

**THERAPEUTIC PRODUCTS AND MEDICINES BILL**  
**SUBMISSION TO GOVERNMENT ADMINISTRATION**  
**SELECT COMMITTEE**  
**BY THE RESEARCHED MEDICINES INDUSTRY**  
**ASSOCIATION OF NEW ZEALAND**

**7 FEBRUARY 2007**

*The Association wishes to also make an oral submission.*

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## **THERAPEUTIC PRODUCTS AND MEDICINES BILL**

### **SUBMISSION TO GOVERNMENT ADMINISTRATION SELECT COMMITTEE BY THE RESEARCHED MEDICINES INDUSTRY ASSOCIATION OF NEW ZEALAND**

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#### **1. INTRODUCTION**

- 1.1 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.
- 1.2 In addition to this written submission, the RMI wishes to make an oral presentation to the Government Administration Committee on this Bill. Appearing before the Committee on behalf of the RMI will be Dr Pippa MacKay, Chairman; Lesley Clarke, Chief Executive Officer; and Debbie Wyber, Manager, Technical & Scientific Affairs.

#### **2. OVERVIEW**

##### **2.1 General**

- 2.1.1 The RMI strongly supports the establishment of the joint Australia New Zealand Therapeutic Products Authority (ANZTPA) for the regulation of therapeutic products in New Zealand and Australia. The establishment of the ANZTPA provides the opportunity for New Zealand to be an equal partner in a world class medicines regulator which meets standards of international best practice.
- 2.1.2 RMI companies are principally involved in the prescription medicines sector of the industry. However, the RMI supports the risk-based regulation of all therapeutic products - including medical devices and complementary medicines, which are

currently unregulated in New Zealand. Risk-based regulation of all therapeutic products will bring New Zealand in to line with international standards and assure consumers of the safety, efficacy and quality of all therapeutic products they use.

2.1.3 The current system of medicines regulation in New Zealand is not sustainable. New Zealand's medicines regulator, Medsafe, does not have the regulatory capacity, today, to evaluate the quality, safety and efficacy of innovative new medicines in a timely manner. Figures provided by Medsafe (personal correspondence), for applications completed in 2005, show that the average time taken to evaluate a new high-risk medicine application in New Zealand was more than 3 years compared to only 15 months in Australia (refer TGA website). The ANZTPA will increase the technical expertise and regulatory capacity available to both New Zealand and Australia at a time when the evaluation of innovative new medicines is becoming increasingly more complex.

2.1.4 Together, New Zealand and Australia can, as equal partners, provide sufficient critical mass to ensure that therapeutic products have been evaluated in a timely manner for safety, quality and efficacy to standards that meet international best practice.

## **2.2 Governance**

2.2.1 The RMI strongly supports the governance structure of the ANZTPA whereby the Ministerial Council, comprising the Australian Minister and the New Zealand Minister, oversees the Agency and the Scheme and requires that all decisions of the Ministerial Council be made with the agreement of both Ministers. This will ensure the Scheme is truly a 50:50 partnership between New Zealand and Australia.

2.2.2 The RMI also supports the Rules and Orders being subject to disallowance by either Parliament as further ensuring New Zealand retains its sovereignty.

## **2.3 Funding**

2.3.1 The ANZTPA will evaluate all therapeutic products (including medical devices and complementary medicines, which are currently unregulated) using a risk-based approach. Risk-based regulation is supported by the RMI as being appropriate - for example, dietary supplements do not require the same level of regulation as prescription medicines and the cost of regulation of such products will also reflect this.

2.3.2 The evaluation of innovative prescription medicines to meet standards of international best practice is rigorous and is associated with high costs. In August 2006, Medsafe increased its fee for evaluation of an innovative new medicine from \$15,300 to \$122,165. The New Zealand market is very small and access to the market is significantly limited under the current reimbursement system. Thus, for many innovative prescription medicines it would not be considered viable to seek approval to supply the medicine

only in New Zealand. However, under the ANZTPA a product will potentially have access to a single trans-Tasman market of 24 million people.

2.3.3 Funding of the Authority is not specifically covered in the Bill but the Agreement states in Article 15 that “the fees and charges shall be designed to recover the full cost of the Agency’s operations under the Scheme...”. Once the legislation is passed in both countries the Agreement will be ratified and come into force.

2.3.4 The RMI accepts cost recovery, via fees and charges, of direct regulatory activities only, e.g. evaluation fees. The RMI does not support full cost recovery of the Authority’s operations from industry through fees and charges. The RMI strongly recommends that consideration is given to the public good aspect as detailed in the New Zealand Treasury’s “Guidelines for Setting Charges in the Public Sector: December 2002”, Clauses 3.1 and 3.2.1 (See Appendix 1).

