



29 July 2008

Steffan Crausaz
Acting General Manager
PHARMAC
PO Box 10-254
Wellington

Dear Steffan,

PHARMAC - Proposal for Levetiracetam

Thank you for your letter of 11 July in response to our expressed concerns with PHARMAC's consultation document.

We are pleased to see that your notification (also dated 11 July) specifies that only the UCB brand of Keppra will be available under the Levetiracetam Special Access (LSA) regime that you will establish. We note that the LSA will expire once the generic brand Levetiracetam - Rex is available and publicly funded from 2010, assuming that it gains Medsafe registration.

In your letter you explained to us that the consultation letter used general language when referring to unregistered brands and that you could understand the interpretation that we reached.

We do not believe that the offending paragraphs of your consultation document can be dismissed so lightly. The language used was not 'general' as you claim, but rather it was highly specific and unequivocal. It is rather disingenuous of you to say that you can understand our (mis)interpretation when no other interpretation of your stated intent was possible.

Keppra is the innovator's brand of Levetiracetam and the proposal outlined in your consultation document clearly made provision for the funding of any brand whether registered by Medsafe or not.

I invite you to reflect on the offending clauses of the consultation document which stated:

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“Applicants would also be required to provide details of the pharmacy where the patient would collect their medication (the nominated pharmacy) and details of the dose of Levetiracetam required, the brand of Levetiracetam that the pharmacy intends to dispense (if known), and an estimate of the cost of Levetiracetam (as quoted by the nominated pharmacy). Funding of Levetiracetam under this scheme would be available for any brand of Levetiracetam that the pharmacy is able to source whether it is registered by Medsafe or not at the pharmacy’s purchase price (known as ‘cost brand source’).

If at a later date a fully funded version of Levetiracetam is listed in the Pharmaceutical Schedule, approvals under the Special Access scheme would eventually lapse and funding would then be available only for the listed version(s) of Levetiracetam (with surety of supply and pricing).

I have added the underlining to demonstrate the very specific character of PHARMAC’s proposal outlined in the consultation document.

In your letter you state your belief that our letters of concern to relevant Ministers of the Crown were premature. We must disagree.

PHARMAC released a consultative document which proposed mechanisms to access Levetiracetam which, if implemented, would have breached section 23(b) of the Medicines Act (1981) and seriously jeopardized New Zealand’s standing as a trading nation that plays by the WTO rules.

These are not minor matters that can be nonchalantly dismissed.

While the final notification does not contain the offending clauses we note that PHARMAC did not withdraw the consultative document even after the egregious elements were exposed and drawn to your attention.

This consultation document could still prove to be an embarrassment to government, particularly in future trade liberalization negotiations.

Under these circumstances it would have been remiss of RMI to be aware of the situation and to not advise the appropriate Ministers of the Crown.

We note that the complex and somewhat convoluted Levetiracetam special access regime involving a panel of clinicians and special forms is being established essentially as a barrier to throttle demand rather than for any clinical purpose. This is evidenced by your stated intention to remove the special authority approval once the generic substitute is available.

The only reason Medsafe approved Keppra is not available on the New Zealand market is intransigence over pricing negotiations with the innovator company, even though PTAC recommended this medicine with a ‘high priority’ classification in 2005.

In summary we wish to emphasise the point that PHARMAC’s enthusiasm to exert commercial leverage and contain costs must not be expressed in a manner that breaches

the Medicines Act and undermines intellectual property rights that New Zealand has committed to uphold as a signatory party to international trade agreements.

Yours sincerely,

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

Ken Shirley
Chief Executive Officer