CONSULTATION

PHARMAC
Pharmaceutical Management Agency

14 July 2015

Proposal relating to the funding of TNF inhibitors (Humira and Enbrel) and gabapentin (Neurontin)

PHARMAC is seeking feedback on a proposal relating to the funding of the TNF-inhibitor medicines adalimumab (Humira) and etanercept (Enbrel), both used to treat people with various autoimmune and immune-mediated conditions, and gabapentin (Neurontin), used to treat epilepsy and neuropathic pain.

The effect of the proposal would be to make the funding of the TNF-inhibitor treatments and Neurontin more cost-effective and to create savings of more than $20 million over 5 years that would enable PHARMAC to deliver greater health outcomes from available pharmaceutical funding.

PHARMAC welcomes feedback on this proposal by **5pm on Tuesday, 11 August 2015**

Summary of Proposal

In summary the proposal is to:

- amend the Special Authority criteria and hospital restrictions applying to all presentations of adalimumab (Humira and HumiraPen) listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 January 2016 to make etanercept the first-line funded TNF inhibitor medicine for new rheumatology and dermatology patients, and
- through a provisional agreement with Pfizer New Zealand Limited:
  - reduce the list prices, subsidies and net costs of all presentations of etanercept (Enbrel) listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 October 2015, and
  - from 1 November 2015:
    - reduce the list prices and subsidies of gabapentin 100 mg, 300 mg and 400 mg capsules (Neurontin) listed in Section B of the Pharmaceutical Schedule
    - amend the Special Authority applying to gabapentin 100 mg, 300 mg and 400 mg capsules (Neurontin) in Section B of the Pharmaceutical Schedule
    - list gabapentin 100 mg, 300 mg and 400 mg capsules (Neurontin) in Part II of Section H of the Pharmaceutical Schedule, and
    - delist gabapentin 600 mg tablets (Neurontin) from Section B and Part II of Section H of the Pharmaceutical Schedule.

Summary of the impact of the proposal on patients and prescribers

The effect of the proposed changes would be that:

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- From 1 January 2016 adalimumab funding for new rheumatology[1] and dermatology[2] patients would be limited to patients who are intolerant of, or whose disease has not responded to, etanercept. Etanercept would be the first-line funded TNF inhibitor medicine for these patients, with adalimumab funded second-line.
- There would be no change to the funding of adalimumab for any:
  - current patients using it (for any indication); or
  - new patients who have Crohns or Fistulising Crohns disease.

  All of these patients would continue to have funded access to adalimumab as a first-line TNF inhibitor treatment.
- The Neurontin brand of gabapentin capsules (100 mg, 300 mg and 400 mg) would be fully funded under the same Special Authority/Hospital Restriction criteria that currently apply to other brands of gabapentin (Arrow-Gabapentin and Nupentin).
- Patients currently being treated with gabapentin 600 mg tablets (Neurontin) would need to switch to an alternative funded strength of gabapentin from 1 November 2015, for example 2 x 300 mg capsules, to continue to receive funded treatment.

Purpose of consultation

The purpose of this consultation is to seek feedback on the proposal, including any practical, clinical or other issues that PHARMAC should be aware of, before PHARMAC makes a decision on the proposal.

This consultation document contains the following sections:

1. background to the proposal
2. details of the proposal, and
3. how to provide feedback.

1. Background to the proposal

TNF inhibitor medicines (Enbrel and Humira)

Etanercept (brand name Enbrel, supplied by Pfizer) and adalimumab (brand names Humira and HumiraPen, supplied by AbbVie) are tumour necrosis factor (TNF)-alpha inhibitor medicines, a class of biologic treatments used to treat various autoimmune and immune-mediated conditions including rheumatoid arthritis, psoriatic arthritis and psoriasis. Adalimumab and etanercept are both administered by subcutaneous injection in the community. Dosing across indications can vary, but in general etanercept is administered 50 mg once weekly and adalimumab is administered 40 mg once fortnightly.

Both treatments are approved by Medsafe for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis and juvenile idiopathic arthritis. Etanercept, but not adalimumab, is also indicated for paediatric plaque psoriasis. Adalimumab, but not etanercept, is also indicated for axial spondyloarthritis (similar to ankylosing spondylitis), Crohn's disease and ulcerative colitis. The contraindications of the two treatments are also similar with the exception that, unlike etanercept, adalimumab is also contraindicated in patients with moderate to severe heart failure.

