



21 May 2009

Stewart Jessamine  
Group Manager, Medsafe  
Ministry of Health  
PO Box 5014  
Wellington

Dear Stewart

### **Proposed Changes to Fees Payable Under the Medicines Regulations 1984**

The RMI welcomes the opportunity to forward this submission in response to the Proposed Changes to Fees Payable Under the Medicines Regulations 1984.

The RMI supports reducing fees for innovative new medicine applications, clinical trial applications and changed medicine notifications to redress the current over-recovery of costs from these activities, as recognized by Parliament's Regulatory Review Committee and identified in the subsequent 2008 review.

The RMI specifically supports the following proposed changes:

- That applications for approval of new medicines, where two or more strengths, flavours or trade names are applied for at the same, will not incur an extra fee for the additional strengths, flavours or trade names.
- The way fees are calculated for changed medicines. The current fee schedule is very complex and it can be difficult to determine what fees will be charged. Reducing the fees schedule to 4 categories should be a significant improvement.
- Where a change or set of changes affects additional strengths of the same dose form of a product in an identical manner and is supported by the provision of a single dataset, a single fee will apply.
- Where a change or set of changes affects more than one product in an identical manner, and a complete and identical set of supporting documents is supplied for each product affected, a single fee will apply.

- The \$400 fee for Category D (self-assessable) changes would not apply if self-assessable changes were notified at the same time as any Category A, B or C changes to the same product.

Thank you for the opportunity to comment on these proposed changes.

Yours sincerely

A handwritten signature in black ink, appearing to read "Ken Shirley". The signature is written in a cursive style with a large, looping initial "K".

**Ken Shirley**  
Chief Executive Officer