Therapeutic Products Bill and Therapeutic Products Regulatory Scheme

Submission to the Ministry of Health

Date: 18 April 2019

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About the New Zealand Nurses Organisation

NZNO is the leading professional nursing association and union for nurses in Aotearoa New Zealand. NZNO represents over 52,000 nurses, midwives, students, kaimahi hauora and health workers on professional and employment related matters. NZNO is affiliated to the International Council of Nurses and the New Zealand Council of Trade Unions.

NZNO promotes and advocates for professional excellence in nursing by providing leadership, research and education to inspire and progress the profession of nursing. NZNO represents members on employment and industrial matters and negotiates collective employment agreements.

NZNO embraces te Tiriti o Waitangi and contributes to the improvement of the health status and outcomes of all peoples of Aotearoa New Zealand through influencing health, employment and social policy development enabling quality nursing care provision. NZNO's vision is *Freed to care, Proud to nurse*.

EXECUTIVE SUMMARY

1. New Zealand Nurses Organisation *Tōpūtanga Tapuhi Kaitiaki o Aotearoa* (NZNO) welcomes the opportunity to comment on the exposure draft of the Therapeutic Products Bill and Therapeutic Products Regulatory Scheme consultation document.

2. NZNO is supportive of the intent of the draft Bill and regulatory scheme to be principles-based, bench-marked internationally, and sufficiently high level to accommodate 'emergent' technology.

3. The lack of detail in the draft Bill, making it difficult to assess how nurses in the four scopes of practice (Nurse Practitioners, Registered Nurse Prescribers, Registered Nurses and Enrolled Nurses) can function within their scope and the proposed regulatory scheme, needs to be addressed by regulations which must be developed in conjunction with health practitioners who can inform regulation development with the complexities and realities of professional practice.

4. Implementation of the proposed changes are of concern to nurses in some areas of practice where, for example, standing orders are used enabling large numbers of services users to receive care. While acknowledging that much more detail will emerge as the 'regulator' is established and the regulatory scheme is rolled out, it is at this juncture that unintended consequences for the everyday practice of nurses and other health professionals may emerge.

5. NZNO has consulted its members and staff in the preparation of this submission, in particular Nurse Practitioners, RN prescribers, professional nurse advisors and the medico-legal team.

6. NZNO has discussed the proposal with the wider nursing sector including the Nursing Council of New Zealand (NCNZ), College of Nurses Aotearoa (CONA) and Office of the Chief Nursing Officer at the Ministry of Health.

7. Stakeholder consultation sessions with Ministry of Health officials have also been attended and we have had the benefit of reading the submission from the New Zealand Medical Association (NZMA).

8. NZNO does not wish to make an oral submission.

CONSULTATION QUESTIONS

This written submission from NZNO is instead of using the online tool and focuses on the impact on nursing practice of the Bill and proposed Regulatory Scheme. It is anticipated that individual nurses, especially those working in prescribing roles will make submissions online and will seek clarity on if and how the Bill and regulatory scheme if enacted will be enabling of their practice.

1) NZNO welcomes the intent of the Bill to:

align the regulation of therapeutic products with how international partners are managing this complex responsibility;

enable nurses to work to the full breadth of their scope thereby improving access to health services and resources particularly in communities with high needs such as rural Māori communities with limited access to doctors, pharmacists and pharmacies and high health literacy needs; and

offer a principles-based legislation that enables regulation, thereby being more responsive to emerging technologies and healthcare trends.

Practice realities for nurses

2) NZNO would like to draw your attention to '*Guidelines for nurses on the administration of medicines',* a comprehensive set of guidelines published by NZNO after wide consultation with the membership and which cover the breadth of situations in which nurses have responsibility for administering and in some cases prescribing medicines. The guidelines include a glossary in which 'standing orders', 'supply' and 'dispense' among other functions are defined (NZNO, 2018). In developing the glossary of definitions, experience tells us that workable definitions are best achieved with health practitioners whose practice is being defined. NZNO expects to be involved in developing these definitions with the regulator.

NZNO members working with '*Guidelines for nurses on the administration of medicines'* include nurse-led clinics, for example eye clinics, and a diabetes service including 4 nurse prescribers with 15 registered nurses working with standing orders. They are seeking clarification on the draft Bill (section 40), 'Meanings of standing order and complying standing order' and are concerned about the impact on their service to care recipients if the way they

use standing orders 'slows' their service delivery and reduces the volume of people they can see in a day.