[1] Patients with rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, juvenile idiopathic arthritis and adult-onset still's disease

[2] Patients with severe chronic plaque psoriasis and pyoderma gengrenosum

Adalimumab and etanercept are currently fully funded with similar criteria for patients with rheumatoid arthritis, ankylosing spondylitis, severe chronic plaque psoriasis and psoriatic arthritis, for patients with severe disease that has not adequately benefitted from, or where patients cannot tolerate, at least two other non-biologic community funded DMARDs[3]. Both treatments are also funded for the unregistered indications of adult onset Still's disease and pyoderma gangrenosum.

Adalimumab, but not etanercept, is also funded for patients with Crohn's disease and fistulising Crohn's disease (etanercept is not registered or funded for these indications).

Clinicians and patients currently have the option of making a special authority application for funding for either etanercept or adalimumab as a first line TNF inhibitor medicine, with the option of switching to the other treatment second line if the disease fails to respond to, or the patient is intolerant of, the first line option. This would change under the proposal.

Adalimumab is currently the Combined Pharmaceutical Budget's highest annual gross expenditure medicine, with etanercept number four. Current gross annual expenditure on both of these treatments is approximately $94 million[4] combined and costs are growing rapidly with 15 percent growth in the last year alone, with around 6,400 patients having received funded adalimumab or etanercept in the last year. TNF inhibitor usage is likely to continue to increase because people are living longer and more uses are being discovered for these treatments.

PHARMAC sought advice from the Pharmacology and Therapeutics Advisory Committee (PTAC) when developing this proposal. PTAC considered that it would be clinically reasonable for etanercept to be the mandated first-line funded TNF inhibitor for all new patients for currently funded indications (excluding Crohn's disease and fistulising Crohn's disease for which etanercept is not registered or funded). PTAC recommended PHARMAC progress with the proposal. Minutes can be found on the PHARMAC website.

The proposed changes would enable PHARMAC to make the funding of TNF-inhibitors more cost-effective and would create savings of more than $20 million over 5 years that would enable PHARMAC to deliver greater health outcomes from available pharmaceutical funding.

PHARMAC is aware that this proposal, if implemented, would have an impact on prescribers, new patients and their families. If the proposal was progressed, PHARMAC would work with relevant clinical and patient groups and pharmaceutical suppliers to ensure adequate support and resources would be in place before, during and after any funding changes.

Gabapentin (Neurontin)

There are currently three brands of gabapentin funded on the Pharmaceutical Schedule: Nupentin (supplied by Mylan), Arrow-Gabapentin (supplied by Actavis) and Neurontin (supplied by Pfizer). Nupentin and Arrow-Gabapentin are fully funded for any patient who meets the Special Authority criteria for epilepsy and neuropathic pain or chronic kidney disease associated-pruritus. Neurontin is currently only funded for patients with epilepsy who had an approval for Neurontin prior to 1 August 2009. This funding situation arose from a previous PHARMAC competitive procurement process for the supply of gabapentin.

[3] disease-modifying antirheumatic drugs, or DMARDs, work by curbing the underlying processes that cause certain forms of inflammatory arthritis including rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis. DMARDs include hydroxychloroquine, leflunomide, cyclosporine, sulfasalazine, methotrexate, azathioprine and cyclophosphamide

[4] Both adalimumab and etanercept are currently subject to confidential rebates that reduce the net price to the funder

This proposal would amend the price, subsidy and Special Authority criteria of the Neurontin brand of gabapentin to match that of Nupentin and Arrow-Gabapentin. At the same time, it is also proposed that the 600 mg tablet presentation of Neurontin, which is used by less than <1% of patients, be delisted from the Pharmaceutical Schedule. PHARMAC considers that the very small number of patients currently taking this presentation could be safely switched to an alternative funded strength of gabapentin (e.g. 2 x 300 mg tablets); however before making a decision on the proposal we are keen to understand if there would be any circumstances where this might not be the case.

