacists will also need to check issuance of SCNSAs and determine whether the prescriber's scope allows them to issue the authority.

251. There are many subsidised unapproved medicines routinely used in practice. The Council expects more time to ensure that the implementation of the proposed extra administrative burden can occur.

252. The Council supports the issue of permits authorising the personal importation of prescription medicines in certain situations. It recommends the proposed regulator ensures that patients have enough time to apply for these permits without compromising access to medicines and continuity of care.

Schedule 1 - Clause 31 - Twelve-Month Temporary Authorisation For Existing Standing Orders

253. The Council is concerned that this provision may interrupt continuity of services e.g. the Hutt Valley rheumatic fever pharmacist clinic service. Pharmacists will need to ensure that replacement orders by the clinical lead medical practitioners are issued in time to prevent disruption to the service.

Schedule 1 - Clause 33 - Temporary Licences for Medical Devices

254. The Council recommends the temporary licencing provisions give enough time to ensure continuity of care for patients using devices supplied through a pharmacy. Pharmacists will need to ensure sponsors for the devices they supply are engaging with the process and the device has a full or temporary licence.

255. The Council is concerned that without the detail likely to be in subordinate legislative instruments it appears that the definition of *medical devices* outlined in Clause 2 is broad and ambiguous, creating uncertainty. It recommends greater clarity and guidance on which products fall within the definition of *medical devices* to ensure compliance. This means significant input from the proposed regulator to determine which products fall within the regulations and which are exempt. A list of included products and excluded products would be helpful to ensure consistency.

Schedule 1 - Clause 34 - Temporary Licences For Supply of Products That Become Therapeutic Products on Commencement

256. The Council is concerned that this provision may affect patient safety through the interruption of continuity of care for patients using products supplied through pharmacies. The proposed regulator must ensure that product sponsors engage with the process and the need for a product licence. The Council is concerned about how the Ministry will discover the products, the sponsors affected, and how they will liaise with them to ensure continuity of patient care.

257. The Council expects the proposed regulator to raise pharmacist awareness of the issues arising from these requirements to ensure a reduction of the likelihood of problems occurring.

258. The Council is also concerned that the meaning of *therapeutic product, medicine and medical devices* are broad, and place a heavy reliance on the proposed regulator making decisions on a product by product basis. Greater clarity of inclusion/exclusion criteria of products is required so patient continuity of care is not compromised.

Schedule 1 - Clause 35 - Twelve-Month Temporary Licence For Existing Approved Clinical Trials

259. The Council is concerned that this provision may interrupt continuity of trials. It recommends the proposed regulator ensures significant publicity occurs to avoid health practitioners, (including pharmacists) involved in trials, having to notify the investigators of the need to engage with the process and obtain ongoing approval for the trial within the required period.

Schedule 1 - Clause 36- Six-Month Temporary Licence For Existing Unapproved Clinical Trials

260. The Council is concerned that this provision may interrupt continuity of trials. It requests enough lead time for investigators to engage with the process and obtain ongoing approval for the trial within the required period without disadvantaging patients.

Schedule - Clause 37- Licences Created Under This Subpart

261. The Council requests further clarity on this clause to enable health practitioners and pharmacists to understand how it may affect patient care and safety.

Question C4

Please provide any comments on the approach to post-market controls.

262. The Council agrees with the approach taken by these provisions and supports:

a. the creation of a publicly available and regularly updated database;

b. the introduction of product vigilance activities for medical devices; and

c. mandatory reporting of medicine-related adverse effects by health professionals to a pharmacovigilance programme supporting the safety of medicines and enhancing patient safety.

263. The Council agrees with the proposal to place an obligation on the proposed regulator to ensure it has a monitoring system ensuring the safety of lawfully supplied products, viz Clause 160.

Question C5

Please provide any comments on the manufacturing-related definitions.

264. The Council has concerns about the proposed manufacturing-related definitions.

265. The definition of *manufacture* includes compounding and dispensing activities undertaken by pharmacists, needing compliance with good manufacturing practice (GMP). Excluding *preparing a medicine for administration* from the definition of *manufacture* means there is no requisite requirement for compliance with GMP standards nor safeguards that ensure patient safety.

266. Including *compounding* and *dispensing* activities in the definition of *manufacturing*, albeit as a specific type of manufacturing, means the boundaries for medicine preparation expand, which creates a more complex practice environment than at present. This change needs communication to the pharmacy profession.

267. As with other controlled activities, the Council expects the proposed regulator to hold persons authorised by Part 3 to *compound* or *dispense* a medicine to the same level of accountability, including pharmacy practice audits to ensure patient safety.

268. The new regulatory regime must be able to empower pharmacists to devolve some aspects of the dispensing process related to the packing of medicines to other specialist pharmacy providers to have time for the provision of clinical services to support high needs patients. It will be important not to over–regulate devolved dispensing processes to ensure the approach to shared service provision is practically, and economically, deliverable without compromising patient safety through insufficient oversight.

269. The definition of *prepare a medicine for administration* also includes a broad range of activities concurrent to compounding i.e. to dissolve, disperse, dilute, mix the medicine in or with another substance. The TPB sets no safeguards or requirements to follow GMP for preparing medicine for administration. This risks a failure to lift existing unsatisfactory processes to a satisfactory level to ensure patient safety.

