

Council Submission on the Draft Therapeutic Products Bill (TPB)

Pharmacy Council has made an extensive submission to the Ministry of Health on the draft Therapeutic Products Bill (TPB). It is a submission written for the purposes of helping the policy makers get the changes right for the requirements of future health practice.

Our submission is limited to offering views only on those issues relevant to our regulatory role. As it is not within our role to advocate for pharmacists per se, our submission does not cover such issues.¹ This means our submission focusses on issues about patient safety and the roles and responsibilities of pharmacists. Where the TPB relates to pharmacies, our submission retains the focus on how this relates to pharmacist practice in the context of patient safety. We exist first and foremost for the public to assure them about pharmacists operating as fit and competent health professionals. This summary provides a brief overview to support a wider understanding of our submission.

The Council supports the direction of the Therapeutic Products regulatory scheme changes and endorses much of the draft TPB. We support overall because it better reflects contemporary practice, and enables future models of health care delivery. However, there is a lot of detail at a regulatory level yet to be determined, and therefore some areas are difficult to provide clear feedback on at this stage in the process.

We believe the proposed TPB has significant positive benefits in terms of providing mechanisms for legislation to keep pace with evolving practice, supporting innovative models of care, increasing flexibility in pharmacy licensing and supporting information sharing between regulators.

It also establishes a new regulator who will regulate manufacturing, distribution, supply, prescribing and dispensing of medicines and medical devices. This regulator could either be part of the Ministry of Health or an independent entity.

Council has also expressed concern on some of the proposed changes and considers further discussion is required between the Ministry of Health, regulators and the sector to ensure the legislation is drafted in a way that can effectively achieve its' goals.

One regulator or two?

We believe further discussion is required. The TPB proposes retaining the existing regulatory regime, a regulator of pharmacies (similar to Medicines Control, Medsafe within Ministry of Health) and Pharmacy Council as the regulator of pharmacists. The Ministry's consultation document debates whether the regulator of pharmacies should operate outside the Ministry and proposes it carries out functions that would overlap with Council's.

The overlaps and gaps between the regulation of pharmacies and pharmacists has been a concern to us, as there is potential for public safety risk. There are also missed opportunities which would enable effective and efficient use of resources, through working together. Medsafe, Medicines Control and Pharmacy Council have been working together to mitigate this risk through a recently developed Memorandum of Understanding. This is supported in the TPB by an information sharing proposal. We support this proposal, but believe some of the changes may increase the gap between the two regulators in some areas and cause overlaps in others. This could ultimately jeopardise public safety.

¹ The role of advocating for pharmacists is the role of representative bodies, with whom we work closely, such as PSNZ, PGNZ, NZHPA, CAPA and others.

We believe further discussion is required to resolve these issues, before it can be determined what the correct regulatory form and functions are, for efficient and effective regulation of the pharmacy sector.

Access to one integrated patient health information database

This is critical to implementing the objectives outlined in the proposed therapeutic products regime.

A database that maintains all patient information and is available to all health practitioners (i.e. one database source of the patients' health history) is fundamental to ensuring patient safety. Council believes such a national database needs to be implemented before the TPB is formalised. Council has not heard with certainty that such a database will be implemented prior to the commencement of the new therapeutics regime.

Is effective control of pharmacies best achieved by Option 1 or Option 2?²

Council has proposed a third option. We believe ensuring that pharmacy activities are under the control of a pharmacist is critical for patient safety. The TPB consultation document requires consideration of whether effective regulation can be applied through the ownership of pharmacies (existing ownership model or option one) or through the introduction of regulations that control the pharmacist who is in effective control of the pharmacy (option two). A combination of option two overlaid on the current ownership model provides Council the greatest confidence that patient safety could best be protected because effective control would be real and practical to apply. The pharmacist (holding a current annual practising certificate relevant to the competence standards) must be in effective control. Regrettably, Pharmacy Council has had to respond to cases where effective control has not been exerted under the current ownership model, it is for this reason that we have proposed a strengthening of controls through this third option.

In summary, *Council proposes that pharmacists retain majority interest in pharmacies AND also have additional requirements to ensure the pharmacist in control (the responsible person) can exert the level of control required.*

Other areas of concern to Pharmacy Council

There were a number of other areas where Council had concerns which were of a more detailed nature, these included:

- The operation of the proposed regulatory system which as proposed does not retain, upfront, the importance of professionalism and ethical behaviour as a primary principle;
- Inconsistencies in regulation of different health practitioners and overregulation of the pharmacy sector compared to other classes of health practitioners;
- The proposal to enable supply of pharmacy only medicines by other health practitioners and their staff without the same level of oversight, operating standards, and other safeguards expected of pharmacists to protect patient safety;
- Proposed definition and categorisation of “dispensing”, “manufacture” and “preparing for administration” with the potential to increase risks to patient safety;
- The proposed mechanism for tightening the requirements for prescribing and supply of unapproved medicines.

Our full submission is available [here](#) for your consideration.

² It is possible that in isolation Council's view on ownership models could be misunderstood. It is important that our view on this area in our submission is read in its entirety (paragraphs 291 to 326.)