Nurses working in community palliative care also need reassurance that their ability to access controlled drugs according to the (sudden) changing needs of the terminally ill is not compromised. And members working in appearance medicine who also use standing orders are seeking clarity from legislation on how medicines and medical devices they use routinely will be regulated as they progress the development of standards for the appearance medicine sector which continues to grow significantly.

Legal terminology and interpretation

3) A question has been raised by the NZNO medico-legal team about the intent of section 41 of the draft Bill, specifically 41(5) 'a person who is authorised by a complying standing order to do something is taken to be the *agent* of the person who issued the order'. Is the intent that a nurse using a standing order is *liable* as an agent (ie the prescriber) would be? Currently standing orders are widely used so changes to how nurses (prescribers and non-prescribers) work with these in the new regulations needs to carefully consider the complexities and realities of the practice context.

In addition section 38(4) of the exposure draft states '*a prescription may be issued orally, in writing* ***or*** *in any other form.'* Use of '**or**' indicates that a prescription may be issued but not documented. Is this inclusion intentional? NZNO is often contacted by members with questions about their role in administering prescribed medicines and many of these questions are about documentation or lack of, with respect to what has been prescribed and how the nurse should document actions taken, or not taken.

Opportunity to address existing anomalies

4) The draft Bill and Regulatory Scheme also present opportunities to address anomalies in the current legislation and regulations. For example, the requirement for Medical Officers of Health to authorise registered nurse vaccinators (Medicines Regulations 1984 clause 44A (2)) are archaic and need to be actively removed at this stage so that 'business as usual' is not an unintended consequence of the principles-based approach being presented. Nurses are responsible and accountable for their practice and currently complete a nationally approved and recognised programme to become an authorised vaccinator. They then need to be certified by a medical officer of health to vaccinate in a particular DHB. The requirements of each Medical Officer of Health can differ and a nurse moving from DHB to DHB has to resubmit an authorisation request for each DHB and then be recertified every two years. NZNO strongly recommends the removal of any requirement for Medical Officers of Health to oversee or approve the practice of nurses. The regulations that will follow this legislation should remove this requirement so that certification of nurses as vaccinators is a responsibility of the nursing profession.

5) The timeliness of medicine lists updates also causes concern for members. Recently a drug used in diabetes (vildaglipton) became fully funded but the ability of nurses to prescribe it delayed by the medicines lists maintained by NCNZ, not being updated. With the regulations developed under the Regulatory Scheme enabling regulatory authorities, for example NCNZ, to maintain 'other logical groupings' rather than medicines list, will prescribers and medicines users be sufficiently protected from harm? How will costs of maintaining the 'logical groupings' of medicines and medical devices be split between government and 'industry' which in this case is nursing's regulatory authority?

6) NZNO supports the inclusion of access to category 2 and 3 medicines of non-prescribing RNs. For example, members who are school nurses welcome the greater flexibility this will give them to supply medicines they would otherwise be suggesting a young person or family member purchase from a pharmacy or supermarket, reducing the likelihood that the medicine is accessed.

De-prescribing

7) Another consideration as the regulations are developed is how *de-prescribing* can be facilitated. Appropriately much focus and energy is on safe prescribing. Equally, de-prescribing needs to be enabled as issues such a poly-pharmacy, anti-microbial resistance and the opioid crisis are addressed. All three scenarios are in part the result of inappropriate practice by a number of parties including health practitioners (prescribers and non-prescribers), regulators, manufacturers and retailers. The new regulatory scheme needs to have sufficient regulatory 'muscle' to require change in practice where this is necessary.

8) Direct-to-consumer advertising (DTCA), allowed under the current and proposed legislation, but at odds with the international benchmarking used in the development of the proposals for the regulatory scheme and the Bill, is unlikely to enable de-prescribing. NZNO advocates for the removal of provision for DCTA, primarily because there is no evidence that it improves access to medicines for those individuals and communities with high health and literacy needs.

CONCLUSION

In conclusion, NZNO supports the Bill and has a number of recommendations:

Terms of reference for the regulator should be developed in consultation with those groups, regulatory authorities and professions, including nurses, whose practice will be impacted on a daily basis by the decisions of the regulator.

Groups currently underserved by the current system and legislation resulting in inequitable access to health resources including medicines and medical devices, should be consulted with and then represented in the regulatory scheme.

Anomalies in the current Medicines Act and Regulations, such as the requirement for the Medical Officer of Health to certify nurse vaccinators, should be actively identified and remedied in this process.

Direct-to-consumer-advertising should be discontinued, Aotearoa New Zealand being one of only two developed world jurisdictions that allow this practice for which there is no evidence of benefit to those whose equitable access is already compromised.

Nāku noa, nā

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