



12 June 2008

Geraldine MacGibbon
Therapeutic Group Manager
PHARMAC
PO Box 10-254
Wellington

Dear Geraldine,

Proposal for levetiracetam

Thank you for the opportunity to respond to the PHARMAC proposal which is of considerable significance to the pharmaceutical industry and patients in terms of the precedence that it would establish.

While we would otherwise welcome access to any new treatment, we are very concerned about a number of aspects of this particular proposal.

Ad hoc policy making

Based on the information in your consultation letter, it would appear that PHARMAC does not intend to list levetiracetam on the Pharmaceutical Schedule prior to approval of Rex's brand by Medsafe. We are not aware of any precedent for establishing a product-specific panel to administer access to an unlisted pharmaceutical. Consequently, we would like this proposal more with the Exceptional Circumstances (EC) policy than any other listing policy previously adopted by PHARMAC. We consider that this proposal represents an extension of EC and, as an ad hoc amendment to that policy, has been consulted on incorrectly.

Equity

PHARMAC appears to be proposing the funding of levetiracetam without proper consultation on the specific access criteria. Your consultation letter contains details of "minimum" criteria, the application of which would appear to be entirely subjective and at the discretion of the panel. It also suggests PHARMAC will be keeping close control over the costs of access to this drug.

Level 1, Perpetual Trust House
111 Customhouse Quay
PO Box 10447
Wellington 6143
Telephone: 04-499 4277
Facsimile: 04-499 4276
www.rmianz.co.nz

We question whether this means PHARMAC could subsequently tighten the criteria (or instruct the panel to use its discretion to further limit access by declining applications) if expenditure exceeds expectation. Clearly this would result in some patients being declined access to a subsidy despite having a clinical presentation identical to other patients for whom a subsidy has previously been approved. This inequity would be unacceptable in light of the way in which PHARMAC has consulted.

Contractual relationships

This proposal appears to be motivated by UCB's apparent refusal to sign up to certain terms within a standard PHARMAC contract. By developing this novel approach to access to subsidies for unregistered pharmaceuticals, PHARMAC appears to be attempting to make an example of a supplier for not agreeing to its increasingly onerous and draconian contractual terms. These strong-arm tactics are unacceptable and inappropriate. While we understand the rationale for strict contractual provisions relating to continued supply, we note that they cannot prevent an out-of-stock situation. Furthermore, indemnity provisions are of limited use in situations like this where there is no clinically appropriate alternative product.

We believe that continuity of supply is critical in this particular market and that PHARMAC would be exposing patients to undue and unacceptable risk by funding levetiracetam as proposed. We believe that a contract for Keppra in which damages for failure to supply had to be softened would have given patients more certainty and clinical security than the proposed arrangement in which supply, by PHARMAC's own admission, cannot be guaranteed.

If PHARMAC intends to source levetiracetam from Rex under Section 29 of the Medicines Act instead of contracting legitimately and in good faith with the supplier of the registered brand, then this is a gross misuse of the Section 29 provisions.

Intellectual Property

In addition to misusing and exploiting Section 29 of the Medicines Act 1981, this proposal by PHARMAC subverts the provisions of Section 23B of the same Act "Protection of confidential information supporting information about innovative medicines".

Any supplier of an alternative brand would need to rely upon the "safety" and "efficacy" data presented by UCB which is covered by the five year data exclusivity provisions established in the Uruguay round of the General Agreement on Tariffs and Trade (GATT). New Zealand Governments have regularly expressed ongoing commitment to data protection under the WTO's trade related aspects of Intellectual Property Rights Agreement (TRIPs).

I have no doubt that PHARMAC's proposed actions would cause great embarrassment to Government and weaken this country's credibility in any future trade negotiations.

Patient Safety

PHARMAC's objective is "To secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided."

PHARMAC's inability to "secure" supply of levetiracetam in this case would appear to be inconsistent with its objective. We also question whether this proposal represents "the best health outcomes that are reasonably achievable from pharmaceutical treatment" when patients face serious health consequences if treatment is commenced and subsequently the patient is required to change brands. In the case of epilepsy, there is significant and compelling evidence from clinicians and patients to indicate that a number of people experience difficulties in the management of their condition when switching from a different version of an anti-epileptic drug (AED).

We do not believe PHARMAC can demonstrate that this proposal represents the best use of limited funding.

Conclusion

We believe that this proposal is motivated by an emotional and/or strategic response to a supplier's reaction to PHARMAC's intransigent attitudes to contracts rather than any sense of urgency in relation to the needs of patients who might be prescribed levetiracetam. The proposal does not appear to be well thought out, adequately consulted on, or justifiable under PHARMAC's decision criteria.

We cannot support a proposal which clearly puts PHARMAC's cost containment agenda ahead of the safety issues related to uncertain access to and availability of the product.

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