

Media release

5 May 2008

Herceptin consultation underway

PHARMAC has today begun consulting on a proposal to decline funding for 12 months' treatment for HER2 positive early breast cancer with Herceptin.

The consultation is a result of the High Court judgment on a judicial review of PHARMAC's Herceptin decisions. The judgment set aside a 2006 decision by PHARMAC not to fund Herceptin, and directed PHARMAC to consult on 12 months' Herceptin funding.

Chief Executive Matthew Brougham says PHARMAC has taken time to consider the implications of the judgment, and is implementing the Court's direction.

PHARMAC's proposal is that funding for 12 months' Herceptin be declined.

"We acknowledge that a number of people have hopes of a 12 month treatment being funded. 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. This and any other new information, along with consultation responses, will be taken into account before any decision is made."

"To help people make meaningful responses, and to be transparent about our current thinking, it is important we make it clear in consultation what our proposal is – the proposal is for funding to be declined."

Matthew Brougham says PHARMAC has an open mind and will give serious consideration to all information that is received, before any decision is made.

"We want to hear any and all views that people want to share. We are expecting a high level of interest in the proposal, but consultation is not about counting votes. Consultation is about ensuring the decision maker has all relevant information before it when making a decision. As PHARMAC will need to carefully assess submissions, people are encouraged to identify and explain the reasons supporting their view."

"We want to assure people that PHARMAC has an open mind and is treating this as an opportunity to review all available materials, hear from all interested parties, and to ultimately make a robust decision having followed a fair and open process."

PHARMAC is also aware of a major oncology conference in the United States at the end of May, where further relevant data may be presented on Herceptin. If further information is presented at the conference or elsewhere, PHARMAC will consider it.

Given the high level of public interest, PHARMAC is consulting on the proposal until 9 June, including meetings with a number of interested groups and individuals, as well as obtaining written feedback.

“The consultation process on this proposal will be similar to our consultation around funding 9 weeks’ Herceptin in early 2007, which the Court found to be more than adequate.”

A consultation letter, outlining the funding decline proposal and seeking feedback, is being sent to interested groups today, and posted on PHARMAC’s website (www.pharmac.govt.nz).

Matthew Brougham says it is important to remember that a full and effective treatment of Herceptin remains funded and available to New Zealanders at this time – the 9 week treatment concurrent with a taxane.

With respect to 12 months treatment, even if the Board decides not to fund such a treatment following this consultation, PHARMAC could still reconsider that decision in future if new information shows that funding could be justified under PHARMAC’s decision criteria.

ENDS

Background

Why is PHARMAC again consulting on Herceptin?

A High Court judicial review decision has directed PHARMAC to consult on its decision not to fund Herceptin for HER 2 positive early breast cancer in July 2006. The previous consultation that PHARMAC conducted in March/April 2007 was on a proposal to fund 9 weeks' treatment with Herceptin for HER 2 positive early breast cancer.

What is PHARMAC consulting on?

The consultation is on a proposal to decline funding for 12 months' Herceptin. PHARMAC decided not to fund Herceptin in July 2006 and, after a thorough consideration of the evidence, economic analysis and with advice from its clinical advisory committees, decided in April 2007 to fund 9 weeks treatment with Herceptin from 1 June 2007. Since then some new information has become available, however our preliminary view is that this new information would not cause us to make a different proposal at this time. That's why the current proposal is to decline funding for 12 months' Herceptin.

Who is being consulted with?

We're interested in the views of anyone (including clinicians, public groups or individuals) who may be affected by, or have a view on, the proposal to decline to fund 12 months' Herceptin. As well as being posted on our website, our consultation letter is being sent to our usual consultation list (over 200 organisations), and we are identifying groups with a specific interest to meet with such as breast cancer groups, women's health groups, oncologists and District Health Boards.

How will PHARMAC be conducting consultation?

In addition to our usual approach of issuing a consultation letter and seeking written feedback, we will be offering a number of groups with a particular interest the opportunity to meet with us face to face.

In recognition of the high public interest in funding for Herceptin we will be conducting consultation for five weeks.

What will happen then?

We will be considering all the feedback we receive during consultation and this will be used to inform our recommendation to the PHARMAC Board. We often make changes to our proposals in the light of consultation responses.

We anticipate that a decision on this proposal would be made by the Board in June 2008. However, we may delay a decision after we take into account consultation responses and any new information that comes to light as a result of presentation of relevant new material (e.g. at the American Society of Clinical Oncology conference in May/June).