2. Details of the proposal

In relation to etanercept (Enbrel)

- From 1 October 2015 the prices and subsidies of etanercept (Enbrel) would be reduced in Section B and Part II of Section H of the Pharmaceutical Schedule as follows (all prices are ex-manufacturer and exclude GST):

Chemical and presentation	Brand	Pack size	Current Price/Subsidy	Proposed Price/Subsidy
Etanercept Inj 25 mg	Enbrel	4	$949.96	$799.96
Etanercept Inj 50 mg autoinjector	Enbrel	4	$1,899.92	$1,599.96
Etanercept Inj 50 mg prefilled syringe	Enbrel	4	$1,899.92	$1,599.96

- Confidential rebates would apply to Enbrel, reducing its net price to the funder and DHB hospitals.

- Enbrel would remain listed in Section B and Part II of Section H of the Pharmaceutical Schedule subject to its current Special Authority and restrictions. These are detailed in the Pharmaceutical Schedule that can be found on the PHARMAC website here http://www.pharmac.health.nz/tools-resources/pharmaceutical-schedule/

- Enbrel would have protection from subsidy reduction, delisting, and Special Authority/ HML restriction changes until 30 June 2019.

In relation to adalimumab (Humira and HumiraPen)

- From 1 January 2016 the Special Authority criteria applying to all presentations of adalimumab[5] (Humira/HumiraPen) listed in Section B of the Pharmaceutical Schedule would be deleted and replaced with the following (similar hospital restriction changes would also be made in Part II of Section H of the Pharmaceutical Schedule):

> Adalimumab
> SAXXX Special Authority for Subsidy
> **Initial application - (rheumatoid arthritis)** only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
> Both:
> 1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
> 2 Either:
> 2.1 The patient has experienced intolerable side effects from etanercept; or
> 2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for rheumatoid arthritis.

[5] Current funding criteria can be found in the Pharmaceutical Schedule on our website here http://www.pharmac.health.nz/tools-resources/pharmaceutical-schedule/

Renewal - (rheumatoid arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Either:
  1.1 Applicant is a rheumatologist; or
  1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
3 Either:
  3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  3.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
4 Either:
  4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
  4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Initial application - (Crohn's disease) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1 Patient has severe active Crohn's disease; and
2 Any of the following:
  2.1 Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or
  2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
  2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
  2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
4 Surgery (or further surgery) is considered to be clinically inappropriate.

Renewal - (Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Either:
  1.1 Applicant is a gastroenterologist; or
  1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
2 Either:
  2.1 Either:
    2.1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
    2.1.2 CDAI score is 150 or less; or
  2.2 Both:
    2.2.1 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
    2.2.2 Applicant to indicate the reason that CDAI score cannot be assessed; and
3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application - (severe chronic plaque psoriasis) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
Both:

1 The patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
2 Either:
  2.1 The patient has experienced intolerable side effects from etanercept; or
  2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for severe chronic plaque psoriasis.

Renewal - (severe chronic plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Either:
  1.1 Applicant is a dermatologist; or
  1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
2 Either:
  2.1 Both:
    2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
    2.1.2 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
  2.2 Both:
    2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
    2.2.2 Either:
      2.2.2.1 Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
      2.2.2.2 Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value; and
3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Note: A treatment course is defined as a minimum of 12 weeks adalimumab treatment.

Initial application - (ankylosing spondylitis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 The patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
2 Either:
  2.1 The patient has experienced intolerable side effects from etanercept; or
  2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for ankylosing spondylitis.

Renewal - (ankylosing spondylitis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Either:
  1.1 Applicant is a rheumatologist; or
  1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
2 Following 12 weeks of adalimumab treatment, BASDAI has improved by 4 or more points from pre-adalimumab baseline on a 10 point scale, or by 50%, whichever is less; and
3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment.. Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm
25-34 years - Male: 7.5 cm; Female: 5.5 cm
35-44 years - Male: 6.5 cm; Female: 4.5 cm
45-54 years - Male: 6.0 cm; Female: 5.0 cm
55-64 years - Male: 5.5 cm; Female: 4.0 cm
65-74 years - Male: 4.0 cm; Female: 4.0 cm
75+ years - Male: 3.0 cm; Female: 2.5 cm

Initial application - (psoriatic arthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 The patient has had an initial Special Authority approval for etanercept for psoriatic arthritis; and
2 Either:
  2.1 The patient has experienced intolerable side effects from etanercept; or
  2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for psoriatic arthritis.

Renewal - (psoriatic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Either:
  1.1 Applicant is a rheumatologist; or
  1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
2 Either:
  2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application - (juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
Both:

1 The patient has had an initial Special Authority approval for etanercept for juvenile idiopathic arthritis (JIA); and
2 Either:
  2.1 The patient has experienced intolerable side effects from etanercept; or
  2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for juvenile idiopathic arthritis.

