



**New Zealand Nurses Organisation (Inc.)**

**Submission to the Joint Agency  
Establishment Group  
Medsafe**

**On the**

**Australia New Zealand Therapeutic  
Products Regulatory Scheme Rule 2006  
(Medicines)**

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## **Introduction**

1. The New Zealand Nurses Organisation (NZNO) is a Te Tiriti o Waitangi based organisation which represents 39,000 members. NZNO is the leading professional body of nurses and nursing union in Aotearoa New Zealand. Our members include nurses, midwives, students, health care workers and other health professionals.
2. The regulation of medicines, other therapeutic products and therapeutic devices is of importance to members because
  - Nurses, midwives and healthcare workers administer therapeutic products, provide patient education and monitor their effect
  - Midwives and Nurse Practitioners with prescriptive authority prescribe medicines.
3. NZNO staff attended the June 2006 consultation meetings. NZNO staff and members have been consulted in the preparation of this submission.

## **General Comment**

4. NZNO welcomes the introduction of an Australasian approach to regulation and the staged consultation process. In this August 2006 consultation round NZNO will be forwarding submissions on the draft
  - Administration and Interpretation Rule 2006
  - Medical Devices Rule 2006
  - Medicines Rule 2006

This submission relates to the draft Medicines Rule.

5. Please note that NZNO will not make submissions to those sections of the Rule covering licensing, manufacturing or auditing, but will direct its submission to:
  - Part 5, Exemption from standards and licensing
  - Part 7, Product and consumer information documents,
  - Part 8, Obtaining information,
  - Part 9, Adverse event reporting, and
  - The Schedule.
6. In general, NZNO is supportive of the draft Rule with the key recommendations relating to changing clauses specifying prescriber disciplinary groups to authorised health practitioner, and thus taking into account new prescriber groups, including Nurse Practitioners and midwives, and addressing the medicines compliance matters in relation to exemptions outlined in point 8 of the submission.

### **Specific Comment**

#### 7. New Prescriber Groups

This draft Rule omits any recognition that there are new prescriber groups emerging, inclusive of Nurse Practitioners with prescriptive authority.

**NZNO recommends that the Rule is enabling of, and does not restrict, new prescribing groups, including Nurse Practitioners with prescriptive authority. The recommended term to replace medical practitioner or other prescribing practitioner referred to in the rule is “authorised health practitioner”.**

#### 8. Division 5.3 Exemptions

NZNO notes that Sections 5.04 and 5.05 are similar to intent to Section 29 of the Medicines Act 1981. Currently, administration of medicines under Section 29 is common. The use of some medicines for certain therapeutic treatments has become standard practice nationally and internationally, and yet individual application for exemption under Section 29 continues to be required

each time these medicines are used for these particular purposes. NZNO sees the introduction of this legislation as being an opportunity to address this bureaucratic process for standard treatments.

One example of such a medicine is IV digoxin. In the 2005 New Zealand Guidelines Group *Guidelines for the Management of Atrial Fibrillation and Atrial Flutter* (p6) IV digoxin is administered frequently in emergency departments. IV digoxin is currently a Section 29 drug.

**NZNO recommends that the Joint Agency Establishment Group gives urgent consideration to amending the Rule so that standard treatments such as those cited above can be exempt from the exemption provisions of 5.04 and 5.05.**

9. Parts 7, 8 and 9

NZNO supports the clauses outlined within these parts of the Rule.

10. Schedule 4, Part 2, 8. Conditional exemptions

NZNO is pleased that this section is inclusive of all medical team members. It is often nurses who accompany patients from one international jurisdiction to another.

## **Conclusion**

11. The NZNO thanks the Joint Agency Establishment Group for the opportunity to submit on this consultation document.

12. NZNO is generally supportive of the proposed Medicines Rule 2006 with further consideration being given to recognition that

- there are new prescriber groups emerging and
- the exemptions should not apply to internationally recognised standard treatments as described in this submission.