



New Zealand Nurses Organisation

Submission to the Government Administration Committee

on the

Therapeutic Products and Medicines Bill

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EXECUTIVE SUMMARY

1. NZNO is supportive of moves toward harmonisation of the Australian and New Zealand therapeutic products and medicines regulatory framework in principle, however, NZNO has major reservations in regard to the regulation of Rongoa (traditional Maori medicines) by non-Maori and until there is an assurance that Rongoa will be exempt as it is under the Medicines Act 1981, then NZNO cannot support the Therapeutic Products component (parts 1 – 5) of the Bill.
2. NZNO supports the need to update the Medicines Act 1981 and its Regulations. NZNO's response proposes that independent nurse prescribers are identified as authorised prescribers and future groups of nurses who may be approved to operate in collaborative prescribing arrangements with medical and nurse practitioners come within the designated prescriber category. NZNO also puts the case that there is no need to describe the circumstances in which a medicine may be prescribed in any prescribing notice prepared by the prescribing authority for the Gazette. These changes will better meet the future health care needs of New Zealanders and rapidly evolving service delivery modalities whilst retaining an appropriate level of regulation and public protection.
3. NZNO would like to make an oral submission.

RECOMMENDATIONS

4. The New Zealand Nurses Organisation recommends that you:
 - **Agree** that, protection of Maori authority over Rongoa regulation is included within the legislation;
 - **note** that, NZNO cannot support the move toward a joint Australia New Zealand Therapeutic Products regulatory scheme and the enactment of the Therapeutic Products Bill until there is assurance that Maori will continue to have authority over Rongoa;

- **agree** that, the inclusion of Te Tiriti o Waitangi/ the Treaty of Waitangi with particular reference to article two in the Therapeutic Products Bill;
- **note** that, NZNO welcomes the update of the outmoded Medicines Act, 1981, and its Regulations;
- **agree** that, Nurse Practitioners with prescriptive authority become authorized prescribers;
- **agree** that, nurses approved to work in collaborative prescribing arrangements with a medical or nurse practitioner are classified as designated prescribers; and
- **agree** that, the requirement for a prescribing notice to specify the circumstances in which listed prescription medicines may be prescribed is removed.

ABOUT THE NEW ZEALAND NURSES ORGANISATION

5. The New Zealand Nurses Organisation (NZNO) is a Te Tiriti o Waitangi based organisation which represents 39,000 nurses and health workers. NZNO is the professional body of nurses and the leading nursing union in Aotearoa New Zealand. Our members include nurses, midwives, students, health care workers and other health professionals.
6. The NZNO vision is “Freed to care, Proud to nurse”. Our members enhance the health and wellbeing of all people of Aotearoa New Zealand through ethically based partnerships. Our members are united in the achievement of their professional and industrial aspirations. Medication management is integral to nursing and midwifery practice and sound legislation will enable safe, effective and timely treatment.
7. NZNO has consulted its members on matters relating to prescribing and administration of medications over many years. NZNO provides educational seminars on medico-legal risk management in regard to medications. NZNO professional nursing and legal advisers are continuously providing advice

around medication management, standing orders and prescribing practice. NZNO has been a leader in development of the nurse practitioner model in New Zealand and in independent nurse prescribing. This background has contributed to the preparation of this submission.

NZNO POSITION

8. The New Zealand Nurses Organisation endorses moves towards greater harmonization of the Australian and New Zealand regulatory framework however cannot support the Bill unless there is assurance that Maori will continue to have authority over rongoa, the provisions include the Treaty of Waitangi particularly article two, and that Nurse Practitioners are deemed authorized prescribers.