270. Furthermore, pharmacy activities may include both the *compounding* and the *administration* of medicines.

271. Although no question on the meaning of *dispensing* exists in the Consultation Document, the Council believes the definition in Clause 29 of the TPB introduces subtle changes to the understanding of pharmacist practice and the legal requirements they must satisfy. For example, pharmacists will need to understand the implications of these definitions when considering any services that separate the technical dispensing process from the cognitive and clinical aspects.

272. The Council also believes the meaning of *dispensing* in the TPB needs a focus on clinical appropriateness as outlined in the *Pharmacy Services Standard* NZS 8134.7:2010 which creates a solid foundation to ensure that pharmacy services reflect good practice, and that should not be left for the supporting regulations to define.

Question C6

Please provide any comments on the approach to authorising hawkers as part of the relevant wholesale licence.

273. The Council supports the approach taken by these provisions, particularly with a publicly accessible register built into the licensing arrangements.

Question C13

Please provide any comments on the proposal to enable some medical devices to have restrictions applied to their use or supply.

274. The Council supports the ability to restrict devices where the condition under treatment requires specialist skills, training, or experience to manage or the safe use of a device requires specialist skills, training, or experience.

Question C14

Please provide any comments on the transition arrangements for product approval controls for medical devices.

275. The Council considers that the general approach of supporting continuity of care and patient safety during the transition should apply.

Question C16

Please provide any comments on the change in approach to regulating clinical trials.

276. The Council supports the inclusion of medical device and cell and tissue researchers working in regulated trial environments.

Question C17

Please provide any comments on the transitional arrangements for clinical trials.

277. The Council considers that there is a need for clarity around responsibility and accountability and education of professionals and the public on the new scheme.

Question C18

What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?

278. The Council agrees with the ban this provision places on the importation of Category 1 medicines. For other categories of medicines, the Council supports the use of official channels for the importation of unapproved medicines for individual patients rather than the current unofficial arrangements, if for no other reason than to effectively manage the import of all medicines into New Zealand and ensure their safety and efficacy.

279. The Council is aware of the potential issues this approach engenders and takes the view that there is a need for further support and funding for patients needing unapproved medicines. This is particularly necessary to help patients and health care professionals work through the treatment options a patient may require when that treatment is not available in New Zealand.

280. The Council recognises the resource implications of this view and supports ongoing policy work by the Ministry to develop a workable solution to this issue.

Question C19

What type of pharmacy distribution and supply arrangements would you like to see enabled in the future?

281. The Council recognises the merits of the innovative and flexible arrangements the TPB enables, and fully supports any measures which materially improve patient safety, clinical services, and patient access to therapeutic products and medical devices.

282. The Council also notes the absence of key pharmacist activities outlined in the consultation document (Diagram F: Licence and qualification-based requirements). Pharmacy activities also include *prescribing* and *administration of medicines*. Thus, the Council considers that the supply of pharmacy medicines (Category 3) by the holder of a r*etail-only licence* must be subject to similar professional and clinical standards as if supplied by a pharmacy.

283. The Council also recommends the *retail only licence* pairs the retailer with a pharmacist who must give input into the applicable standards and processes.

Question C20

Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?

284. The Council endorses the removal of the 'one-size fits all' approach of the current legislation. The menu of licencing options improves and supports the development of innovative models of practices by tailoring to patient and community needs. While the new legislation will empower service innovation the risk exists that the regulations and rules could undo this empowerment if they are overly burdensome or restrictive or impose operating requirements disproportionate to the risks to patient safety.

285. The Council also notes that integrated healthcare hubs already exist where there are a mix of health practitioners such as GPs, nurses, physiotherapists, pharmacists, and dentists etc. In these hubs prescribers and non-prescribers share the financial costs. Removing the prescriber ownership restriction and allowing a mixed ownership model is a natural next step.

286. Benefits derived from this development include:

    a. Better integration between primary care and community pharmacy;

    b. The possibility of greater innovation with greater financial resources available to both; and

    c. Greater efficiencies in linking back office functions, along with sharing of ideas on improving patient care and health outcomes.

287. The licence application process should also allow the proposed regulator to separate innovative well–founded proposals beneficial to patients from proposals where prescribers are looking to extract financial advantage from their prescribing.

Question C21

Please provide any other comments about enabling different distribution and supply arrangements for pharmacy activities.

288. The Council supports this measure as it enables distinction of pharmacy activities via specialisation and innovation along with rational capital investment based on economies of scale. An example is the use of robots to prepare medicine blister packs at central locations for multiple pharmacies. Via this measure, other health practitioners supplying medicines to patients support expansion of the client base for these operations, while also obviating the risks of skill fade with less specialised suppliers and improving patient access to medicines.

289. The Ministry must ensure robust regulatory support to different distribution and supply arrangements for pharmacy activities, particularly in relation to the appointment of *responsible persons*, to ensure accountability for the responsibilities these people have. It is vital to ensure that pharmacies provide the same standard and quality of service and patient safety is protected.

290. The Council recommends subordinate legislative instruments sets out the criteria *responsible persons* must meet e.g. qualifications, training & competency requirements. It is unclear which entity sets those criteria, and the Council expects to work closely with the proposed regulator when developing the criteria and standards for *responsible persons*. The Council also expects clarity about the entity/s responsible for registering, and monitoring, *responsible persons*.

