

9 November 2009

Notification of decline of funding proposal for Lantus (insulin glargine), Apidra (insulin glulisine) and Betadine (povidone iodine)

PHARMAC wishes to inform that the PHARMAC Board has decided to decline a proposal relating to the widening of 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. This proposal was the subject of a consultation letter dated 15 June 2009.

The proposal that was declined was to:

- widen access to insulin glargine (Lantus) by removing the current Special Authority criteria;
- fund insulin glulisine (Apidra) without any access criteria; and
- amend the terms of listing of povidone iodine (Betadine).

Details of the decision

Consultation on the above proposal closed on 26 June 2009. We received a number of responses to consultation and appreciate all of the feedback that we received. The majority of responses were supportive of the proposal.

Following consultation on the proposal, further information became available regarding the safety of insulin glargine. Four observational studies were published on the website of the journal *Diabetologia*, which discussed a potential association between the use of insulin glargine in people with type 2 diabetes and cancer risk.

The Pharmacology and Therapeutics Advisory Committee (PTAC) and the Diabetes Subcommittee of PTAC, at their respective meetings in August 2009, considered these studies and gave advice on the impact of the studies on the proposal to widen access to insulin glargine. Both committees recommended to PHARMAC that the proposal to widen access to insulin glargine be declined until further evidence becomes available that conclusively addresses the concerns raised in the studies.

Both committees considered that PHARMAC should monitor advice from Medsafe on this issue. Medsafe issued a media release and wrote to healthcare professionals in September 2009 advising that, as a precaution, until further information becomes available, patients should only use insulin glargine when it has specific benefits for them.

Further information can be found via the following website links:

- The journal *Diabetologia*: <http://www.diabetologia-journal.org/>
- PTAC minutes: <http://www.pharmac.govt.nz/2009/10/15/2009-08-14%20PTAC%20minutes%20for%20web%20publishing.pdf>

- Medsafe's press release: <http://www.medsafe.govt.nz/hot/media/2009/Insulin%20glargine.asp>
- Medsafe letter to Healthcare Professionals: <http://www.medsafe.govt.nz/hot/media/2009/Safety%20of%20insulin%20glargine%20-%20information%20for%20healthcare%20professionals.pdf>

At its meeting on 2 November, the PHARMAC Board decided to decline the proposal. In making this decision the Board took into account, among other things, all consultation responses received and the subsequent advice from PTAC and the Diabetes Subcommittee of PTAC.

We note that this decision does not mean that the applications for the widening of access to insulin glargine or for the listing of insulin glulisine on the Pharmaceutical Schedule have been declined. Both applications remain active and PHARMAC will continue to assess the applications, including any new relevant information that becomes available, in accordance with its operating policies and procedures.

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.