THERAPEUTIC PRODUCTS (Sections 1-5)

9. NZNO is supportive of greater Trans-Tasman harmonization of the regulation of therapeutic products. NZNO members believe that greater standardization of the scheme will benefit patients and health professionals who frequently share information between the two countries and work in both jurisdictions.
10. However, NZNO has grave concerns in regard to the potential impact of a joint regulatory body having authority over the New Zealand jurisdiction and, in particular, undermining the authority of Maori as Tangata Whenua over rongoa. In its current form the Therapeutic Products Authority is not required to recognize the relationship that the New Zealand Crown has with Maori and does not recognize the place of Te Tiriti o Waitangi. There is no guarantee that the current exemption of rongoa under the Medicines Act 1981 will continue and the draft Medicine Rules do not guarantee such exclusion.
Until this matter is addressed NZNO cannot support the enactment of the Therapeutic Products Bill.

11. NZNO is pleased that the proposed legislation (clauses 62 – 67) will strengthen the advertising controls on therapeutic products. NZNO has previously submitted on the need for greater control of advertising prescription medications.
12. Likewise, NZNO is pleased that clause 73, product tampering, has been enhanced in the Bill.

MEDICINES (Parts 6 – 7)

13. NZNO acknowledges the need to update the Medicines Act 1981 and its Regulations. In particular, NZNO is supportive of the different approach taken, that is moving towards providing that an activity can be undertaken unless it is prohibited. Nursing systems and roles have changed significantly in the last two decades and at times these changes have resulted in difficulties complying with the current, outmoded legislation. This situation has, at times, resulted in delays to timely medication management for patients. Nursing will continue to evolve to meet changing health need and service developments. An enabling approach within the legislation will result in improved access to timely intervention and the quality of care.

Supply of scheduled medicines other than by wholesale (clauses 351, 356 and 358)

14. NZNO fully supports the inclusion of these clauses. The supply of medicines by a nurse has been a grey area under the previous legislation. The clauses will enable nurses to supply medicines, such as the Emergency Contraceptive Pill (ECP), without the issue of a separate gazette notice as was the case for the ECP Gazette Notice, 4 October 2001. Improved responsiveness to patient needs will result, for example, public health nurses will be able to supply medicines accordingly rather than delaying treatments until a medical practitioner can be located to prescribe the medication.

Standing Orders (clause 381 and transitional arrangements 520)

15. NZNO supports the clause 381 and the transitional arrangements within clause 520. Further, NZNO is pleased that the current Regulations are under review as NZNO's research into the utility of the Standing Orders Regulations showed that they are problematic in a number of areas. NZNO has made submissions on the Regulations review. NZNO has previously submitted on the need for Nurse Practitioners to issue standing orders from time to time. This will be enabled by Nurse Practitioners being classified as authorized, not designated, prescribers (see section below).

Authorized and Designated Prescribers

16. This is the area of the Bill that provides real concerns from NZNO members and one where NZNO seeks substantial change. Key changes sought are in relation to Nurse Practitioners and including them as authorized prescribers rather than designated prescribers.

17. The case for independent nurse prescribing was well made prior to the amendments to the Medicines Amendment Act, 1999, and again during the extensive consultation period prior to the Medicines (Designated Prescriber: Nurse Practitioners) Regulations, 2005. International evidence is conclusive in the safety of Nurse Practitioner prescribing. (References can be provided on request). The first New Zealand Nurse Practitioner prescriber was registered under the 2003 Regulations and so there is a history of safety in Nurse Prescribing for some years and no concerns over nurse prescribing practices have been raised.

18. Nurse Practitioners provide accessible, timely and effective treatment to their client populations, however, having a positive list of medications from which to prescribe has its problems.

19. Firstly, for a number of Nurse Practitioner prescribers, the list is not complete and they have the situation of being able to independently prescribe a range of medications, but having to work under standing orders for others. An example of this is the neonatal nurse practitioner able to manage neonate's

care and treatment in a similar way as a Registrar, but not being able to prescribe the drugs required for intubation if the neonate requires it. Standing orders have to be used for this standard neonatal intensive care procedure, well within the scope of practice of a Nurse Practitioner - Neonatology. This mixed model is flawed and frustrating to all in the health team.