Question C22

Which option do you support?

- Option 1: Strengthened accountability through pharmacist ownership and effective control (including the five-pharmacy limit)
- Option 2: Open ownership with licence requirements targeted at pharmacist control of quality systems and practices within the pharmacy.

291. The Council supports an ownership model that ensures:

    a. Patients receive safe and optimised services;

    b. Pharmacists have effective control of medicine related services;

    c. Quality, ethical, and professional standards apply;

    d. Public trust in the pharmacy profession continues; and

    e. Patients have long-term access to pharmacy services;

292. The Council believes that the licence requirements proposed within Option 2 is better placed to deliver against those goals because it supports pharmacist control of quality systems, and thus better protects patient safety, and maintains professional and ethical standards.

293. However, Council is concerned about the potential of open ownership proposed in Option 2, where regulation of the non-pharmacist owner as a health professional and the mechanisms to manage professional and ethical behaviour under the HPCA will be lost.

294. An ownership model where additional licence requirements ensure increased professional oversight and control of quality systems and practice within a pharmacy overlaid on the current ownership of pharmacies by pharmacists may be the best mechanism to achieve patient safety.

295. To reinforce our position, Council is less concerned about the model of ownership or pharmacy ownership structures and is instead focussed on systems which reward and expect professional and ethical ethos to prevail or have sufficiently strong mechanisms to punish those who fail to maintain the professional and ethical standards expected or seek to undermine the fundamental principles of the TPRS.

296. However, the Council also recognises a stronger system where regulation occurs under two pieces of legislation. Where a pharmacist owns a pharmacy that owner, under the provisions outlined in the TPB, the pharmacist will be subject to regulation as a responsible person under the TPRS and as a health professional under the HPCA. This ensures strong regulation of controlled activities and therefore a combination of the control systems under Option 2 and the status quo ownership model may deliver the best outcome. Greater transparency of the ownership structure would be an advantage to the implementation of such an effective control mechanism.

Question C23

Why do you support that option?

297. The achievement of patient safety is more likely to occur through a model which directly ensures pharmacists manage controlled activities in pharmacies rather than one relying on ownership of pharmacies by pharmacists. The model needs strong regulation to ensure real and effective pharmacist control over services rather than simply assuming pharmacist control exists because a pharmacist owns the practice.

Question C24

What do you consider are the benefits and/or risks that could result from Option 1?

298. The current ownership model works on the assumption that pharmacist owners more effectively manage quality control systems and practices than corporate entities, hence the five premises ownership limit, because of a presumption that diluting ownership by increasing or removing the limit will dilute the effectiveness of quality control systems and practices i.e. there would be reduced oversight by the owner pharmacists.

299. The presumed benefit of Option 1 would be strengthening accountability by closing the ownership loopholes currently exploited by some pharmacists and corporations.

300. The Council considers the arguments for keeping the ownership quota amount to a perceived improved quality of service and perceived improved patient safety because:

    a. The experience in the deregulated model in other jurisdictions emphasises the commercial interests of the corporate owner and sales targets and profit margins, along with skewed product ranges and disenfranchised, often under-resourced workforces inadequately invested in the business and their patients;

b. Deregulation supports the establishment of new pharmacies in urban areas, where the population is high enough to support a retail business, while rural areas will continue to suffer for lack of pharmacy services;

c. Where the pharmacist is the owner or part-owner, there is potential to manage the risks, but where a corporation or an absentee licensee owns a pharmacy, there is greater probability the commercial/professional tension will affect the supervisory pharmacist's ability to deliver professional and ethical standards of practice. Incentives matter and it is more likely that incentives within a pharmacist owned business will see more of a balance between a focus on financial return and an emphasis on professional service; and

d. Pharmacists are accountable to the Pharmacy Council for their conduct, whereas corporate license holders are not, and there is a risk that the removal by the TPB of the current professional and ethical standards of pharmacy practice, as set out in Section 55C of the Medicines Act, will encourage future corporate owners to apply undue influence on their pharmacist staff, with a resulting risk to patient safety.

301. However, the Council recognises the body of evidence supporting the view that ownership under the present regime does not guarantee the maintenance of professional and ethical standards of practice.

302. The limited ownership model also risks opportunity losses through limited commercial investment caused by reduced economies of scale, investment, and innovation. This runs counter to the Ministry's goals of improving access to medicines, increasing innovation in health service delivery, and improving affordability, while not compromising patient safety.

303. Having said that, investment in technology and innovation by owner-operator pharmacists is happening, with many pharmacies delivering innovative services to their customers, such as robotic dispensing. Economies of scale and increased affordability occur through buying groups of pharmacists (for Category 2 and 3 medicines, since the price of Category 1 medicines is set by PHARMAC).

304. A further point is that the competitive business model can stifle the professional and ethical framework necessary for the practice of pharmacy. While viability of a business is essential, pharmacists are often more motivated by their professional integrity and duty to the profession and patient safety. The erosion of pharmacy ownership or control of business decisions heightens the difficulty in achieving the fine balance in the duality of interests.

Question C25

Are there ways in which Option 1 could be improved?

