



Submission on the Ministry of Health's Therapeutics Bill and Therapeutic Products Regulatory Scheme Consultation Document

April 2019

The contact person for this submission is:

Professor Jenny Carryer RN PhD FCNA (NZ) MNZM

Executive Director

College of Nurses (Aotearoa) NZ

PO Box 1258

PALMERSTON NORTH

Tel: 027 4491302

Email: J.B.Carryer@massey.ac.nz

1. Summary

This submission has been made on behalf of:

Organisation: College of Nurses (Aotearoa) NZ

Email address: J.B.Carryer@massey.ac.nz

Profile (tick all that apply):

Perspective

- Consumer Disabled person Māori Pacific peoples
- Other Professional Organisation

Health sector

- Professional body (eg, Colleges, Pharmaceutical Society etc)
- Health service provider (eg, Ambulance, Māori or Pacific health provider etc)
- Private hospital
- Pharmacy organisation
- District Health Board (DHB) - please state which service area: [Click here to enter text.](#)

2. The College of Nurses (Aotearoa) NZ

The College of Nurses (Aotearoa) NZ – “the College” is a professional organisation of New Zealand nurses from across all regions and specialties which aims for excellence in nursing practice and health care delivery by supporting nurses in their ongoing professional development.

We provide a leading voice for the nursing profession and professional commentary on issues which affect nurses and the health of the community we serve by developing strategic consumer alliances with the aim of creating 100% access and zero disparities in New Zealand health care.

The College was established in 1992, recognising that nurses as key members of the health care team work in diverse community and hospital settings delivering numerous health services to different population groups and cultures. The many challenges and complexities inherent in the current health environment demands a planned and tactical approach. The purpose of the College is to:

- Promote and facilitate professional development in clinical practice, nursing management, nursing education and research
- Monitor, comment and advise on consistency and outcomes of education for nursing practice
- Identify, examine and take action on issues of significance to nursing practice and the health of our community
- Disseminate information on issues of significance to nurses
- Initiate, promote and publish nursing and health related research
- Adopt a collegial relationship with other professional bodies.

One of our key aims is to provide a voice for the nursing profession as a whole, speaking out on issues that affect not only nurses but the health of our community. We monitor and influence policies and legislation and contribute to many committees.

This submission is the result of analysis undertaken by the College, internal consultation, and direct discussions with College members in leadership positions across the health sector. College members have also attended workshops facilitated by the Ministry of Health.

2. Submission

2.1 *General*

The Ministry of Health is seeking feedback on the draft Therapeutic Products Bill (the Bill) and the Therapeutic Products Regulatory Scheme which proposes to repeal and replace the Medicines Act 1981 to provide modern, comprehensive, and cost-effective regulation of therapeutic products in New Zealand.

Feedback from the College largely relates to:

- Interpretations and definitions which require clarification
- Scopes of practice and medicines lists

2.2 *Interpretation and definitions*

The College has a number of concerns about the definitions and meanings set out in section B4, Part 4 in relation to definitions and meanings. All definitions used in the Bill should have the meaning set

out in the *Interpretation* section even if the same definition or meaning is repeated in other sections of the Bill. The current approach is confusing for readers. In addition, some of the definitions provided lack clarity and are confusing. In particular:

- S38(4): *a prescription may be issued orally, in writing, or in any other form* – this is unclear. The responsibilities of prescriber and administrator would require close attention particularly for oral orders (does this mean verbal orders) and other forms of prescription.
- S41: Clarity is required in relation to standing orders and liability. If a registered nurse is the agent of the person who issues the standing order, are they also liable as an agent. Attribution of liability is explained at s239-241 but it is extremely difficult to follow the explanation.
- S43: the use of the term ‘non-wholesale’ is confusing. We understand the intention is to differentiate between wholesale and non-wholesale supply to enable the application of different controls. The College supports replacing the term ‘non-wholesale’ with the term *retail* since this is less confusing.
- The use of the term health practitioner worker is confusing and may be interpreted as including unregulated categories such as health support worker or health care assistant. The College proposes that the term ‘health practitioner worker’ be replaced with *health practitioner employee/contractor*.

