



New Zealand Nurses Organisation (Inc.)

Submission to the Joint Agency Establishment Group Medsafe

on the

Australia New Zealand Therapeutic Products Regulatory Scheme Rule 2006 (Medical Devices)

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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 Medical Devices Rule.

Specific Comment

5. While NZNO acknowledges that the introduction of regulation of medical devices in New Zealand is necessary for public safety, there is concern that compliance costs will significantly increase health treatment costs, thus reducing access to treatment. NZNO is unaware that there has been any significant problem or failure of medical devices within New Zealand. NZNO recognises that the majority of companies are meticulous in their development and testing of medical devices.

NZNO recommends that the standards, licensing and monitory processes for medical devices are streamlined, imposing minimal compliance costs on companies.

Conclusion

6. NZNO's submission does not comment directly on the Rule which deals mainly with product licensing, but the potential impact the introduction of the Rule will have on New Zealand's health services. In NZNO's view the regulatory scheme should be developed to minimise compliance costs for companies which will flow on to health consumers.