

PHARMAC

Pharmaceutical Management Agency

Media release

PHARMAC welcomes Medsafe approval of Herceptin

Medsafe's decision to provisionally approve the wider use of the breast cancer drug Herceptin is welcomed and will enable PHARMAC to progress its assessment further, says PHARMAC spokeswoman Dr Dilky Rasiah.

Data on Herceptin has been reviewed by the expert clinical committee PTAC. Further data has been received and will be taken to PTAC's cancer treatments sub-committee in April.

"Now that Medsafe has granted provisional approval we are in a good position to move forward," Dr Rasiah says.

"We have already moved quickly to examine the preliminary data. The next step is to obtain advice from the cancer treatments sub-committee, and a final recommendation from PTAC."

Dr Rasiah says in addition to the clinical data, an economic analysis of Herceptin and the total budgetary cost will also be important factors for PHARMAC and DHBs to consider. Because Herceptin is a drug administered in hospitals, it would be funded from DHB hospital budgets.

"At this stage we can't guarantee that Herceptin will be funded. We have to determine if the clinical data and cost-effectiveness stacks up. If it does, we then have to reach an agreement with the supplier, Roche, that could make it affordable for DHBs. Finally, DHBs will have to decide if this is something they can afford."

"In looking at Herceptin we have to consider what impact a decision to fund it might have on our ability to fund other drugs in the future. Spending \$30 million on Herceptin would constrain our ability to fund other drugs we are currently considering, so we are keen to work with Roche to find a way to make it affordable."

Dr Rasiah says PHARMAC will continue working with Roche and District Health Boards to progress the assessment of Herceptin as quickly as possible.

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For more information call (021) 863-342.

Herceptin timelines

Timeline to date

- **December 2005:** PHARMAC receives application from Roche to fund Herceptin for early breast cancer.
- **18 February 2006:** The Pharmacology and Therapeutics Advisory Committee (PTAC) considers application for early breast cancer. PTAC recommends further information be sought from Roche and for Herceptin to be considered by the cancer treatments sub-committee, should Herceptin be approved by Medsafe.
- **23 March 2006:** Medsafe grants provisional consent to Herceptin

Provisional timeline going forward

- **March 2006:** PHARMAC receives additional information from Roche
- **March-May 2006:** Discussions continue with Roche
- **March-May 2006:** Cost-utility analysis undertaken
- **April 2006:** Cancer Treatments Sub-Committee holds teleconference
- **April -June 2006:** Formal negotiations occur with Roche regarding supply terms and pricing
- **25 May 2006:** CaTSOP recommendation considered by PTAC
- **June 2006:** Recommendation for funding considered by DHB CEOs
- **June/July 2006:** Decision by PHARMAC Board