What is the nature of PHARMAC's consultation?

PHARMAC wants to make its decisions after assessing all relevant information. Part of this information gathering is asking the wider public for its input.

Consultation is not about counting votes but rather ensuring that the decision maker – in this case the PHARMAC Board – has all relevant information before it when it makes a decision. The purpose of consultation is to ensure that decision makers make a robust and well-informed decision. As PHARMAC will need to carefully assess submissions, people responding to consultation are encouraged to identify and explain the reasons supporting their view.

Will Herceptin still be funded?

Yes. At present New Zealand women continue to have fully funded access to an effective and full course of Herceptin treatment – 9 weeks' concurrent treatment with a taxane drug.

Currently about 350 women each year are eligible for treatment with Herceptin for early breast cancer.

If, having considered consultation responses, the Board approves the proposal to decline funding for a 12 months Herceptin treatment, the 9 week funded treatment would remain available.

With respect to 12 months treatment, even if the Board decides not to fund such a treatment following this consultation, PHARMAC could still reconsider that decision in future if new information shows that funding could be justified under our decision criteria.

What would be the cost of funding a 12 month treatment regimen?

A nine-week regimen of Herceptin is currently funded and this is estimated to cost DHBs about \$6 million per year. Funding 12 months' Herceptin at the current price would cost about \$25 million per year.

Why is NZ currently funding a different treatment regimen to other countries?

PHARMAC's role is to make funding decisions that are sustainable and in the best interests of New Zealand. This means making our own carefully thought-out decisions independently of other countries.

Concurrent 9 week Herceptin is available as a treatment choice in other countries (including Australia), and international debate about the need for longer duration treatment continues.

PHARMAC is helping to fund an international clinical trial (SOLD), to help answer the question of whether it is worth adding longer-duration treatment to a concurrent 9 week regimen.

How effective is Herceptin?

Herceptin (trastuzumab) has been tested in clinical trials in two main ways – sequential (after chemotherapy) and concurrent (at the same time as chemotherapy) treatment. It provides additional benefit over standard chemotherapy alone.

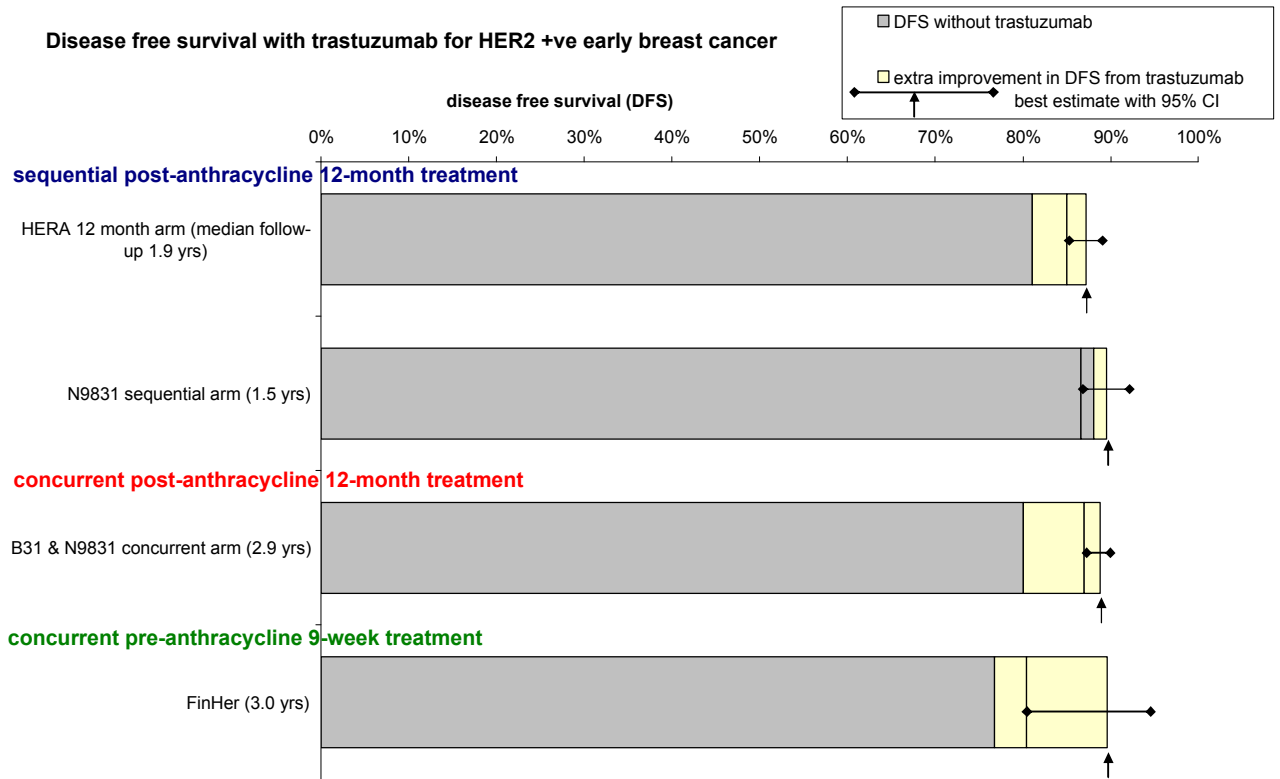
Herceptin is a relatively new treatment and the studies show it improves disease-free survival compared to standard chemotherapy. Follow-up data on these studies suggest this improvement may wane over time.

