

5 October 2005

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

**Proposal to list adalimumab (Humira)**

PHARMAC has entered into a provisional agreement with Abbott Laboratories NZ Ltd (Abbott) to list adalimumab (Humira) in Section B and in Section H of the Pharmaceutical Schedule, and to reduce the price and subsidy of leuprorelin (Lucrin Depot) in Section B and Section H of the Pharmaceutical Schedule.

Details of the proposed Special Authority criteria applying only to the prescribing of adalimumab in Section B are attached. The final criteria that will be presented to the PHARMAC Board may be modified to reflect responses received from this consultation process.

The provisional agreement with Abbott includes the following features:

- The prices (including the price to hospitals) and subsidies of Humira would be as follows from 1 December 2005:

<b>Chemical</b>	<b>Brand</b>	<b>Pack size</b>	<b>Form</b>	<b>Proposed price and subsidy</b>
adalimumab	Humira	2 x 0.8 mL syringe	Solution for Injection	\$1,799.92

- Adalimumab would be subject to the following Special Authority criteria:

**Special Authority for Subsidy**

Initial application only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

1. All of the following
  - 1.1 Patient is an adult who has had severe and active erosive Rheumatoid Arthritis for six months duration or longer; and
  - 1.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 1.3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
  - 1.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with at least two of the following (triple therapy): sulphasalazine, prednisone at a dose of at least 7.5 mg per day, azathioprine, intramuscular gold, or hydroxychloroquine sulphate (at maximum tolerated doses); and
  - 1.5 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of either:
    - 1.5.1 Cyclosporin alone or in combination with another agent; or
    - 1.5.2 Leflunomide alone or in combination with another agent.

AND

2. Both:

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- 2.1 Either:
    - 2.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 active, swollen, tender joints; or
    - 2.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
  - 2.2 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application.
- AND
3. The patient consents to details of their treatment being held on a central registry and has signed a consent form outlining the conditions of ongoing treatment.

Renewal only from a rheumatologist or general physician on the recommendation from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

1. Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  2. Either:
    - 3.0 Following 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
    - 3.1 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.
- PHARMAC would propose a formal peer review process, in consultation with rheumatologists, to ensure entry and exit criteria are maintained.
  - If PHARMAC lists any other TNF alpha inhibitors on the Pharmaceutical Schedule for the same patient group for which adalimumab is funded, adalimumab would be the first line agent, and any other TNF alpha inhibitors would be listed as second line agents until 30 November 2008.
  - Humira would also be subject to confidential risk-sharing arrangements.
  - The price (including the price to hospitals) and subsidy of leuprorelin would be reduced from 1 December 2005 as follows:

Chemical	Brand	Strength	Pack size	Current price and subsidy	Proposed price and subsidy
leuprorelin	Lucrin Depot	11.25 mg	1 syringe	\$739.60	\$591.68
leuprorelin	Lucrin Depot	3.75 mg	1 syringe	\$277.00	\$221.60

Note all prices are ex-manufacturer, ex-GST

- Lucrin Depot would maintain its current sole supply status until 30 June 2007. PHARMAC would not delist Lucrin Depot before 1 January 2009, and would not reduce the subsidy or purchase price payable for Lucrin Depot before 1 January 2008.
- Goserelin would be referenced priced to the price of leuprorelin from 1 December 2005 as follows:

<b>Chemical</b>	<b>Brand</b>	<b>Strength</b>	<b>Pack size</b>	<b>Current subsidy and price</b>	<b>Proposed new subsidy</b>
goserelin acetate	Zoladex	10.8 mg	1 syringe	\$739.60	\$591.68
goserelin acetate	Zoladex	3.6 mg	1 syringe	\$277.00	\$221.60

Note all prices are ex-manufacturer, ex-GST

It is anticipated that the proposed changes, if accepted by PHARMAC's Board, would take effect from 1 December 2005. If you wish to make comments for the PHARMAC Board to consider when making its decision on whether to accept this proposal, please forward them to PHARMAC by **5.00 pm on Tuesday, 18 October 2005**.

Yours sincerely



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Therapeutic Group Manager Intern