305. The Council's view is that the ownership model may have been relevant in the past, but the convoluted lengths that pharmacists and their financial backers take in

structuring their holdings to meet the existing ownership requirements constitutes a clear indicator that it is a deeply flawed model which fails to deliver adequate accountability and thus is no longer applicable.

306. The Council also doubts it would be possible to create a strengthened regime capable of preventing the convoluted systems currently used to thwart the intent of ownership requirements.

307. While the Ministry may endorse a limited ownership model, the practical problems associated with allowing pharmacists to own a limited number of pharmacies are considerable.

308. From the Council's perspective, what matters is ensuring pharmacists work within an innovative and effectively regulated system which safely and efficiently delivers high quality, safe pharmacy services to patients. Applying a limited ownership model is not the way to achieve that.

309. The Council favours a model that holds the professional and ethical obligations associated with the delivery of safe, high quality pharmacy services as paramount. Such an option could retain current pharmacist ownership requirements, with additional enforcement provisions and increased licencing requirements to ensure a pharmacist is effectively controlling the clinical, professional and ethical provision of safe high-quality pharmacy services. The Council appreciates there may be other, equally appropriate, ways to achieve a similar end-point.

Question C26

What activities do you consider a pharmacist ownership requirement should cover?

310. There are no specific activities that are required in a pharmacist ownership model, but the Council believes a practical and sensible approach is to control all activities relating to the sale, supply or provision of advice in relation to medicines in categories 1, 2 and 3. The risk of not controlling all activities is that some pharmacy activities which should be controlled, and are therefore activities which a pharmacist ownership requirement should apply to may not be appropriately controlled.

Question C27

For an ownership requirement to be effective, do you think the same pharmacist(s) need to have both majority ownership and effective control or could those responsibilities be separated?

311. A pharmacist owner manager is more likely to endeavour to achieve a balance between the delivery of safe professional services for patients and financial return. This situation proffers a variant on Option Two where a pharmacist or pharmacists acts

as corporate investors. Under those circumstances the same controls applying to any corporate investor should apply.

Question C28

Should the current five-pharmacy limit continue or be replaced by a licence requirement that the pharmacist would have appropriate oversight of the pharmacy (taking into account the number, scale and location of the other pharmacies they are responsible for)?

312. The Council does not believe the current five pharmacy limit is practical to enforce and instead it recommends pharmacists have oversight mechanisms that ensure effective control of all controlled activities carried out irrespective of the number of pharmacies owned by the organisation.

Question C29

If the five-pharmacy limit was retained, how should it be applied when pharmacists jointly share responsibility for the pharmacy?

313. The Council does not believe there is merit in supporting the five-pharmacy limit. The more important aspect is effective control to ensure professionalism, adherence with delivery of quality standards, and ethical practice promoting patient safety.

Question C30

Do you have any information on the potential impact on the pharmacy sector of an improved majority pharmacist ownership requirement?

314. It would appear the main impact for the pharmacy profession would be increased compliance costs as the proposed regulator ensures all licence applications meet current and future requirements. It would also require regularising the ownership and control of a considerable number of pharmacies. That could well result in pharmacy closures and losses of service to many communities.

Question C31

What transition time do you consider would be required if Option 1 was implemented?

315. The Council estimates a need for between three to five years for current pharmacy owners to unpick the complex ownership arrangements they have developed.

However, it does not consider this option is the best mechanism to achieve the required regulatory outcomes.

Question C32

Do you consider friendly societies should continue to be exempt from this requirement or should this exemption be removed after a transition period?

316. The Council notes that while Friendly Societies are not investor owners but service providers, they should not be exempt from pharmacist ownership regulation.

317. Originally a form of cooperative to support access to medical and related services by members and targeted primarily towards lower income individuals, they are no longer necessary given the other ways people can access both GP services and medicines today. The small number of Friendly Society practices means they make a minor overall contribution to care for low income people.

Question C33

What do you consider are the benefits and/or risks that could result from Option 2?

318. The Council notes that the potential advantages of Option 2 are:

    a. The deregulated ownership model enables the opportunity for greater innovation, specialisation, and resource inputs from corporate owners, including corporate governance skills;

    b. Widens the scope of access to consumers by enabling entities like supermarkets, maraes, and other community focussed organisations to embed pharmacies in their operations; and

    c. Promises to reduce the cost of medicines and medical devices through bulk buying by chains.

319. The Council also notes some disadvantages. They include:

    a. There is a risk that malpractice by non–pharmacist directors and senior managers would go unpunished. Some Health Practitioner Disciplinary Tribunal cases have highlighted the importance of the *Code of Ethics*, where the only breach upheld has been from the Code. In such situations the Council would lack the capability required to rule on cases of licence holders pressuring pharmacists to act outside the *Code of Ethics*. Passing the responsibility for the application of the *Code of Ethics* to the supervisory pharmacist in charge shifts the burden of responsibility to the pharmacist, when they may have little control of the business activities and impact of management on the pharmacy. As foreshadowed in Part 7 - Sub-Part 4 of the TPB, prosecution of relevant senior

managers, and directors must complement disciplinary action against supervising pharmacists. Failure to achieving co–ordination of these activities between the regulators could see non–professional malpractice activities go unpunished. Corporate marketing strategies and advertising occur with little or no input from pharmacists, and it would unfair to penalise the pharmacist for such actions; and

b. The risk of the *supervisory pharmacist* role not being able to report or address safety concerns. This is a real risk if the role does not have power and effective protection. The issue is the practical enforceability of measures such as ensuring licensees name pharmacists as *responsible persons* and giving them the authority and resources to fulfil their obligations.