2.3.5 Further, the public good aspect of therapeutic products is tacit in the Government’s support packages provided for the New Zealand complementary medicines and medical devices sectors.

**The RMI strongly recommends that under the ANZTPA, cost recovery from industry is limited to direct regulatory activity and that the costs associated with public good are recovered from the community as a whole.**

## 2.4 Issues

2.4.1 There are three sections within Parts 1-5 of the Bill which the RMI strongly recommends are revised:

- Clause 62 Publishing or broadcasting proscribed advertisements
- Clauses 180-184 Protected Active Ingredient Information
- Clauses 273-304 Transitional provisions relating to scheme

2.4.2 The RMI’s concerns and recommendations regarding these sections are detailed below.

### **THERAPEUTIC PRODUCTS AND MEDICINES BILL**

#### ***Clause 62 Publishing or broadcasting proscribed advertisements***

*(1) In this section, **proscribed advertisement** means an advertisement about a therapeutic product that does any of the following:*

*(d) targets people who are not healthcare practitioners and makes claims about an active ingredient in a therapeutic product:*

The RMI is extremely concerned that the wording of Clause 62 (1) (d) makes it illegal to advertise to consumers **any** therapeutic product, be it a prescription medicine or a dietary supplement, where the advertisement makes a claim about an active ingredient.

**The RMI strongly opposes any section of legislation which would ban direct-to-consumer advertising of prescription medicines in New Zealand.**

Annette King, in a press release on 6<sup>th</sup> December 2006 announcing that the Therapeutic Products and Medicines Bill had been tabled in the House, stated "Direct to consumer advertising (DTCA) of prescription medicines will continue to be permitted".

Further, advice (personal communication) from the Ministry of Health in regard to Clause 62 stated that "the provision is not designed to make DTCA an offence. The operative words in the provision are 'active ingredient'. For this provision to prevent DTCA it would need to say 'makes claims about a therapeutic product'."

However, Clause 6 of the Bill and Article 1 of the Agreement give the following definition for therapeutic product:

"therapeutic product: (a) means:

(ii) an ingredient or component in the manufacture of a product referred to in subparagraph (i)"

where subparagraph (i) defines therapeutic product as "a product that is .....likely to be taken for a therapeutic use".

**The RMI strongly recommends that Clause 62 (1) (d) be reworded to ensure that direct to consumer advertising of therapeutic products, specifically prescription medicines, is retained in New Zealand.**

### *Part 3 Administrative law matters*

#### *Clauses 180-184 Protected Active Ingredient Information*

Clauses 180-184 outline New Zealand's ongoing commitment to data protection under the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

Clause 184 (1) ensures that Clauses 23B and 23C of the Medicines Act continue to apply to all confidential supporting material supplied before the date on which the transitional provisions of the scheme come into effect. However, Clause 184 (2) states:

(2) *To avoid doubt, nothing in this section applies to information received by the Australian Therapeutic Goods Agency before its disestablishment, even if the information is the same as the confidential supporting information received by Medsafe.*

The RMI understands that, in some instances, material received by the TGA may no longer be protected under the TRIPS agreement (i.e. it is outside the protected periods) and therefore the Authority can use this data for approving a generic medicine.

However, the RMI believes that the supply of such a generic product in New Zealand, prior to the end of the data protection period in New Zealand, would contravene the obligations of New Zealand, as a WTO member country, under the TRIPS Agreement.

**The RMI recommends that Clause 184 of the Bill be amended to reflect that a supplier can market a generic product in Australia only, following the expiry of the Australian data protection period, until such time as the data protection period ends in New Zealand.**

### *Part 5 Regulations, and transitional and miscellaneous provisions*

#### *Subpart 2 Transitional provisions relating to the scheme*

The RMI acknowledges that the transitional provisions in the Bill generally take a practical approach to facilitate the transition of medicines with an existing or pending consent in New Zealand into the joint scheme.

Some products with a transitional approval will require variations to be made to the licence e.g. safety data, change of manufacturing site, etc, prior to a full ANZTPA product licence being able to be applied for and granted. The timing of such changes is not determined by the local licence holder.

**The RMI strongly recommends that variations to transitional licences be permitted by the Authority.**

Similarly, clinical trials approved under Section 30 of the Medicines Act may need to be modified. The RMI acknowledges that the Medicines Act will be repealed and therefore, modifications will not be able to be made under Section 30 (as noted in Clause 294). However, this should not require that a new clinical trial application be submitted.

