

1 May 2024

PHARMAC
PO Box 10254
The Terrace
Wellington 6143

Sent via email to: consult@pharmac.govt.nz

Dear Sir/Madam,

Re: Proposal to fund levetiracetam injection for people receiving palliative care in the community

Thank you for the opportunity to provide feedback on the above proposal.

The Pharmacy Guild of New Zealand (Inc.) (the Guild) is a national membership organisation representing the majority of community pharmacy owners. We provide leadership on all issues affecting the sector and advocate for the business and professional interests of community pharmacy.

Our feedback on this consultation focuses on Guild members' concerns around general economic, funding and supply issues. Guild submissions should not be taken as any endorsement of, or any attempt to comment on, issues of safety, efficacy, or individual patient utility.

We would like to express our support for your proposal to fund levetiracetam injection for individuals receiving palliative care in the community. However, we have concerns about the recommendation from the Analgesic Advisory Committee that levetiracetam injection can be administered subcutaneously as this poses a challenge as subcutaneous injection of levetiracetam injection would be considered an "off-label use" or "unapproved use" according to the Levetiracetam-AFT brand's data sheet, which clearly states that "*Levetiracetam-AFT concentrate solution for IV infusion is for intravenous use only and must be diluted in at least 100ml of a compatible diluent and administered as a 15 minute intravenous infusion.*"

As Levetiracetam injection is not Medsafe approved for subcutaneous use, an authorised prescriber would need to prescribe the use of this medicine in accordance with section 25 of the Medicines Act 1981.

There are a number of authorised prescribers involved in the care of a person receiving palliative care in the community who may be unfamiliar with the unapproved use of levetiracetam injection and there is increased professional responsibility and liability accompanying the prescribing of medicines for unapproved purposes.

We believe that if levetiracetam injection is to be funded for individuals receiving palliative care in the community for subcutaneous use, that structured guidelines and protocols for the prescribing and administration should be created by specialist physicians in the field of palliative care for all authorised prescribers to support their clinical decision-making, and that these recommendations are based on sufficient evidence from studies that have investigated the safety and/or effectiveness of drug administration, particularly when administered to highly vulnerable patients, in order to prevent adverse drug events that may affect quality of life.

Information should also be available for pharmacists to utilise when reviewing the prescribing of this medicine for unapproved use. And importantly, affected patients and their carers must be adequately informed and consent to the unapproved treatment as described in the Code of Health and Disability Consumers' Rights.

In addition, levetiracetam injection would not be routinely held in stock by community pharmacies, therefore an early discussion with the community pharmacy would be required to determine whether the pharmacy is able/willing to order the IV levetiracetam injection within a suitable timeframe. As the levetiracetam injection will not be regularly prescribed, either the provision of a whole pack or claimable wastage should be assigned to this medicine so that the pharmacy is not left with stock that will not be utilised within its expiry date.

The other brand of levetiracetam injection available, Keppra, is currently unapproved in New Zealand and therefore only medical practitioners would be able to prescribe this medicine under section 29 of the Medicines Act 1981. This would limit the ability for this brand of levetiracetam injection to be prescribed by other health professionals working in the field of palliative care and would cause undue workforce pressures and potentially delays in the medicine being available to vulnerable people. We would again like to spotlight this issue for Pharmac's attention, as it is bound to become an issue more frequently amidst global supply issues and needs to be urgently addressed and mitigated as per our previous discussions.

Thank you for your consideration of our response. If you have any questions about our feedback, please contact our Senior Advisory Pharmacists, Martin Lowis (martin@pgnz.org.nz, 04 802 8218) or Cathy Martin (cathy@pgnz.org.nz, 04 802 8214).

Yours sincerely,



Nicole Rickman

General Manager – Membership and Professional Services