

**MEDSAFE PROPOSALS TO AMEND ASPECTS OF  
NEW ZEALAND'S MEDICINES LAW  
NOVEMBER 2002**

**SUBMISSION BY RESEARCHED MEDICINES INDUSTRY  
ASSOCIATION OF NEW ZEALAND INCORPORATED**

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9 January 2002

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**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 24 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.

This submission focuses on those aspects of the Medsafe discussion document that have a direct impact on the activities of RMI member companies. Hence, comments have been limited to those sections of the discussion document that relate to the prescribing, dispensing and wholesaling of prescription medicines.

**PRINCIPLES UNDERPINNING THE PROPOSED AMENDMENTS**

RMI agrees with the general principles underpinning the proposed amendments. RMI supports the regulation of therapeutic products commensurate with the level of potential risk, but is keen to see such regulation achieved without imposing excessive compliance costs or unduly restricting consumer choice.

**ISSUE: INTERNET SALES OF PRESCRIPTION MEDICINES**

**Question 4: Do you agree that Internet sales of prescription medicines should be prohibited, unless pursuant to a licence issued under the Medicines Act?**

RMI supports the proposal to prohibit the exportation of prescription medicines unless the exporter is suitably licensed and the sale is consistent with the licence.

**ISSUE: ELECTRONIC PRESCRIBING**

**Question 5: Do you agree that New Zealand's medicines law should enable electronic prescribing?**

RMI supports the development of mechanisms to enable electronic prescribing of medicines, provided appropriate safeguards (patient privacy, security, etc.) are met.

**ISSUE: INFORMATION REQUIREMENTS FOR PRESCRIPTIONS**

**Question 9: Are there any other information requirements you think are necessary for prescriptions...?**

RMI recommends that the "appropriate information about the medicine being prescribed" should, where appropriate, include the Trade Name of the product. This is important for narrow therapeutic index medicines where there would be safety concerns if the wrong proprietary brand was dispensed. Also, for other products where the prescriber clearly wishes a particular medicine to be dispensed, rather than a generic equivalent.

**ISSUE: SUBSTITUTION OF MEDICINES**

**Question 17: Do you agree that medicines legislation should enable regulations of guidelines to be developed so that pharmacists could substitute medicines in certain circumstances?**

**Question 18: If so, in what circumstances should this be allowed?**

Although RMI acknowledges that substitution of branded medicines with generic equivalents may be appropriate in certain circumstances, RMI does not support automatic substitution by the pharmacist without the direct input of the prescriber and the informed consent of the patient.

As the discussion document correctly states, matters of convenience must be secondary to the primary imperative of ensuring public safety. While generic products published by Medsafe on the interchangeable multi-source medicines (IMM) list have been assessed against recognised safety, quality and efficacy parameters, there have been notable examples in recent years of IMM listed products failing to meet the standards of the innovator products.

Switching between different “equivalent” products can undermine confidence of patients in their medicines, which may adversely affect patient compliance and ultimately clinical efficacy. This situation may be compounded by the PHARMAC tender processes, whereby the medicine granted sole-supply status may change after each tender round.

Hence, RMI proposes that for any prescription the actual medicine stated on the prescription form should be dispensed, whether that is a branded or generic medicine, i.e. the “default” should be to *not* substitute, rather to automatically substitute. Where a branded medicine has been prescribed, a generic equivalent should only be dispensed where:

- the pharmacist has received a written authorisation from the prescriber to routinely dispense generic equivalents of branded products, or the pharmacist has directly contacted the prescriber for permission to substitute;
- the substituted product is included on the IMM list; and
- the prescriber has discussed the issue of substitution with the patient, and the patient has consented to receiving another product on the IMM list.

Even where the prescriber has authorised the routine dispensing of generic equivalents of branded products, the prescriber must have the option in individual cases to state “no substitution” on the prescription form.