**The RMI strongly supports the ability for clinical trials, with transitional approval, to be modified/varied under the Rules of the ANZTPA**

## **3. ADDITIONAL COMMENTS**

### **3.1 Clause 3 Object**

Subject to qualification, as provided in this submission, the RMI supports the establishment of a joint scheme between New Zealand and Australia for the regulation of therapeutic products.

### **3.2 Part 1 Preliminary, and Rules and Orders Clause 4 Purpose of Parts 1 to 5**

Consistent with international best practice, the RMI supports the risk-based regulation of all therapeutic products under the Scheme - prescription and non-prescription medicines, complementary medicines and medical devices - ensuring New Zealand consumers can have confidence in the safety, efficacy and quality of all therapeutic products.

### **3.3 Clause 5 Overview of Parts 1 to 5**

*Subclause (2):* The RMI acknowledges that while the ANZTPA will be established under Australian law to give it legal entity, the ANZTPA will be a 50:50 partnership between New Zealand and Australia which is accountable to the Health Ministers and Parliaments of both countries.

### **3.4 Clause 12 Involvement of Finance Minister in making certain Rules**

The RMI supports the involvement of the Finance Minister in the making of Rules dealing with the governance or the accountability of the Authority as this provides a further check and balance for the Authority.

### **3.5 Clauses 21-27 Disallowance of Rules and Orders**

The RMI strongly supports the provisions for the disallowance of Rules and Orders by either Parliament. Disallowance is a further means by which New Zealand can exercise its sovereignty under the joint regulatory scheme.

The RMI strongly recommends that a process is developed whereby stakeholders are given reasonable notification that a Rule or Order is to be presented to the House.

### **3.6 Part 2 Enforcement of regulatory scheme**

The RMI acknowledges that the Medicines Act 1981 has outdated enforcement powers/options. The RMI supports the principle of a tiered offence regime that provides for both criminal and civil penalties for breaches of the Regulatory Scheme and which has the objective of early detection and correction of breaches.

### **3.7 Clause 52 Manufacture, import, export, or supply without product licence or correct product licence**

The RMI strongly supports the requirement that only the Product Licence (PL) holder can import or export a product as this will prevent parallel-trading.

### **3.8 Subpart 4 Search and Seizure**

The RMI notes that the Search and Seizure provisions in the Bill have been updated compared to those in the Medicines Act 1981 and are similar to those of other New Zealand legislation made following the Bill of Rights Act 1990.

### **3.9 Part 3 Administrative law matters**

#### **Subpart 1 Merits review**

The RMI supports the provisions and processes in the Bill for a Merits Review of regulatory decisions by a (New Zealand) review tribunal with rights of appeal to the

New Zealand High Court. Access to merits review enhances both the transparency and accountability of the Authority.

### **3.10 Part 4 Governance and accountability**

The RMI supports the establishment, role and function of the Ministerial Council which ensures that New Zealand has an equal voice with Australia in all aspects of the joint regulatory scheme. All decisions of the Council shall be made with the agreement of both members of the Council.

The RMI strongly supports the Authority having accountability requirements and financial controls broadly equivalent to those that would apply under the Crown Entities Act 2002 including the New Zealand Auditor-General being an Auditor of the Authority.

### **3.11 Parts 6 & 7**

The RMI notes that this is an omnibus Bill and Parts 6 and 7 will become the New Zealand specific Medicines Act 2006.

### **3.12 Part 7 Substantive provisions relating to medicines**

#### **Subpart 10 Scheduled medicines and referring to medicines**

The RMI supports the harmonisation of medicine scheduling between New Zealand and Australia but recognises that on occasion the public health needs of New Zealand may require a different scheduling in each country. The RMI supports the Minister being able to depart from the Managing Director's listing of scheduled medicines as necessary.

**7 February 2007**

**Researched Medicines Industry Association**

## APPENDIX 1

### New Zealand Treasury “Guidelines for Setting Charges in the Public Sector: December 2002”

Section 3, Outputs and outcomes, of the Guidelines states: “The analysis of output and outcomes forms the options for charges.

3.1. . . . It is important to extend the analysis beyond the outcome which is the intended objective of the output, and also identify the output’s other effects. Who else benefits, or would be adversely affected if the output were not provided? . . .

3.2.1 Public Goods . . . There is a good case for recovering the costs of a public good from the community as a whole, either by general taxation or . . .”.