

15 June 2009

Funding proposal for Lantus (insulin glargine), Apidra (insulin glulisine) and Betadine (povidone iodine)

Proposal summary

PHARMAC and Sanofi-Aventis New Zealand Ltd have entered into a provisional agreement that would result in widening access to a long-acting insulin treatment for diabetes mellitus, funding a new rapid-acting insulin treatment for diabetes mellitus, as well as amending the terms of listing of one currently funded pharmaceutical. The agreement includes the following components:

- Widening access to insulin glargine (Lantus) by removing the current Special Authority criteria.
- Funding insulin glulisine (Apidra) without any access criteria.
- Amending the terms of listing of povidone iodine (Betadine).

Further details of the proposal can be found on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by 4 pm on **Friday 26 June 2009** to:

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Therapeutic Group Manager	Fax: 04 460 4995
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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

Insulin Glargine (Lantus)

- Lantus would be listed in Section B and Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST) from 1 August 2009:

Pharmaceutical	Brand	Form and Strength	Pack Size	Proposed price and subsidy
Insulin glargine	Lantus	Injection 100 IU/ml	5 x 3 ml pre-filled cartridge	\$94.50
Insulin glargine	Lantus	Injection 100 IU/ml	5 x 3 ml cartridge	\$94.50
Insulin glargine	Lantus	Injection 100 IU/ml	1 x 10 ml vial	\$63.00

- The current Special Authority that applies to Lantus would be removed from 1 August 2009.
- Confidential rebates would apply to Lantus, reducing the net subsidy paid for this medicine.
- Lantus would have protection from subsidy reduction and delisting until 1 August 2014.

Insulin glulisine (Apidra)

- Apidra would be listed in Section B and Section H of the Pharmaceutical Schedule as soon as practical following a clinical review and positive recommendation for funding (ex-manufacturer, excluding GST) as follows:

Pharmaceutical	Brand	Form and Strength	Pack Size	Proposed price and subsidy
Insulin glulisine	Apidra	Injection 100 IU/ml	5 x 3 ml pre-filled cartridge	\$59.52
Insulin glulisine	Apidra	Injection 100 IU/ml	1 x 10 ml vial	\$34.92

- It is anticipated that Apidra would be reviewed by the Diabetes Subcommittee of PTAC at its meeting in August this year.
- Apidra would be listed with no Special Authority or endorsement restrictions.
- Confidential rebates would apply to Apidra, reducing the net subsidy paid for this product.
- Apidra would have protection from subsidy reduction and delisting until 1 August 2012.

Povidone iodine (Betadine)

- The listing for Betadine would be amended (where applicable) in Section B and Section H of the Pharmaceutical Schedule from 1 August 2009 as follows:

Pharmaceutical	Brand	Form and Strength	Pack Size	Proposed price and subsidy
Povidone iodine	Betadine	Ointment 10%	25 g	\$3.27
Povidone iodine	Betadine	Antiseptic solution 10%	500 ml	\$6.20
Povidone iodine	Betadine	Alcohol skin preparation 10% with 30% alcohol	500 ml	\$10.00

- The manufacturers' surcharge that currently applies to Betadine in the community would be removed.
- An annual fixed rebate would apply to Betadine ointment for expenditure in the community.
- Betadine would have protection from subsidy reduction and delisting until 1 August 2012.

Background information

Lantus is a long-acting insulin, with a flat action profile, that is currently listed with Special Authority criteria which restrict funded access to a particular group of patients with type 1 diabetes. The Pharmacology and Therapeutics Advisory Committee (PTAC) and the Diabetes Subcommittee of PTAC have reviewed an application to widen access (by removing the Special Authority criteria) to insulin glargine (Lantus) for the treatment of diabetes mellitus.

PTAC considered that there was no clinical reason not to fund insulin glargine for patients with type 2 diabetes; however, PTAC considered that widening access as proposed could have a significant fiscal impact. The Diabetes Subcommittee of PTAC has reviewed the Special Authority criteria for Lantus on several occasions. The Subcommittee recommended that access to insulin glargine be widened to include patients with type 2 diabetes who are receiving an intensive regimen of insulin, because these patients carry the same risk of severe hypoglycaemia as patients with type 1 diabetes on intensive insulin regimens.

Apidra was approved by Medsafe in 2007, and up until now has not been considered by PHARMAC for funding. The listing of Apidra would provide an additional funded rapid-acting insulin. Apidra would be available in disposable pen cartridges like Lantus (SoloStar) and may benefit patients who are allergic to zinc (Apidra is zinc-free).