Here is a summary of the results of the main trials:

- HERA trial (sequential treatment, taken for 12 months) – when measured after 2 years, compared to standard chemotherapy, for every 100 women treated with Herceptin, six more would avoid having their tumours recur, and nearly two extra deaths would be avoided.
- N9831 Arm B (sequential 12 month treatment) – no real benefit (a 1.5% improvement in disease-free survival, which was not significantly better than standard care) after 18 months.
- Romond study (concurrent 12 month treatment) – for every 100 women treated, compared with standard chemotherapy, about 8 would avoid having their tumours recur, and two additional deaths would be avoided (measured at 2 years follow up).
- FinHer (concurrent 9 week treatment) – for every 100 women treated with Herceptin, compared with standard chemotherapy, 13 more women would avoid having their tumours recur, when measured after three years.

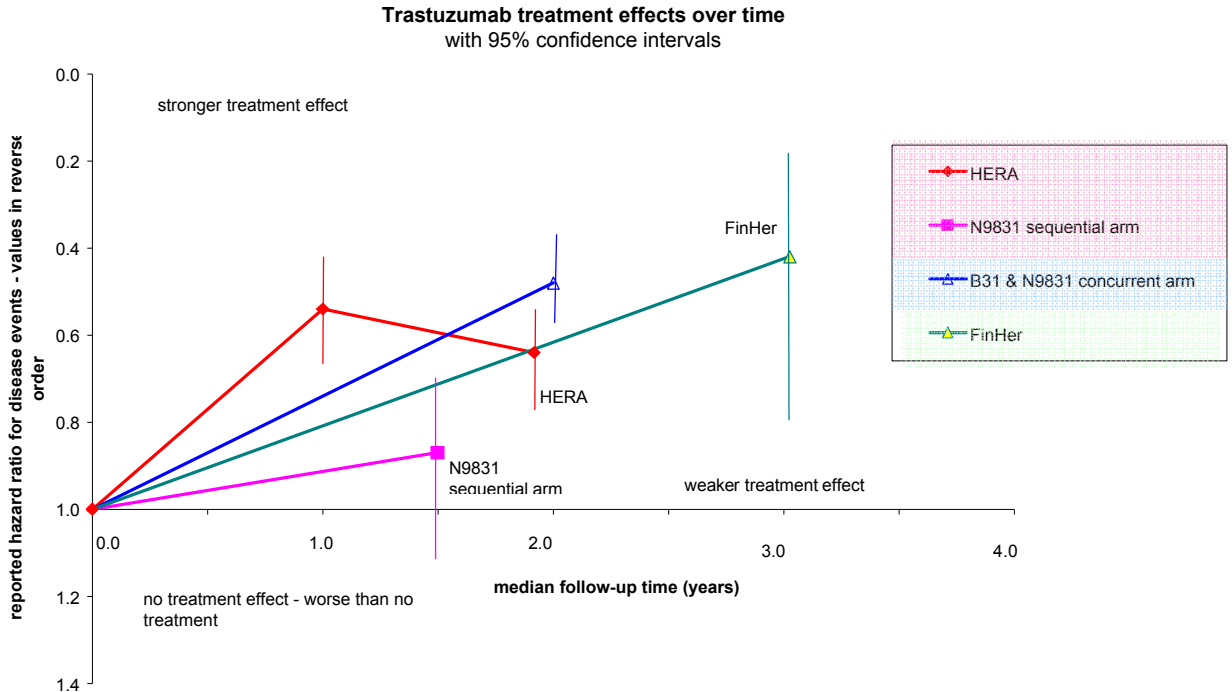
The larger studies provide greater certainty of the accuracy of the evidence, providing greater confidence in the result. Smaller studies, such as FinHer, have greater confidence intervals than larger studies, however the results are still statistically significant. The following graphs illustrate the effects of the trials, with confidence intervals,