20. Secondly, there are difficulties and delays in having lists changed as availability of medications and advances in treatment occur. This reduces the responsiveness and effectiveness of Nurse Practitioners and constrains best practice unnecessarily.
21. Thirdly, it is also a resource-intensive process to meet the requirements set out in clause 373, prescribing notices, and when extensive research has already identified the safety of independent nurse prescribing then one questions the value in this process. The requirement for notices to not only set out the medicines or classes of medicines **but also** the circumstances in which those prescriptions may be prescribed is onerous and prohibitive. The current Medicines (Designated Prescriber: Nurse Practitioners) Regulations 2005 lists 1379 medications. Setting out the circumstances is not currently required. To expect that the circumstances will be set out for each of these medicines is unreasonable and unnecessary. Nurse prescribers have been found to be both conservative and safe in their prescribing practices, referring on appropriately. They are highly experienced and trained professionals, very well aware of their scope of practice.
22. Registered Nurse Practitioners with prescriptive authority in their area of practice have undergone extensive preparation. Not only have they had to work in that particular area of practice for a minimum of five years as a Registered Nurse, they are Masters prepared in advanced practice (this is not the case for other health practitioners who are authorized prescribers) and have undertaken post-graduate papers in advanced clinical assessment skills and prescribing. There is an equivalency between their educational preparation for the prescribing role and other authorized prescribers such as

midwives. The registration process itself involves completion of a clinical Masters with approved prescribing papers, a year long prescribing practicum working alongside a prescriber within the specialty, an extensive written portfolio application demonstrating specified criteria and an extensive interview and clinical viva by a panel of experts. This process is rigorous and assures the public of competency to become an authorized prescriber. There is a sound case for Nurse Practitioners with prescriptive authority to be identified under the authorized prescriber definitions and clauses.

23. Currently there is an emerging national discussion about collaborative prescribing arrangements between specified doctors and expert specialty nurses to increase access and responsiveness to patient care. For example, the Society of Anaesthetists met with NZNO officials during 2006 to discuss the feasibility of nurse specialists in pain management having limited prescriptive authority in collaboration with a medical practitioner. NZNO has long advocated a continuum of medication management by nurses which includes independent prescribing, collaborative prescribing, operating under standing orders, and administration from prescription. There has been further discussion within the Ministry of Health centred on limited prescriptive authority for specialized expert nurses.

24. The shift in Nurse Practitioners with prescriptive authority (note: not all Nurse Practitioners are registered as independent prescribers) to the authorized prescriber category will enable the designated prescriber category to be used for nurses who would work in collaborative arrangements with named medical or nurse practitioners. This would be a clear differentiation between the two categories of nurse prescribers and would be enabling for future health service delivery options which would deliver on better health outcomes. Nurse Practitioners with prescriptive authority would be authorized prescribers; nurses approved to work in dependent, collaborative prescribing arrangements would be designated prescribers.

STRATEGIES AND SOLUTIONS

25. NZNO recommends the following suggested changes, or solutions for achieving the purpose of the Bill.

- a) That Maori authority over rongoa regulation is protected;
- b) That the Treaty of Waitangi be included in the provisions
- c) That Nurse Practitioners with prescriptive authority become authorized prescribers;
- d) That the designated prescriber category is used for nurses who will be regulated to work in collaborative arrangements with medical and nurse practitioners;
- e) That all relevant clauses are changed to reflect recommendations c) and d); and
- f) That the requirement for a prescribing notice to specify the circumstances in which listed prescription medicines may be prescribed is deleted (c373).

CONCLUSION

26. NZNO is supportive of moves toward the introduction of the Australasian therapeutic products scheme and the proposed Therapeutic Products Act **only** if there is recognition and protection of Maori authority over rongoa. NZNO welcomes the legislation updating the Medicines Act 1981 however proposes significant changes in the authorised and designated prescriber categories. This includes shifting Nurse Practitioner prescribers to the authorised prescriber category and enabling new dependent prescribing groups of nurses working in collaboration with medical and/or nurse practitioners to be entered into the designated prescriber group. The other change recommended is in regard to the requirements for a prescribing notice by the prescribing authority.

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REFERENCES

Literature on the safety and efficacy of nurse prescribing can be provided on request.