

2 February 2007

To All Pharmaceutical Suppliers, Medical Groups and Interested Parties

Consultation on a provisional agreement with Eli Lilly and Company (NZ) Limited for the amendment of the terms of listing of pioglitazone (Actos) on the Pharmaceutical Schedule

PHARMAC and Eli Lilly have entered into a provisional agreement to amend the terms of listing of pioglitazone (Actos) in Section B and Section H of the Pharmaceutical Schedule.

Key aspects of this proposal are as follows:

- The price and subsidy for Actos in Section B, and the price for Actos in Section H of the Pharmaceutical Schedule, would be as follows from 1 April 2007 (ex-manufacturer, excluding GST):

Form	Strength	Pack Size	Current price & subsidy	Proposed price & subsidy
Tablet	15 mg	28	\$61.04	\$61.04
Tablet	30 mg	28	\$93.90	\$93.90
Tablet	45 mg	28	\$119.18	\$119.18

- Actos would be subject to a confidential rebate.
- PHARMAC would not delist, or reduce the subsidy paid for Actos before 1 July 2009.
- The Special Authority criteria applying to pioglitazone would be amended as shown in Appendix One.

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, 19 February 2007**. All comments submitted by this date will be considered.

Yours sincerely



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Therapeutic Group Manager

P11-1-8 #107156

Investing in Health

Appendix One

Proposed changes to pioglitazone Special Authority Criteria.

Proposed changes by PHARMAC in bold and strikethrough.

Initial Criteria:

Initial application for patients with type 2 diabetes only from **any relevant practitioner** a ~~relevant specialist~~.

Approvals valid for one year for applications meeting the following criteria:
Any of the following:

Monotherapy

1 All of the following:

- 1.1 To be used as monotherapy for patients who after six months of diet and lifestyle changes have inadequate glycaemic control (defined as HbA1c > 7.0% in tests carried out at least two months apart); and
- 1.2 Metformin is contraindicated or not tolerated after a minimum of a four week trial period; and
- 1.3 Sulphonylurea is contraindicated or not tolerated or the patient **is obese (usually defined as body mass index (BMI) greater than 33 kg/m²)**; or

In combination with sulphonylurea

2 Both:

- 2.1 For use in combination with a sulphonylurea for patients who after diet and lifestyle changes and a six-month trial of sulphonylurea have poor glycaemic control (defined as HbA1c > 8.0%) measured within the last month of the six month period); and
- 2.2 Metformin is contraindicated or not tolerated after a minimum of a four-week trial period; or

In combination with metformin

3 Both:

- 3.1 For use in combination with metformin for patients who after diet and lifestyle changes and a six-month trial of the maximum tolerated dose of metformin have poor glycaemic control (defined as HbA1c > 8.0%) measured within the last month of the six month period); and
- 3.2 Sulphonylurea is contraindicated or not tolerated or the patient **is obese (usually defined as body mass index (BMI) greater than 33 kg/m²)**; or

In combination with metformin after a trial of metformin and sulphonylurea

- 4 For use in combination with metformin for patients who after diet and lifestyle changes and a six-month trial of a combination of metformin and sulphonylurea at maximum tolerated doses have poor glycaemic control (defined as HbA1c > 8.0%) measured within the last month of the six month period); or

In combination with insulin

- 5 For use in combination with insulin in patients requiring more than 1.5 units per kilogram of insulin a day for at least 6 months in conjunction with metformin if tolerated.

Note

Pioglitazone is not to be used in triple oral combination (defined as a combination of metformin, sulphonylurea and pioglitazone)

Pioglitazone should not be used in patients with heart failure.

Liver function tests should be performed at baseline.

Gastrointestinal side effects are relatively common when initiating metformin therapy. Upward titration of metformin dose over several weeks and taking metformin with food will help to minimize these side effects.

Intolerance and contraindications for metformin include:

i) Serum creatinine ≥ 0.15 or creatinine clearance < 60 ml/min

ii) Significant liver impairment

iii) Severe left ventricular dysfunction

iv) Intolerable gastrointestinal side effects that persist beyond 4 weeks duration.

Intolerance for sulphonylurea includes: nausea; diarrhoea; rash; blood disorders (thrombocytopenia, agranulocytosis, aplastic anaemia); erythema multiforme, exfoliative dermatitis, hepatitis; and syndrome of inappropriate antidiuretic hormone secretion (SIADH) with water retention and hyponatraemia.

Maximum tolerated dose of metformin defined as: A dose up to a maximum of 3 g daily.

Maximum tolerated dose of sulphonylurea defined as: A dose up to a maximum of glibenclamide 20 mg daily or glipizide 20 mg daily or gliclazide 320 mg daily.

Renewal Criteria

Renewal for patients with type 2 diabetes only from **any relevant practitioner** ~~a relevant specialist~~.

Approvals valid for one year where the **patient is continuing to derive benefit from treatment** for applications ~~meeting the following criteria:~~

~~6 Patient has had two consecutive HbA1c levels test results of $< 8.0\%$ (at least two months apart) in the last six month period of pioglitazone treatment and~~

~~7 Either:~~

~~7.1 The patient is not on insulin combination therapy; or~~

~~7.2 Following the addition of pioglitazone, there has been at least a 30% reduction in insulin dosage~~