Graph 1



Graph 1 shows the extra improvements through using trastuzumab, as outlined in the trial summary commentary above. The graph shows both the best estimates and the range within which we can be sure the true value lies (each result's 95% confidence interval). For instance, with the two trials for sequential 12 month Herceptin (HERA and N9831 arm B), overall the best estimate is a 4% reduction in disease events over nearly 1.8 years, with the 95% confidence range being as high as 6% and low as 3%.

Graph 2



Graph 2 shows how effective Herceptin treatment has been in the clinical trials, with the results displayed over time.

The higher up the graph, the more effective the treatment. Below the horizontal (1.0) line, it is not effective at all (and is worse than no treatment).

Vertical lines indicate confidence intervals. The narrower the confidence interval, the more sure are the results. The graph shows, for instance in the HERA trial, there appears to be a waning of effect, seeming to be less effective when patients were followed up for a median of two years than when they were measured at one year; while FinHer's results span a median of three years' follow-up.

Herceptin timeline

- **December 2005:** PHARMAC receives application from Roche to fund Herceptin for 12 months' sequential treatment for HER 2 positive early breast cancer (an indication not then approved by Medsafe).
- **18 February 2006:** The Pharmacology and Therapeutics Advisory Committee (PTAC) considers application from Roche. PTAC recommends further information be sought from Roche and for Herceptin to be considered by the Cancer Treatments Sub-Committee (CaTSoP), should Herceptin be approved by Medsafe.
- **23 March 2006:** Medsafe grants provisional consent to Herceptin for treatment for HER 2 positive early breast cancer.
- **March-May 2006:** Cost-utility analysis of 12 months' treatment with Herceptin for HER 2 positive early breast cancer prepared by PHARMAC.
- **April 2006:** CaTSoP reviews Roche's Herceptin application.
- **April - June 2006:** Negotiations occur between PHARMAC and Roche regarding supply terms and pricing.
- **25 May 2006:** CaTSOP recommendation provided to PTAC. PTAC considered there was insufficient evidence to justify a funding recommendation for 12 months' treatment, and sought further information.
- **June/July 2006:** DHBs and PHARMAC decide not to fund Herceptin at that time, and commit to an ongoing review of Herceptin.
- **August 2006:** Further data on Herceptin considered by PTAC. PTAC asks CaTSoP to consider clinical appropriateness of any funding regimen consistent with a nine week treatment of Herceptin.
- **October 2006:** CaTSoP meets. Recommends that in the absence of funding for 12 months, 9 weeks' Herceptin treatment would be reasonable.
- **November 2006:** PTAC receives CaTSoP minute. PTAC recommends nine week treatment be funded (high priority). PTAC also notes more clinical research is needed (specifically a study comparing 12 months' treatment with 9 weeks').
- **December-February 2006-07:** Cost utility analysis of nine week treatment undertaken by PHARMAC; investigation of NZ participation in international clinical trial.
- **16 February 2007:** PHARMAC commits to supporting the SOLD clinical trial.
- **22 February 2007:** PTAC examines further information from Roche on Herceptin. Reiterates recommendation that nine weeks' treatment be funded.
- **Early March 2007:** Following consultation with DHBs, public consultation occurs on a draft proposal to fund Herceptin (nine weeks' concurrent). The Consumer Advisory Committee recommends the development of a patient oriented resource relating to any funding decision.

- **April 2007:** PHARMAC Board approves funding for 9 weeks' treatment with Herceptin for HER 2 positive early breast cancer from 1 June 2007.
- **1 June 2007:** Herceptin funded for women with HER 2 positive early breast cancer.
- **29 June 2007:** Eight women file proceedings in the High Court seeking judicial review of PHARMAC's Herceptin decisions.
- **August 2007:** High Court hears application for interim orders on these proceedings. Finds in favour of PHARMAC.
- **February 2008:** High Court hearing on judicial review application takes place over 6 days.
- **3 April 2008:** High Court issues ruling on judicial review application, and upholds one of the 28 grounds for judicial review. PHARMAC is directed to consult on its decision not to fund 12 months' Herceptin in July 2006.
- **2 May 2008:** PHARMAC consults on proposal to decline 12 months' Herceptin funding.