



13<sup>th</sup> March 2006

Mr David Nicholson  
Manager, Medsafe  
PO Box 5013  
Wellington

Dear David

### **Proposal to Increase Fees**

Thank-you for the opportunity to make a submission on Medsafe's Proposal to Increase Fees Payable Under the Medicines Act 1981 and Misuse of Drugs Act 1975.

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.

Industry acknowledges that Medsafe's current fees are low and have not been increased in many years. However, the RMI has major concerns about

- the lack of commitment to improved service/ shorter evaluation times;
- the impact and timing of fee increases of this magnitude;
- the methodology used to determine the proposed fee structure, particularly for evaluation activities; and
- the lack of timely and comprehensive information supporting the proposal and its failure to be distributed to all stakeholders.

Industry is not opposed to the principle of cost recovery where it improves economic efficiency and resource allocation, and there is transparency and accountability. The proposed fees do not appear to be about cost recovery, or providing a service, but providing a means by which Medsafe will "break-even", financially.

## Proposed fee for an application for consent to distribute a new medicine

The rationale for linking the proposed evaluation fees for innovative new medicine applications to those of the TGA (as a proxy for the ANZTPA) is inappropriate, as is making simple comparisons with other international regulatory bodies. This approach does not take into consideration purchasing power parity, service level, whether a full cost recovery model is used, or the size of the market and, therefore, the ability of industry to recover the cost.

Further, there is no justification for the proposed fee based on the efficient cost of performing an evaluation.

The Treasury "Guidelines for Setting Charges in the Public Sector" 5.2.1 notes that "when charges are set at greater than cost-recovery there is a danger that a user charge becomes a tax. A tax must be expressly authorised in legislation, it is not sufficient to rely on general charge-setting empowering provisions."

The volume assumptions underpinning the calculation of the proposed fees were determined without input from industry. With an increase in the fee for evaluation of a new medicine from \$15, 300 to \$122, 625 (all figures GST inclusive), industry feedback indicates that the actual drop in volume for new chemical and biological entities will be around 100%.

There are a number of reasons that volumes will decrease so dramatically:

1. *The long evaluation timelines.*

All indications from Medsafe are that the resources available in the Evaluation Team will not increase. Companies are already frustrated by the delays in evaluation of new medicines and are unwilling to pay an 8-fold increase for the same service.

2. *The high cost.*

Company budgets will have been set some time ago and no allowance will have been made for increased regulatory costs with Medsafe during 2006 and into 2007. Potentially, the fee for one NMA will consume more than 100% of a company's existing regulatory budget. Wherever possible, companies will submit applications prior to the proposed starting date for the new fees. This will not help Medsafe's financial position and will further contribute to the backlog of applications.

3. *The New Zealand pharmaceutical market.*  
For many products a fee of this magnitude could not be recovered through sales in the New Zealand market even if the product was listed on the Pharmaceutical Schedule and there are few guarantees of such a listing.
4. *Anticipation of Joint Agency.*  
With the high proposed fees and long evaluation timelines in New Zealand, companies will elect to file only in Australia and seek a dual country licence under the joint agency.

Given the uncertainty surrounding the timing of the commencement of the joint agency, or even whether it will ultimately proceed, the proposed fees increase puts at risk the future availability of new medicines in New Zealand. At particular risk are those medicines for rare diseases and/or medicines which have little prospect of government funding but which individuals may wish to purchase privately (e.g. current treatments for Alzheimer's).

**The RMI recommends that, at a minimum, the proposed fee increase be deferred until such time as the establishment of the joint agency is legislatively completed and the timing of its implementation is confirmed.**

#### Fee Waivers

Currently, "new medicine applications" for a new strength/dose form, etc of an approved medicine have fees related to the complexity of the application.

Medsafe introduced, in December 2004, improvements to the evaluation process by making greater use of TGA evaluation reports for applications that are already approved in Australia. Applications meeting the criteria are assigned to a Technical Secretariat for evaluation of key elements. Thus, the complexity of the application, with regard to Medsafe's resource input, is greatly reduced and this should be reflected in the fee.

**The RMI recommends that fee waivers continue to be applied to NMAs with regard to the degree of complexity involved e.g. line extensions and that the application of waivers be extended to include applications processed by the Technical Secretariat.**

Similarly, the Director-General may waive (or refund) in whole or in part, fees for applications in "the interests of public health in New Zealand" such as orphan drugs or service lines.

**The RMI supports the current use of fee waivers for applications in the interests of public health in New Zealand and recommends that this practice continues following any future fees increase.**

#### Application for approval of a clinical trial

The RMI acknowledges the statement that a 2003 activity based costing study, conducted by Medsafe, was used to derive the fee for an application for approval of a clinical trial but is disappointed that no further information was provided to validate the proposed fee.

New Zealand is one of a number of countries competing internationally for clinical trial work. The value of clinical research to New Zealand is acknowledged by the government which has made efforts to increase the amount of clinical research carried out in New Zealand.

Companies bidding for clinical trials have to overcome barriers resulting from the commercial environment in which the New Zealand pharmaceutical industry operates and which has already contributed to a reduction in the volume of clinical research being conducted here.

A 350% increase in the fee for an application for the approval of a clinical trial will reduce New Zealand's international competitiveness when bidding for clinical trials. In particular, it should be noted that the cost of a CTN (clinical trial notification) in Australia is \$A 260 and the CTN is the process used for almost all clinical trials in Australia.

#### Licence to Hawk Medicines

A costing model was used by Medsafe to calculate fees for a number of licences including a licence to hawk medicines. Although some information has been provided regarding the model inputs it is difficult to reconcile the proposed fee increase of more than 1200%, to \$845 per annum, with the activity associated with the renewal of a hawker's licence.

The RMI would like to put forward for Medsafe's consideration the suggestion that companies hold a licence (possibly incorporated into their licence to wholesale medicines) permitting approved employees to hawk medicines.

## Conclusion

Industry is not opposed to the principle of cost recovery where it improves economic efficiency and resource allocation, and there is transparency and accountability. The RMI accepts that Medsafe has been under-resourced for some time and that the fees charged to industry are low. However, as there will not be an increase in the resources available within the Evaluation Team, the purpose of the proposed fee increase is simply reducing a financial deficit.

Thus, the RMI is extremely concerned that despite the proposed, not insignificant, fee increases there is no commitment to improved service to industry – especially with regard to evaluation timelines.

The RMI is also concerned that the timing of introduction of the new fees and the high level of the fees in a commercially challenging and small market puts at risk the future availability of innovative new medicines for New Zealand patients.

Yours sincerely

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Manager, Technical & Scientific Affairs