

29 April 2005

To All Pharmaceutical Suppliers, Hospital Pharmacists, Medical Groups and Interested Parties

*By facsimile (4 pages)***Consultation on provisional agreement with Pfizer New Zealand Limited for subsidising gabapentin (Neurontin) for neuropathic pain**

PHARMAC has entered into a provisional agreement with Pfizer New Zealand Limited for the amended listing of gabapentin (Neurontin) in sections B and H of the Pharmaceutical Schedule to enable it to be funded for neuropathic pain.

The proposed amendments to the current restrictions in section B applying to the prescribing of gabapentin are attached. It should be noted that, while the current Special Authority applies to all New Anti-Epilepsy Drugs, the changes would apply only to Neurontin. It is also proposed that:

- Neurontin would be listed in section B of the Pharmaceutical Schedule at the following prices and subsidies:

Chemical	Strength	Pack Size	Price/Subsidy
gabapentin	100 mg	100 capsules	\$29.46
gabapentin	300 mg	100 capsules	\$88.36
gabapentin	400 mg	100 capsules	\$117.81

- The 600 mg and 800 mg tablets of gabapentin may be listed in the Pharmaceutical Schedule at a later time with the following prices and subsidies:

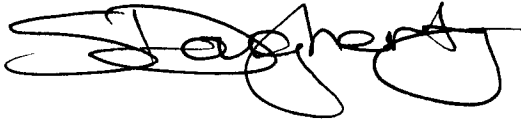
Chemical	Strength	Pack Size	Price/Subsidy
gabapentin	600 mg	100 tablets	\$150.00
gabapentin	800 mg	100 tablets	\$190.00

- Neurontin would be subject to a confidential financial risk-sharing arrangement between PHARMAC and Pfizer New Zealand Limited until 1 July 2007.
- Neurontin would be listed in Section H at the above prices, although a confidential discount on invoice would apply to DHB hospitals after 30 June 2006. The effective prices for Neurontin to DHB Hospitals would be notified to DHB Hospitals closer to this date, and would be confidential to DHB Hospitals, PHARMAC and Pfizer.
- Neurontin would be protected from reference pricing and tendering until 1 July 2007.

It is anticipated that the proposed changes, if accepted by PHARMAC's Board, would take effect from 1 July 2005. If you wish to make comments for the PHARMAC Board or Chief Executive

to consider when making its decision on whether to accept this proposal, please forward them to Sean Dougherty at PHARMAC by **4:00 pm, 13 May 2005**.

Yours sincerely

A handwritten signature in black ink, appearing to read "Sean Dougherty". The signature is stylized with loops and a horizontal line across the middle.

Sean Dougherty
Therapeutic Group Manager

Proposed Special Authority Criteria for Neurontin (changes in bold):

Special Authority for Subsidy

Initial application - (Single NAED Therapy) only from a paediatrician, neurologist or general physician. Approvals valid for 15 months for applications meeting the following criteria:

Any of the following:

- 1 Was on NAED therapy before 1 September 2000; or
- 2 Seizures are not adequately controlled with optimal older anti-epilepsy drug treatment; or
- 3 Seizures are controlled adequately but who experience unacceptable side effects from older anti-epilepsy drug treatment.

Note

"Optimal older anti-epilepsy drug therapy" is defined as treatment with those older anti-epilepsy drugs which are indicated and clinically appropriate for the patient, given singly and in combination in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance

Initial application - (Dual NAED Therapy) only from a paediatrician, neurologist or general physician. Approvals valid for 18 months for applications meeting the following criteria:

Either:

- 4 Stabilised on two NAEDs on or before 31 July 2000; or
- 5 Both:
 - 5.1 A second NAED has been added; and
 - 5.2 An attempt to withdraw one NAED has been made and was unsuccessful.

Initial application - (Neuropathic pain - gabapentin only) only from a relevant specialist or general practitioner on the recommendation of such a specialist. Approvals valid for 2 months where the patient has tried and failed, or has been unable to tolerate, treatment with a tricyclic antidepressant AND an anticonvulsant agent.

Note

Gabapentin is not interchangeable with other NAEDs when used for treating neuropathic pain.

Renewal - (Single or Dual NAED Therapy) only from a paediatrician, neurologist or general physician. Approvals valid for 18 months for applications meeting the following criteria:

Either:

- 6 Both:
 - 6.1 Patient has been prescribed adequate doses of gabapentin, lamotrigine, topiramate or vigabatrin; and
 - 6.2 Patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life ; or
- 7 Patient has had a previous approval but has not yet trialed monotherapy with all available NAEDs.

Note

As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anti-convulsant therapy and have assessed quality of life from the patient's perspective

Renewal - (Triple NAED Therapy) only from a paediatrician, neurologist or general physician. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 8 Patient is on dual therapy; and
- 9 Patient switching from vigabatrin to another NAED.

Renewal - (Neuropathic pain - gabapentin only) only from a relevant specialist or general practitioner on the recommendation of such a specialist. Approvals valid for 2 years where the patient has demonstrated a marked improvement in their control of pain (prescriber determined).

Note

Gabapentin is not interchangeable with other NAEDs when used for neuropathic pain.

Note: Special Authority applications and reapplications for NAEDs (for use in epilepsy) must be made by a neurologist or paediatric neurologist. Applications from a general physician or paediatrician will be accepted if access to neurology or paediatric neurology services is limited in the locality in which they practice.