320. Option 2 mirrors the Superintendent Pharmacist role existing in the UK and thus generates a level of safeguard. However, a criticism of the Superintendent Pharmacist role is that it is often nominal and under resourced. Assuming the NZ model was similar then there is a risk that the supervisory pharmacist controls do not deliver the accountability promised.

Question C34

Are there ways in which Option 2 could be improved?

321. The Council considers the key weakness of the supervisory pharmacist model the risk of undue influence by corporate owners on pharmacy operations. The Council notes the TPB includes whistle blower protections but empowering supervisory pharmacists to be able to overrule corporate instructions affecting patient safety would allay the Council's concerns.

322. However, the Council is concerned at the reality of any mechanism being strong enough to ensure this and therefore prefers the effective control enhancements of Option 2 overlaid on the status quo ownership model.

Question C35

Are the requirements adequate to ensure the 'supervisory pharmacist' would be able to effectively perform this function?

323. The draft regulatory scheme obliges licence holders to empower pharmacists with the authority, mandate, and resources to enable them to perform their functions (with penalties for not doing so).

324. The Council is interested in how the proposed regulator plans to audit pharmacy operations to ensure this occurs. The model relies on 'the ambulance at the bottom of the cliff' approach, with complaints the only means by which the proposed regulator

discovers licence breaches, meaning a considerable number of breaches could go undetected which could further embolden the actors concerned, and encourage others to drop their standards to compete effectively with them.

325. To work, Option 2 requires the creation of a regulator or third-party audit process capable of detecting undue corporate influence while ensuring supervisory pharmacists are both effective and, as the same time, not adversely affecting pharmacist autonomy and patient safety.

326. The Council is concerned about the possibility of implementing such a mechanism and the degree of additional protection it will have were pharmacist ownership no longer be a requirement. The potential for erosion of professional and ethic practice standards and therefore patient safety associated with a more commercially focussed model owned by a non-health practitioner remains the concern.

Question C36

Do you think the requirement for a pharmacist to be present should be broadened to allow a pharmacist to provide clinical advice and oversight remotely (s 159)? If so, which pharmacy activities or circumstances do you think this would be appropriate for?

327. The Council considers it essential to take advantage of recent improvements in communication technology, as they apply to pharmacy and pharmacist services, when New Zealand has many remote communities poorly or not serviced by pharmacists.

328. Using remote communication technology pharmacists can interview patients, depending on the quality of the televisual link, and deliver clinical advice in the same manner as they can in person. The corollary is that pharmacists need to:

    a. Have access to a patient's relevant dispensing history;

    b. Monitor clinical outcomes; and

    c. Are subject to standards while doing so.

329. The Council expects that the provision of services where physical patient assessment is necessary for patient safety, such as blood pressure measurement for sildenafil supply without prescription by a suitably qualified pharmacist, will still require face to face consultation unless technology supports a high-quality assessment.

330. Requiring licence applicants to show their approach to remote supervision would mitigate the risk of inadequate oversight before granting applications for licences involving new supervision approaches.

Question C37

Do you consider restricting prescribers from taking a financial interest in a pharmacy is still required (s 94)? What would be the risks and/or benefits of retaining or removing this prescriber ownership restriction?

331. Prescribers owning pharmacies raises the fear of undue or inappropriate prescribing for profit, a fact-of-life internationally and the Council agrees with the Ministry's concerns. However, the Council notes the existence of mixed ownership models in which prescribers have ownership interests in pharmacies and conversely, where pharmacist prescribers have financial interest in medical centres. In fact, the health practitioner prescriber model described elsewhere in the Consultation Document proposes to expand this situation. Efforts to manage prescriber interests could occur through limits on the amounts of personal shareholding along with standards supporting ethical obligations vs. personal interest.

332. The TPB removes the separation of the prescribing and medicine review/dispensing/supply activities, and allows prescribers to supply, prescribe, administer, and dispense approved medicines without any checks and balances. This may create perceived and actual conflicts of interest and minimise patient safety.

333. By removing the separation between prescribing, dispensing, and supplying approved medicines to patients without 'second checks' as currently happens in pharmacy, there is a potential risk to the patient.

334. As the Ministry plans to expand this situation by enabling health practitioner dispensing, then the Ministry has the responsibility for developing a regulatory system including right–touch licensing of practices, involving such elements as:

    a. Regular auditing, which detects undue prescribing for profit rather than clinical need;

    b. Manages conflicts of interest;

    c. Ensures patient autonomy; and that

    d. There is no impact on the quality use of medicines.

Question C38

Are there particular situations where you could see a permit would be a useful tool for authorising pharmacy activities?

335. Permitting pharmacies to undertake specific controlled activities for events like music festivals, agricultural field days, or natural disasters, is an entirely rational approach to dealing with short-term events needing pharmacy services.

