



RMI SUBMISSION ON THE AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS REGULATORY SCHEME (ADMINISTRATION AND INTERPRETATION) RULE 2006

EXTRACTS RELATING TO THE SCHEDULING OF THERAPEUTIC SUBSTANCES

PREAMBLE

The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of New Zealand's research-based pharmaceutical industry. Its 18 member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of medical and scientific knowledge about their products.

SUBMISSION

It is the understanding of the RMI that New Zealand will only adopt the schedules for pharmacy only, pharmacist only and prescription medicines and that the Misuse Use of Drugs Act (1975) schedules will be retained. The Misuse of Drugs Regulations (1984) prescribe specific labelling requirements for controlled drugs in New Zealand including stating the scheduling of the medicine. Thus, to ensure that a single, harmonised pack can be distributed in both countries it will be necessary for affected packs to carry two signal headings on the principal display panel (PDP) or, where practical, have two PDPs per pack.

The RMI strongly recommends that the labelling of medicines listed in the Schedules to the Misuse of Drugs Act 1975 be permitted to have two signal headings to ensure compliance with the MODA while allowing harmonisation of labelling under the ANZTPA.

Division 8.7 Medicines Scheduling Committee

Subdivision 8.7.2 Establishment, functions and constitution of Committee

8.34 Constitution

The RMI acknowledges that the Medicines Scheduling Committee (MSC) will be an expert committee and not a representative/jurisdictional committee. However, the RMI is concerned that as each Australian State/Territory and New Zealand are entitled to nominate a person for appointment to the Committee there will be a tendency to nominate persons with expertise in the regulation of substances. If this occurs, the Ministerial Council would need to appoint a further 6 experts to ensure the MSC has the full mix of expertise listed in

subsections (3) and (6). Subsection (7) notes that "...it is intended, as far as reasonably practical, the membership of the Committee should include the widest possible range of the qualifications mentioned in subsection (3)". Further, the RMI is concerned that the functioning of the Committee may be compromised if any one area of expertise dominates the Committee.

The RMI is also concerned that a larger committee (15 or 16 members) may be less efficient and will be more expensive than a committee of 12 members. Indeed, the RMI considers that the minimum size of the Committee should be 10, which was the minimum size proposed during the consultation in 2005.

The RMI recommends that the Authority, New Zealand and each State or Territory be permitted to nominate one person qualified in each of the ways indicated in subsection (3) and from these nominations the Authority can recommend the appointments to ensure the Committee has the widest possible range of expertise and is balanced.

The RMI recommends that the minimum number of members on the Committee be 10.

The RMI recommends that stakeholders have the opportunity to provide the Authority with nominations for the MSC where appropriate, e.g. industry is well placed to provide nominations for a member with expertise in industry issues.

Division 10.4 Rescheduling of substances

When the Authority decides on its own initiative to reconsider the scheduling of a substance, or receives a proposal for rescheduling which is not from the Product Licence holder(s), the Product Licence holder will wish to make a submission either in support or opposition to the proposal. The RMI considers that the time needed by industry to develop an effective submission is 3 months.

The RMI recommends that the Authority notify affected Product Licence holders as soon as practicable after a proposal for rescheduling of a substance is received; and that there is a minimum of 3 months from this notification and the closing date for public submissions.

Division 10.5 Notification and reconsideration of scheduling decisions

10.21 Submissions for reconsideration

(3) A submission for reconsideration of a scheduling decision that was made as a result of a proposal by a person for the scheduling or rescheduling of a substance must not be on the basis of data not submitted in relation to the proposal.

This subclause lacks readability and, therefore, clarity. The RMI proposes that it be altered to read as follows:

"(3) "A submission for reconsideration of a scheduling decision of a substance must be on the basis of data submitted in relation to the original submission".