#### **ISSUE: GENERAL LICENSING LAW NOT COVERED BY THE JOINT AGENCY PROPOSAL**

**Question 25: Do you agree that it is appropriate to roll over much of current licensing law that will not be regulated by the joint agency proposal, or are there aspects you would like to see changed?**

RMI supports the proposal to develop different categories of wholesaler licences. As recently conveyed to Medsafe in a separate communication, RMI recommends that details of wholesaler licences be placed on the Medsafe website. In this way, companies can be assured that controlled drugs or other products that may be subject to misuse (e.g. containing pseudoephedrine) are being supplied to *bone fide* wholesalers.

RMI has concerns about the bulk exporting of medicines by pharmacists holding a wholesaler licence. Large orders of e.g. 1000 units can be shipped to overseas countries, without any patient involvement, but the practice is not illegal because the pharmacist is acting as a wholesaler supplying another wholesaler. This is different from the Internet sales issue but the RMI would like to see it controlled in a similar manner.

RMI supports the proposal to replace licences for individual hawkers with a system whereby the companies are responsible for maintaining a record of hawking activities, as a condition of their wholesaler licences. As in many other areas, RMI considers that self-regulation by the industry is the most effective method of control.

**ISSUE: ACCOMMODATING NEW DEVELOPMENTS AND DOCUMENTATION PROCESSES**

**Question 28: Are there parts of the current law regarding information requirements or record keeping that you consider need to be modernised ...?**

RMI supports the proposal to allow those authorised to possess, handle and deal in Controlled Drugs the option to use an appropriate computer record keeping system.

**ISSUE: PENALTY PROVISIONS**

**Question 30: Are there any penalties in the Medicines Act that you consider need reviewing?**

RMI supports the proposal to review and overhaul the penalties for breaches of the medicines legislation. The level of penalty should primarily be commensurate with the level of risk placed on consumers as a result of any breach.

**ISSUE: GENERAL FEEDBACK ABOUT NEW ZEALAND-SPECIFIC MEDICINES LAW**

**Question 33: If you have a New Zealand-specific medicines law issue not covered in this document, please give specific details of the issue, relevant law and any proposed solution**

RMI notes that the discussion document “does not seek to initiate significant new policy reviews, consider significant policy issues being developed in other contexts, or revisit policy decisions recently implemented”. However, RMI considers that this would be an opportune time to review certain parts of the existing legislation that have caused difficulties for both the industry and the regulatory authority. A number of issues have been subject to discussions between industry and Medsafe over many years, without satisfactory resolution.

RMI recommends that the following issues be considered as part of the current review of legislation. Please note that time constraints have precluded a full work-up of the background to these issues and recommended solutions. In due course, RMI would be pleased to provide a more detailed submission and recommendations on these issues.

### **Labelling**

RMI notes that the discussion document states “Where possible, opportunities to consolidate or make the law more consistent should be taken.” In view of the recent development of the proposals for a trans-Tasman agency to regulate therapeutic products, it would be appropriate to amend the New Zealand labelling requirements, in order to *fully* harmonise with Australian requirements. Previous attempts to allow greater harmonisation of labelling fell short of allowing all products to use packaging that could be used in both countries. Although this may be covered by new legislation for the trans-Tasman agency, an early provision for trans-Tasman packaging would smooth transition to the new regulatory regime. Any changes should ensure consistency of labelling requirements for Controlled Drugs between the Medicines legislation and Misuse of Drugs legislation.

### **Reclassification of medicines**

Following recent problems highlighted by the change of classification for insulins, RMI would like to see a review of the stock-in-trade provisions for the use of medicines following re-classification. Currently there is some ambiguity between the provisions of Regulation 16(2) of the Medicines Regulations (within 3 months of re-classification) and Section 105(6) of the Medicines Act (within 12 months of a Regulation change). Note that a Gazette notice for re-classification is a “temporary” measure, since the Minister is required to follow that up with a Regulation change within 6 months (Section 106(3) of the Act). Hence, one could argue that suppliers have 12 months to use up re-classified stock, commencing from the date of the subsequent Regulation change. RMI recommends that a suitable compromise would be to allow a 6-month stock-in-trade provisions following re-classification.