2.3 *Scopes of practice and medicines lists*

The College supports the Bill’s intent to link prescribing authority to scopes of practice, rather than by regulation. We also support that responsibility for ensuring the competence of prescribers rests with the relevant responsible authority.

Medicines lists

In regard to medicines lists, registered nurses working in specialist roles find the lists are increasingly not fit for purpose as evidence and practice evolve over time. There are two distinct levels of prescriber within the registered nurse scope of practice which when updated will require reference to two distinct medicine lists. A preferred approach to medicine lists is for nurse prescribers to nominate medicines relevant to their specialty area that are within their knowledge and competence. Responsibility for ensuring the competence of registered nurses would sit with the Nursing Council of New Zealand.

Should the decision to be made to retain medicines list, the proposal for ‘logical groupings’ of medicines for the lists is not practical for registered nurse prescribing lists. The Nursing Council of New Zealand consulted extensively on medicines lists when they were introduced and the current restrictions in relation to route, dose, and preparation would make class grouping extremely challenging.

Access to category 2 and 3 medicines for registered nurses without prescribing authority

Enabling registered nurses without prescribing authority to supply to category 3 medicines to their patients is a welcome move, particularly for nurses working in schools (for example).

Similarly, the College supports the enabling of registered nurses without prescribing authority to supply category 2 medicines, provided they meet any requirements as determined by the Nursing Council of New Zealand.

To be useful, provision for a nurse to place a [Rural] Practitioner Supply Order for relevant category 2 and 3 medicines will be needed.

Registered nurse vaccinators

The College notes that the Bill provides an opportunity to remove outdated requirements in relation to nurse vaccinators. At present, Medical Officers of Health are required to authorise registered nurse vaccinators who have already completed a nationally approved programme to become an authorised vaccinator. We support the removal of the requirement for Medical Officer authorisation. Registered nurses practice independently and in collaboration with other disciplines and it is not appropriate for another discipline to oversee or approve the practice of nurses.

Unapproved medicines

The proposal to restrict the issue of special clinical needs authority for unapproved products to medical practitioners is inappropriate and should be extended to include nurse practitioners. Restricting this activity to medical practitioners, even for the initial consultation, is an unnecessary additional consultation for a patient when nurse practitioners have the same legal prescriptive authority as their medical colleagues. Nurse Practitioners therefore have equivalent ability in weighing the risks and benefits of products that are unapproved.

Other health practitioner prescribers should be able to prescribe unapproved products once a medical or nurse practitioner has issued a special clinical needs supply authority for that medicine for a patient.

At the request of another health practitioner prescriber

The College finds this phrase found mostly in section 61 confusing and it is unclear how this would work in practice. The phrase refers to the prescription of a medicine that is 'at the request of another health practitioner prescriber'. In general, this is an unusual provision since all prescribers should complete their own examination and assessment of a patient before making a clinical decision that includes provision of a prescription.

For registered nurses who are prescribers, the phrase is problematic. At present, registered nurse prescribers are able to provide a continuation prescription to a patient only if they have assessed the patient themselves and are satisfied that the patient requires continuation of the medication initially prescribed. However, 'at the request of another practitioner prescriber' the registered nurse may be required to issue repeat prescriptions to patients they have not assessed themselves. We are concerned that this provision could be used inappropriately. We are also concerned about the risk for registered nurses in relation to the issue of a prescription that is based on the clinical decision making of another practitioner. This appears to contradict safe practice.

Impact on the Nursing Council of New Zealand

While we acknowledge that the operational detail relating to most of the issues raised will arise in the regulations, the College notes the need to be mindful of the impact that extending monitoring requirements of registered nurse prescribing will have on the Nursing Council of New Zealand. Inevitably the cost of increased monitoring would need to be met by the profession via increased annual practising certificate fees that apply to all nurses whether or not they have prescribing rights.

3. Summary

The College looks forward to engaging further with the Ministry of Health on the development of the Bill and the regulations arising consequent to the Bill.



Professor Jenny Carryer RN PhD FCNA(NZ) MNZM
Executive Director
College of Nurses Aotearoa (NZ)