



1 July 2008

Hon David Cunliffe  
Minister of Health  
Parliament Buildings  
Wellington

Dear Minister,

### **PHARMAC and International Trade Obligations**

I enclose a copy of a letter sent by the RMI to your colleague Hon Phil Goff, Minister of Trade, drawing to his attention the concerns the RMI have with a PHARMAC public consultation document titled "proposal for levetiracetam". A copy of this consultation document with the offending clauses highlighted is also enclosed.

At the time of writing to the Minister of Trade last week we believed that PHARMAC would be withdrawing the consultation document but we have subsequently been advised that PHARMAC offers no such assurance.

Our concerns are threefold

1. The PHARMAC proposal involves the funding of unapproved generic products which raises issues of clinical safety and undermines the role of the regulatory agency Medsafe.
2. It appears that the PHARMAC proposal could only be implemented by using section 29 of the Medicines Act 1981 which is intended to meet the clinical needs of particular patients and should not be used as a PHARMAC tool for the purposes of commercial leverage.
3. This proposal, if implemented, would breach New Zealand's obligations to WTO's Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS). Section 23(b) of the Medicines Act 1981 titled "protection of confidential information supporting information about innovative medicines" was inserted to underpin New Zealand's commitment to the TRIPS agreement.

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It appears to us that the public consultation document issued by PHARMAC is potentially damaging to this country's reputation and no doubt Government will wish to ensure that PHARMAC does not continue to act in this manner.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Ken Shirley". The signature is written in a cursive, flowing style.

**Ken Shirley**  
Chief Executive Officer

cc: Director-General of Health  
Manager, Medsafe, Ministry of Health