

## RMI Submission on

### Fees and Charges under the Australia New Zealand Therapeutic Products Regulatory Scheme - May 2006

#### 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 The different nature of RMI companies (size, commercial focus, regional reporting lines, etc) is reflected in a range of views on the proposed fees and charges. This submission concentrates on areas where there is broad industry consensus from RMI members. In addition to this submission on behalf of its members, the RMI has recommended that member companies make their own submissions.

#### 2. FULL COST RECOVERY

- 2.1 The "Agreement between the Government of Australia and the Government of New Zealand for the establishment of a joint scheme for the regulation of therapeutic products" (the "Treaty") was signed by both parties in December 2003. Article 15 of the Treaty outlines the funding arrangements for the Australia New Zealand Therapeutic Products Authority (ANZTPA). The following excerpts being relevant to this consultation:

*Article 15.1 The Parties shall provide initial funding to the Agency, and transfer to the Agency certain assets employed by each of them in connection with the regulation of therapeutic products prior to the commencement of the Scheme, on such terms as may be agreed between them prior to the establishment of the Agency.*

*15.2: The fees and charges that may be levied by the Agency in connection with the performance of its functions shall be prescribed in the Rules. The fees and charges shall:  
(a) be designed to recover the full costs of the Agency's operations under the Scheme in an equitable and efficient manner...*

- 2.2 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 Agency's operations from industry through fees and charges. Although government cost recovery guidelines in Australia and New Zealand provide for full cost recovery

of regulatory activities the RMI 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" and outlined in the excerpts below.

- 2.3 In Section 3 Outputs and outcomes of the Guidelines it states: "The analysis of outputs and outcomes forms the basis for identifying 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....
- 2.4 Further, the 2002 Australian Productivity Commission report "Cost Recovery by Government Agencies" made a number of recommendations in respect of this issue. In particular, recommendation 7.2 states "cost recovery arrangements should apply to specific activities of products, and not to the agency as a whole.  
...In principle, the cost of activities that are aimed at meeting the policy and advice needs of Government and Ministers should not be recovered directly from industry or other user groups. It is important that these 'higher level' Government policy activities maintain both the appearance and the reality of independence and accountability to Government. Recovering the cost of such activities from industry may compromise that independence".
- 2.5 The Commission also recommended (7.5) that "the practice of the Government setting targets that require agencies to recover a specific proportion of total agency costs should be discontinued".

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

### **3. TRANSPARENCY AND ACCOUNTABILITY**

- 3.1 As it is intended that the Authority will recover 100% of its costs from industry it is imperative that the Authority is transparent in its activities and accountable to stakeholders, including industry. The Governance and Accountability arrangements for the Authority are to be covered in the Administration and Interpretation Rule.
- 3.2 In addition to any statutory requirements the Authority should have an ongoing commitment to consult with industry on fees and charges.

**The RMI strongly recommends that the Authority develops a forum for regular ongoing dialogue with industry to**

- **report on the Authority's performance and financial results**
- **consult on any proposed changes to fees and charges.**

Dated : 14 August 2006