

17 April 2019

Sheila Swan  
Chief Advisor  
Regulatory Policy  
Ministry of Health  
Po Box 5013  
**Wellington 6140**

Dear Sheila

**Submission on the Therapeutic Products Regulatory Scheme and Draft Therapeutic Products Bill**

We are delighted to respond to the Ministry's request for submissions on its Therapeutic Products Regulatory Scheme (TPRS) Consultation Document. The Council's feedback has been submitted through the Ministry's online submission process and is also attached. It will also be made available to the sector via the Council's website.

We congratulate the Ministry and its Regulatory Policy team for the magnificent work it has achieved against a most ambitious target, a reform of the Medicines Act and all the regulatory mechanisms it encompasses. It is a once-in-a-generation programme and the Council team are both honoured and privileged to contribute to it.

Overall, the Council supports the intent of the reform programme, and it found much in the proposed regulatory scheme and the draft Therapeutic Products Bill (TPB) it wholeheartedly endorses. It has disagreed with some elements of the proposals, and it has said as much and why in the submission.

Patient safety forms the core of the Council's statutory purpose, and it was through the lens of patient safety that the Council examined the proposals. Accordingly, it endorsed the proposals supporting or enhancing patient safety and service quality, and suggested alternatives wherever possible for those it felt reduced patient safety and service quality.

The Council supports:

- 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.

The Council is concerned about the following areas:

- a. The expansive powers and 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 Health Practitioners Competence Assurance Act 2003'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.

### **Effective Regulation of Pharmacy Practice by Two Regulators**

The Council supports the information sharing provisions proposed in section 209 of the TPB, and recently entered into a Memorandum of Understanding (MOU) with Medsafe (Medicines Control), effective from 1 March 2019, to endeavour 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 are unclear.

Although early days, we remain concerned that it is at times difficult to be sure of honouring the “slight” differing legislative purposes, whilst fundamentally meeting the primary intent of optimising patient safety.

The Council commissioned New Zealand Institute of Economic Research (NZIER) to review options to optimise the regulation of pharmacy in New Zealand and it invites further discussion with the Ministry ahead of revisions being made to the TPB. It is critical that in depth discussion considers the best mechanism to regulate pharmacy practice during this window of opportunity afforded by the drafting of the TPB to replace the Medicines Act 1981. We will be happy to meet with the Ministry policy team to discuss the content of the NZIER reports on this subject.

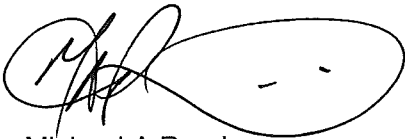
The range of issues raised in our submission are extensive, the Council therefore invites you and your team to discuss the Council's submission in person, at your convenience.

The Council team looks forward to the results of the analysis of the submissions made on the Consultation Document.

We also look forward to the next round of consultation on the Therapeutic Products Regulatory Scheme and the Therapeutic Products Bill early next year after the Bill is introduced into the House.

Again, my congratulations on your team's tremendous work.

Yours sincerely

A handwritten signature in black ink, appearing to be 'M. Peard', enclosed within a large, hand-drawn oval. There are two small dashes to the right of the oval.

Michael A Peard  
**Chief Executive**