336. For natural disasters, the capability needs to be in place as part of disaster planning to ensure it can work quickly and pragmatically when required. The Council supports developing this capability.

Question C39

Please provide any comments on the intended approach to depots and/or retail-only licences.

337. Depots exist to support isolated communities without access to pharmacy services and must work in ways that ensure patients avoid unacceptable safety risks caused by inadequate oversight. Modern communication technology offers ways of mitigating these risks by improving the link between the pharmacy and its depot.

338. The Council supports the Ministry's policy that depots function under a pharmacy licence, as that ensures necessary professional accountability and regulatory oversight. The Council supports licensing requirements which are pragmatic and relate to the individual community's needs rather than applying a one-size-fits-all set of requirements.

Question C40

Should the circumstances in which a pharmacist or pharmacy worker can compound be expanded to allow them to produce a permitted quantity in anticipation of a request? If you think expanded circumstances are appropriate, why?

339. The Council supports permitting pharmacist or pharmacy workers to produce a permitted quantity in anticipation of a request as allowed by the pharmacy licence and the circumstances.

340. That permission applies to pharmacists wholesaling or those engaged in devolved dispensing under innovative practice models. What matters is that pharmacists work within the spirit and letter of their licences and abide by GMP, i.e. at a suitable compliance level that is achievable and safe.

Question C41

Are there any other situations when you consider it appropriate for a pharmacist to provide medicines by wholesale?

341. The Council considers this a sensible provision. It generates only a small risk provided a permit to supply wholesale medicines clearly defines the maximum quantities allowed and the circumstances e.g. supplying a local pharmacy which has run out of a medicine.

342. Whilst this activity may be widespread and may not particularly affect 'practice', it will regularise an aspect of practice that currently falls outside the regulations.

Question C42

Do you consider the new scheme will have any significant impacts on retailers?

343. The Council thinks significant impacts are not likely if restricted to covering unexpected stock problems. If extended to regular wholesaling activities the purchasing pharmacy would need explicit verification that medicines, especially cold chain products, has been appropriately stored and/or transported.

Question C43

Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?

344. The Council expects that the authority to prescribe should only occur with safeguards and standards that ensure all prescribers take reasonable care and skill when prescribing.

345. The Council supports the arrangement for creating prescribing authority via scopes of practice rather than through legislation. This pragmatic approach recognises that the mechanisms setting scopes of practice, qualification pathways to assurance of competence, and monitoring health practitioners, already exists under the HPCA.

Question C44

Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?

346. The Council considers this a sensible and necessary approach given the risk of unstandardised approaches to the form and content of prescribing provisions. The Council recognises the need for, and the value of, a consistent and standard approach to prescribing for all health professionals with prescribing rights.

347. The Council recommends developing joint prescribing competencies across all health practitioners with prescribing authorities ensuring consistency of standards of practice and supporting interprofessional collaboration and integration.

Question C45

Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.)

348. The Council is concerned that the definition of *standing order* has the potential to expand the types of practice and supply of medicines. This will complicate dispensing medicines prescribed under standing orders if *supply* becomes separated from *prescribing*.

349. In the absence of consistent standards, this creates the potential for inadequately skilled people supplying medicines. On the grounds of patient safety, it is vital that a national shared electronic health record database records all medicine and healthcare provided to patients.

Question C46

What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?

350. The Council considers this approach requires a suitable level of oversight reflecting patient safety risks. That oversight must avoid excessive compliance burdens on the prescriber and dispenser which could result in patients being denied care that cannot be delivered by other means.

Question C47

What do you think about the approach for products that have not been approved in New Zealand? In particular, the proposal that:

- only medical practitioners would be able to issue a special clinical needs supply authority for this type of unapproved product
- other health practitioner prescribers would be able to prescribe them, once a medical practitioner has issued a special clinical needs supply authority for that medicine for a patient?

351. Meeting SCNSA administrative requirements may create heavy administrative s on both prescribers and pharmacists dispensing prescriptions. Without a readily accessible database on patient SCNSA details patient access to medicine may not happen. There is a need to balance patient safety and access to medicines in a manner that does not adversely affect health practitioners wanting the best for their patients.

352. Currently there are over thirty unapproved products funded through the Pharmaceutical Schedule alone, and many others in regular or semi–regular off-label use.

Question C48

In what situations do you consider it is appropriate for a health practitioner prescriber to supply medicines to another health practitioner prescriber?

353. The Council expects any wholesaling activity is subject to auditing and compliance with the necessary GMP standards. Wholesaling of medicines should not extend without GMP standards compliance. The right touch licence for health practitioner premises should include suitable standards covering occasional supply of medicines to other practitioners.

Question C49

Are there situations where it is appropriate for a health practitioner to supply medical devices to another health practitioner? Is this something that occurs currently and would need to be enabled under the new scheme?

354. The wholesaling of medical devices by health practitioners should not occur without compliance with GMP standards and the requisite auditing requirements.

355. For occasional supply, similar standards to those applying to occasional supply of medicines should apply. If the practitioner acts as a supply agent for the sponsor, then the requirements should be set at a higher level.

Question C50

Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?

356. Pharmacies are licenced with trained personnel capable of dealing with these issues, including having routinely audited strict cold chain protocols. The TPB has no comparable requirement for other sites supplying Category 3 medicines, nor requirement to be licenced or meet GMP standards. The Council expects GMP and practice standards to be adhered to by all suppliers of these approved medicines.

