

5 May 2008

Proposal regarding the funding of 12 months treatment with Herceptin (trastuzumab) for HER 2 positive early breast cancer

Overview

Recently the High Court ruled on a Judicial Review of PHARMAC's processes surrounding its decisions to fund a 9 week concurrent treatment regimen of Herceptin (trastuzumab) for HER 2 positive early breast cancer patients, and not to fund a 12 month treatment regimen.

The Court found that in July 2006 PHARMAC should have consulted prior to its decision to decline Roche's application for funding for 12 months treatment with Herceptin, administered following completion of chemotherapy (12 months sequential treatment). The Court set the decision aside and directed PHARMAC to make a new decision regarding Roche's application, following consultation.

The PHARMAC decision to fund 9 weeks treatment with Herceptin administered concurrently with chemotherapy ("9 weeks concurrent treatment") remains in place for New Zealand women to access and this proposal, to decline the funding of 12 months treatment with Herceptin, would not have any impact on the funding for 9 weeks concurrent treatment.

Proposal

We are now seeking comment and additional information on a proposal to decline the funding of 12 months treatment with Herceptin for HER 2 positive early breast cancer.

If the PHARMAC Board approve this proposal it would mean that Roche's application for funding of 12 months sequential treatment with Herceptin, and other proposals relating to the funding of 12 months concurrent treatment with Herceptin, would be declined. PHARMAC would no longer be actively working on any proposal regarding the funding of Herceptin in early breast cancer.

Should information change regarding the relative benefits and costs of Herceptin compared with the currently funded 9 weeks concurrent treatment, PHARMAC would remain open to considering further applications for funding. Any future decisions would then consider the relative merits compared with other funding options available at the time.

Nature of consultation

We consider that good consultation is best achieved through clarity about our proposal for funding applications. This approach ensures PHARMAC is transparent about its current thinking, and enables affected parties to provide meaningful responses on how the proposed decisions may impact on them. This does not mean that a decision has already been made. Rather, it reflects the view we have reached on the basis of available information. This view may change as a result of the information PHARMAC receives through consultation. In this instance, PHARMAC's proposal is to decline funding. PHARMAC will, of course, take into account all information received in consultation when reaching a decision on 12 months treatment with Herceptin for HER 2 positive early breast cancer.

PHARMAC welcomes any and all views on this proposal. PHARMAC's role is not to 'count votes' but rather to ensure that it considers all relevant information in front of it about the potential effects, before reaching a decision.

Comments sought

We would welcome any comment you have on this proposal. To assist PHARMAC's consideration of submissions, submitters are encouraged to provide reasons supporting their views.

In particular comment regarding the comparative risks and benefits between 9 weeks and 12 months (sequential or concurrent) treatment regimens would be helpful. This would assist PHARMAC in considering the merit of investing in extra resources that 12 months (sequential or concurrent) treatment would require, when considering the proposal against its Decision Criteria.

In deciding which medicines to fund, PHARMAC seeks to balance the needs of patients' access to healthcare against its responsibilities to the taxpayer. Given PHARMAC is managing taxpayer funding, PHARMAC's decisions need to represent good value for money for the benefit of all New Zealanders. When considering which medicines to fund PHARMAC therefore takes into account a range of Decision Criteria including:

1. The health needs of all eligible people;
2. The particular health needs of Maori and Pacific peoples;
3. The availability and suitability of existing medicines, therapeutic medical devices and related products and related things;
4. The clinical benefits and risks of pharmaceuticals;
5. The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services;
6. The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Schedule;
7. The direct cost to health service users;
8. The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere; and
9. Such other criteria as PHARMAC thinks fit.

To provide comment please submit an email, fax or letter by **5 pm, Monday 9th June 2008** to:

Jackie Evans
Therapeutic Group Manager
PHARMAC
PO Box 10-254
Wellington 6143

Email: jackie.evans@pharmac.govt.nz

Fax: (04) 460 4995

If you require further information about this proposal you can contact Jackie Evans at jackie.evans@pharmac.govt.nz or (04) 916-7557.

