



New Zealand Nurses Organisation (Inc.)

Submission to the Joint Agency Establishment Group Medsafe

On the

Australia New Zealand Therapeutic Products Regulatory Scheme Rule 2006 (Administration and Interpretation)

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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 responds to the draft Administration and Interpretation Rule.

5. Of particular note for NZNO in the three draft documents is the lack of acknowledgement that there are new prescribing groups of health professionals including midwives and Nurse Practitioners with prescriptive authority. Rules of the ANZTPA regulatory scheme need to recognise that these new prescribing groups have a positive contribution to make in the scheme.

NZNO recommends the Rules are inclusive, and not exclusive, of new prescribing groups of health practitioners.

6. NZNO notes that the draft for consultation Administration and Interpretation Rule 2006 is incomplete and that further sections of the proposed Rule are under development and will be consulted upon in the next phase of consultation documents.

Specific Comment

7. Part 8 Committees

7.1. NZNO supports the establishment of Expert Advisory Committees (EAC) to provide the Authority with scientific and regulatory advice.

7.2. NZNO foresees that there is potential overlap in the role and functions of the EACs for prescription and OTC medicines. Many OTC medicines may also be prescribed medicines.

NZNO recommends that the Joint Agency Establishment Group reviews the decision for separate EACs on prescription medicines and OTC medicines.

7.3. Division 8.2, 8.07 Requirements for associate members.

NZNO recommends that a Nurse Practitioner with prescriptive authority be included within clause 8.07 (2). This position would enhance the contributions made by the associate members by providing input from

- A new prescribing group, and
- The professional discipline which provides the major patient medication education and monitoring role.

7.4. Division 8.3, 8.12 (2), Constitution of the EAC on OTC medicines. NZNO has proposed that the EACs for prescriptive and OTC medicines be combined, however, in the event of them remaining as separate entities, NZNO proposes that an experienced family or primary health care nursing expert would make a positive contribution to this EAC and should be included within the list.

7.5. Division 8.6. NZNO notes that the section on the EAC on Adverse Reactions to Medicine is yet to be finalised and will reserve any comment until the next round of consultation.

7.6. Division 8.9, 8.39, Appointment of Members.

NZNO is concerned that the most appropriate experts are recommended for appointment and believes that the professional bodies are the most appropriate groups to provide that input to the Authority. A fair and transparent process, inclusive of professional groups, is required.

NZNO recommends a new clause be inserted after 8.39 (1) which reads the authority is requested to consult with appropriate professional bodies prior to making a recommendation to the Ministerial Council.

8. Part II, Miscellaneous

8.1 11.03 Delegate exemption for special purpose

NZNO is concerned that situation that currently exists where medicines that have become, or will become, standard treatments but require an approval under Section 29 of the Medicines Act 1981, is addressed in this legislation.

Further detail is provided in NZNO's submission on the draft medicine rule,

point 8. Further, NZNO seeks clarity on 11.03 (2) (b) (ii). In New Zealand there may be an institutional ethics committee and an approved regional ethics committee.

8.2 11.04, 11.05, 11.06 These sections exclude Nurse Practitioners with prescriptive authority in their scope of practice.

NZNO recommends that an authorised Nurse Practitioner with prescriptive authority is included in these exemption clauses.

9. **Schedule I, Part 1, Definitions**

NZNO recommends that Nurse Practitioner with prescriptive authority is added to the list.

10. **Conclusion**

The NZNO thanks the Joint Agency Establishment Group for the opportunity to submit on this consultation document. NZNO is generally supportive of the proposed Administration and Interpretation Rule 2006, with reconsideration being given to the potential role of new prescribing groups within the Australian New Zealand Therapeutic Products Regulatory Scheme.