357. The Council also wants practices restricted to supplying medicines that form part of patient therapy rather than the practice acting as an alternative source for *any* Category 3 medicine.

358. The Council is also concerned about limits to patient treatment, autonomy, and choice because of limits to the range of Category 3 medicines provided by individual health practitioners.

Question C51

Do you consider health practitioners' staff should be authorised to supply pharmacy (category 3) medicines to patients of the practice? What are the benefits and/or risks of allowing this?

359. The Council is concerned about the potential risk to patient safety should health practitioner staff be authorised to supply Category 3 medicines.

360. The Council's concerns are based on the potential for significant health impacts resulting from health practitioners and their staff prescribing and supplying Category 3 medicines. The issue is the absence of professional skills or standards to effectively understand and manage the potential and real impacts of those medicines in conjunction with patient's health conditions and any other prescription medicines prescribed to those patients.

361. To address this the Council recommends the application of consistent standards to all health practitioners and their workers supplying Category 3 medicines. The Council also recommends that supply is limited to situations where direct oversight and responsibility for the clinical appropriateness by the health practitioner in relation to those medicines directly forming part of the patient's treatment can occur.

362. The development of a national shared electronic health record database detailing patient health conditions and medications taken by those patients constitutes an essential mechanism in reducing those risks.

Question C52

Please provide any comments on the advertising requirements and enforcement tools.

363. The Council accepts that medicines and therapeutic products are not considered ordinary items of commerce and as such, any advertising or promotion is highly regulated.

364. Numerous standards and guidelines cover the development and use of advertisements, regardless of the media used e.g. a pharmacy website or in-store promotion.

365. Pharmacists must comply with codes and practice standards requirements when promoting or advertising services or medicines.

Question C53

Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?

366. Whilst this assumes a continuance of the status quo, the Council believes it is necessary for the Ministry to understand the effect of this potentially key influencer on prescribing.

367. Split views on the matter and a mixed evidence base on the impact supports a need to consider whether this practice runs counter to patient safety or is instead another means of liberalisation of the supply of category 1 medicines by increasing consumer knowledge and choice.

368. The Council wants the Ministry to ensure that advertising provides balanced and vetted information about a medicine. The Council does so aware that it is impossible to prevent patients obtaining information from sources other than registered health professionals.

Question C54

What do you think about the approach for veterinarians and veterinary staff?

369. The Council agrees with the Ministry's intention for the TPB to continue to cover therapeutic products used as animal treatments but primarily intended for human use. This sits alongside the expectation that veterinarians apply the same considerations to an animal's clinical need for the therapeutic product as healthcare prescribers would for their patients.

Question C55

Do you consider there are situations when it would be appropriate to authorise someone to personally import medicines (via a permit)?

370. The Council endorses the Ministry's concerns about imports of counterfeit and substandard products and notes that where there is a clinical need for an unapproved product, a medical practitioner could issue a special clinical needs supply authority, and a licensed wholesaler could source the medicine. Patients would then receive the medicine from their doctor or pharmacist. They are better able to deal with suitable accredited suppliers and would be subject to the regulatory oversight of the Therapeutic Products Act, which ensures medicines sourced meet the necessary standards. The downside of this approach is that importers are free to add significantly to the landed price and health practitioners will pass charges on to patients.

371. The Council is also aware that crippling medicine costs means more patients are seeking unapproved medicines offshore to reduce the costs of their therapy, some even flying offshore every three months to pick up their medicines. The Council acknowledges that it would be sensible to handle the risk of personally imported unapproved medicines by putting this process into professional hands. However, if it creates a significant administrative or financial burden that is not remunerated, it could

cause friction between patients and health care professionals or difficulties finding health care professionals to assist patients, leading to treatment difficulty or failure.

372. The administrative burden and costs for pharmacists safely sourcing medicines risks making access to unapproved medicines more difficult. The proposed regulator would be able to issue a permit authorising the personal import of prescription medicines in necessary circumstances.

373. It is unclear whether pharmacists will be willing or able to source these products and to what standards would they be measuring the supplier. Often there is no assurance that medicine manufacture is to an acceptable level of safety or quality and patients need to be aware and involved in the decision to source and take these medicines.

Question C56

Please provide any other comments from a patient, consumer and disabled person's perspective on the approach for the regulation of therapeutic products under this Bill.

374. The Council has no comment to make relating to this question that is not already covered by the body of its submission.

APPENDIX ONE

Extract from NZIER report "Good Regulatory Design – Assessing the regulatory options for the Pharmacy Council and Medicines Control NZIER report to Pharmacy Council 8 April 2019.

Key points

Two regulators?

New Zealand currently separates the regulation of the delivery of pharmacy services between Medicines Control (in the Ministry of Health) who ensure pharmacy service delivery meets required standards and the Pharmacy Council who focus on pharmacist competence. Information sharing between the two regulators is limited and slow.

Or one regulator?

The Pharmacy Council asked NZIER to review the case for moving to one pharmacy regulator. This is a topical issue as the draft Therapeutics Bill and recent memorandum of understanding propose enhanced information sharing but stop short of recommending moving to a single regulator. Several other countries have single regulators.