Renewal - (juvenile idiopathic arthritis) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Either:
  1.1 Applicant is a named specialist or rheumatologist; or
  1.2 Applicant is a Practitioner and confirms that a named specialist or rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
2 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
3 Either:
  3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
  3.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Initial application - (fistulising Crohn's disease) only from a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Patient has confirmed Crohn's disease; and
2 Either:
  2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
  2.2 Patient has one or more rectovaginal fistula(e); and
3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application; and
4 The patient will be assessed for response to treatment after 4 months' adalimumab treatment (see Note).

Note
A maximum of 4 months' adalimumab will be subsidised on an initial Special Authority approval for fistulising Crohn's disease.

Renewal - (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 Either:
  1.1 Applicant is a gastroenterologist; or
  1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and

2 Either:
  2.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
  2.2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain.

Initial application - (pyoderma gangrenosum) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1 The patient has had an initial Special Authority approval for etanercept for pyoderma gangrenosum*; and
2 Either:
  2.1 The patient has experienced intolerable side effects from etanercept; or
  2.2 The patient has received insufficient benefit from at least 3 months treatment with etanercept for pyoderma gangrenosum*; and
3 A maximum of 4 doses.

Note
Indications marked with * are Unapproved Indications (refer to (Interpretations and Definitions).

Renewal - (pyoderma gangrenosum) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1 Patient has shown clinical improvement; and
2 Patient continues to require treatment; and
3 A maximum of 4 doses.

Initial application - (adult-onset Still's disease) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:
1 Either:
  1.1 The patient has had an initial Special Authority approval for etanercept for adult-onset Still's disease (AOSD*); or
  1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules; and
2 Either:
  2.1 The patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
  2.2 The patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab such that they do not meet the renewal criteria for AOSD.

Note
Indications marked with * are Unapproved Indications (refer to (Interpretations and Definitions).

Renewal - (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:
1 Either:
  1.1 Applicant is a rheumatologist; or
  1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
2 The patient has a sustained improvement in inflammatory markers and functional status.

- No changes to the list prices or subsidies for Humira and HumiraPen are proposed. We note that there are confidential rebates for Humira and HumiraPen as a result of PHARMAC's Agreement with AbbVie which reduce the net price of these products to the funder and DHB Hospitals.

In relation to gabapentin (Neurontin)

- From 1 November 2015 the prices and subsidies of gabapentin (Neurontin) would be reduced in Section B of the Pharmaceutical Schedule as follows (all prices are ex-manufacturer and exclude GST):

Chemical and presentation	Brand	Pack size	Current Price/Subsidy	Proposed Price/Subsidy
Gabapentin cap 100 mg	Neurontin	100	$13.26	$7.16
Gabapentin cap 300 mg	Neurontin	100	$39.76	$11.00
Gabapentin cap 400 mg	Neurontin	100	$53.01	$13.75

- Neurontin 100 mg, 300 mg and 400 mg capsules would also be listed in Part II of Section H of the Pharmaceutical Schedule from 1 November 2015 at the above prices (ex-manufacturer, excluding GST).

- From 1 November 2015 the funding of Neurontin 100 mg, 300 mg and 400 mg capsules would be subject to the same restrictions that currently apply to the Nupentin and Arrow-Gabapentin brands of gabapentin (Special Authority in Section B, prescribing restrictions in Part II of Section H).

- Neurontin would have protection from subsidy reduction, delisting, and Special Authority/HML restriction changes until 30 June 2016.

- From 1 November 2015 Neurontin 600 mg tablets would be delisted from Section B and Part II of Section H of the Pharmaceutical Schedule.

3. How to provide feedback

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5pm on Tuesday, 11 August 2015** to:

Jackie Evans
Senior Therapeutic Group Manager
PHARMAC

Email: TNF@pharmac.govt.nz
Fax: 04 460 4995
Post: PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to PHARMAC making a decision on this proposal.

Feedback PHARMAC receives is subject to the Official Information Act 1982 (OIA). PHARMAC will consider any request to have information withheld in accordance with its obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

PHARMAC is not able to treat any part of your feedback as confidential unless you specifically request that it does so, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like PHARMAC to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.