All comment and additional information received before the closing date will be considered by PHARMAC's Board prior to making a decision on this proposal.

Our view in July 2006 was that funding 12 months' Herceptin could not be justified under our decision criteria. Since then some new information has become available. However, our preliminary view is that this new information would not have a material impact on this proposal since the last consideration of this matter by our Pharmacology and Therapeutics Advisory Committee (PTAC). Therefore we have decided to issue this proposal with speed as directed by the Court, and without seeking further advice from PTAC at this time. This and any other new information, along with consultation responses, will be taken into account before any decision is made

We anticipate that a decision would be made in June. However, if new information comes to light as a result of this consultation or as a result of presentation of new material (e.g at the American Society of Clinical Oncology conference in May/June) we will consider whether a delay is needed for further assessment and advice before making a decision.

Background

PHARMAC received an application from Roche for funding 12 months sequential treatment with Herceptin in December 2005. By July 2006 PHARMAC was not in a position to recommend funding of Herceptin, and made a decision at that time to decline funding, pending further review.

PHARMAC decided, after considering advice from the Pharmacology and Therapeutics Advisory Committee (PTAC) and its cancer treatments subcommittee, in April 2007 that under its Decision Criteria funding 9 weeks concurrent treatment with Herceptin was a good use of the funding available compared with other uses, and approved funding on this basis.

Recently the High Court ruled on a Judicial Review of PHARMAC's processes surrounding its decision in April 2007 to fund a 9 week concurrent treatment regimen of Herceptin (trastuzumab) for HER 2 positive early breast cancer patients, and not to fund a 12 month treatment regimen¹.

Of 28 grounds of appeal considered by the Court, 27 were not upheld. However, the Court did find that that PHARMAC ought to have consulted on its July 2006 decision not to fund Herceptin at that time, and for this reason set the July 2006 decision aside.

Given the extensive previous consideration of the matter, the Court has ordered PHARMAC to consult with speed on a new proposal regarding Roche's application for funding 12 months Herceptin for HER 2 positive early breast cancer patients.

The Court found that PHARMAC's decision to fund the 9 weeks concurrent treatment was made appropriately. The decision for funding 9 weeks concurrent treatment with Herceptin therefore remains in place for New Zealand women to access.

We are now consulting on a proposal to decline the funding of 12 months treatment with Herceptin for HER 2 positive early breast cancer. This would mean that Roche's application for funding of 12 months sequential treatment with Herceptin, and proposals relating to the funding of 12 months concurrent treatment with Herceptin, would be declined.

¹ The High Court Judgment can be found at <http://www.pharmac.govt.nz/2008/04/02/090408.pdf>

The available clinical trials for 9 weeks treatment with Herceptin and 12 months treatment with Herceptin have reported similar benefits in terms of cancer-free survival (although it appears that concurrent regimens may be somewhat more efficacious than sequential). We are aware however, that only studies of the 12-month treatment regimens have confirmed that overall survival benefits result from the improvement in cancer-free survival observed in earlier follow up.

The currently funded 9 weeks concurrent treatment regimen costs an estimated \$6 million per year. Funding a 12 month treatment regimen (whether concurrent or sequential) of Herceptin would, at the current price, cost an estimated \$25 million per year, including costs of infusions and other hospital services.

If this proposal to decline the funding of 12 months treatment (whether sequential or concurrent) with Herceptin for HER 2 positive early breast cancer is approved by the Board, PHARMAC would remain open to considering future applications for funding Herceptin for HER 2 positive early breast cancer. This is particularly the case if new information sufficiently demonstrates that an alternate regimen produces additional health gains compared with the currently funded 9 weeks concurrent treatment regimen.

There is uncertainty about the best way to administer (dosing schedule and duration of treatment) Herceptin in HER 2 positive early stage breast cancer, and in our view the optimal regimen cannot be determined from the current evidence.

PHARMAC has been contributing some financial support to a clinical trial since mid-2007 (known as SOLD) for the purpose of obtaining relevant information to help address this uncertainty, and to inform any future decisions regarding Herceptin.