We used Treasury's good design principles to assess the options

Using Treasury's good regulatory design principles, we assessed the three options:

- No information sharing (as was the case pre-memorandum).
- Information sharing as indicated in the memorandum.
- The singular regulator approach (as in the United Kingdom etc.).

We scored each of these options on the extent to which they are proportional, flexible, durable, predictable, transparent, capable regulators and growth supporting (low, medium and high).

Our scoring system depends on public safety improvements and cost

Our low, medium and high scoring system depends on the extent to which each option improves public safety and welfare or reduces costs.

No information sharing is low on good design…

No information sharing scores low to medium in all categories. The restriction on information flow limits regulators' scores across the board. The no information sharing option loses rank in reducing costs, adaptation, authority and consistency in giving guidance, transparency, capability and growth supporting – all because of the lack of information transfer.

…but the new memorandum should improve the status quo

The information sharing option is a big improvement on the pre-memorandum level of information sharing (no information sharing). Information sharing as described in the memorandum will help both regulators make efficiency gains (flexibility), learn about and improve their system (durability), be more certain and predictable with pharmacies and pharmacists (certainty and predictability), and make decisions that account for economic and non-economic objectives (growth supporting).

Information sharing also performs highest on several critical criteria

We graded each of Treasury's criteria in terms of their importance and relevance to social outcomes: essential, very important, somewhat important and not important. Information sharing performed highest in several of the most important criteria: proportional, durable, certain and predictable, and growth supporting.

A single regulator also scores highly on several criteria

In contrast, a single regulator scored highest in terms of flexibility (least cost) and the combination of attributes that define a capable regulator (clarity of purpose and scope as well as the effective use of information).

No option dominates

The preferred option depends on the weightings. One option *dominates* when it scores higher than the other options in some criteria and no lower on any other criteria.

In this analysis we found that no information sharing is dominated by the two other options. However, the information sharing and single regulator options do not dominate each other. Neither option is equal or better than the other on all criteria. As a result, our qualitative analysis shows no clear best option.

Quantitative justification for a single regulator is limited

In our interim report, we scanned the literature on other countries' experience with pharmacy regulation and were unable to come up with a compelling quantitative case for the move to a single regulator (NZIER 2019).

Consider change management

As the memorandum was only signed in March 2019, neither regulator has yet had a chance to see the full effects of the potential from information sharing.

The move to information sharing does not preclude shifting to a single regulator regime if the potential from information sharing proves difficult to achieve. However, moving to a single regulator now means that the potential from information sharing remains untested and unknown.

A short summary of our findings is available below in Table 1.

Table 1 Comparison of pharmacy regulation options

Qualitative rating of low, medium or high fit with good regulatory principles

Criteria Definition Importance	No information sharing	Information sharing	Single regulator
Proportional Change fits the size of the problem **Essential**	NA	**High** The cost is small and the benefit is moderate	**Low** The cost is very high but the change still has a moderate benefit
Flexible Least cost approach to delivering the same service **Somewhat important**	**Low** Some duplication of effort leads to additional cost	**Medium** Less duplication of effort leads to less additional cost	**High** No duplication of effort means economies of scope and scale
Durable Enables opportunities for learning about and improving the system **Very important**	**Low** Limited opportunity for learning about and improving the system	**High** Allows for opportunity to learn about system issues	**Medium** Allows for opportunity to learn about system issues but path dependence could limit future adaptability
Certain and predictable Regulated entities are provided with clear, authoritative and consistent guidance that accounts for their long-term investment decisions **Very important**	**Medium** Guidance is less authoritative Decision-making criteria are clear Limits on consistency between Medicines Control and Pharmacy Council due to lack of information	**High** Guidance can be more authoritative Decision-making criteria are clear More consistency between Medicines Control and Pharmacy Council due to more information	**Medium** Guidance can be more authoritative Decision-making criteria are potentially less clear More consistency between Medicines Control and Pharmacy Council due to more information
Transparent and accountable Public has access to information about pharmacy and pharmacist quality of service **Somewhat important**	**Low** Proven limits on transparency due to aggregated reporting	**Low** Aggregated reporting will still curtail transparency Sharing will enable regulators to have a common view on some issues	**Medium** Aggregated reporting will still curtail transparency Could provide an *overview* of the sector that is accessible to and trusted by the public
Capable regulators Clarity of purpose/role; understands scope; uses information efficiently and effectively **Very important**	**Medium** Regulator is focused on either pharmacy or pharmacist business Potential for one regulator to leave tasks to other operators Minimal opportunity to analyse root cause of non-compliance	**Medium** Regulator is focused on either pharmacy or pharmacist business Potential for one regulator to leave tasks to other operators Opportunity to analyse root cause of non-compliance	**High** Regulator is applying two different frameworks (process compliance and professional competence standards), and favourite tasks are prioritised by staff All tasks covered by the regulator Opportunity to embed systems approach to pharmacy service risks minimisation
Growth supporting Decisions made adequately account for economic and non-economic objectives **Somewhat important**	**Medium** Regulators can still make well informed decisions, and each regulator ensures that they invest to meet their purpose	**High** More information means more informed decisions	**Medium** More information means more informed decisions, but one set of objectives could dominate