

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.

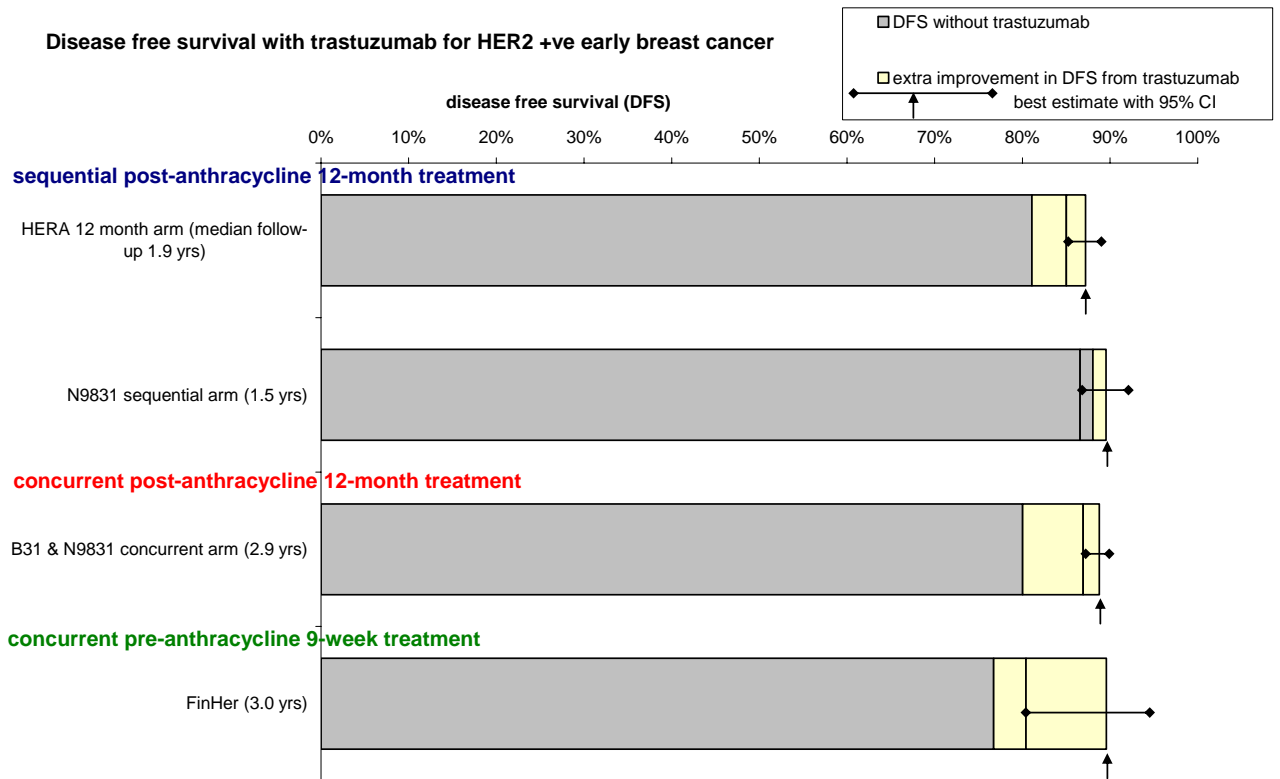
Herceptin is a relatively new treatment and the studies show it improves disease-free survival compared to standard chemotherapy. Follow-up data on these studies suggest this improvement may wane over time.

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.

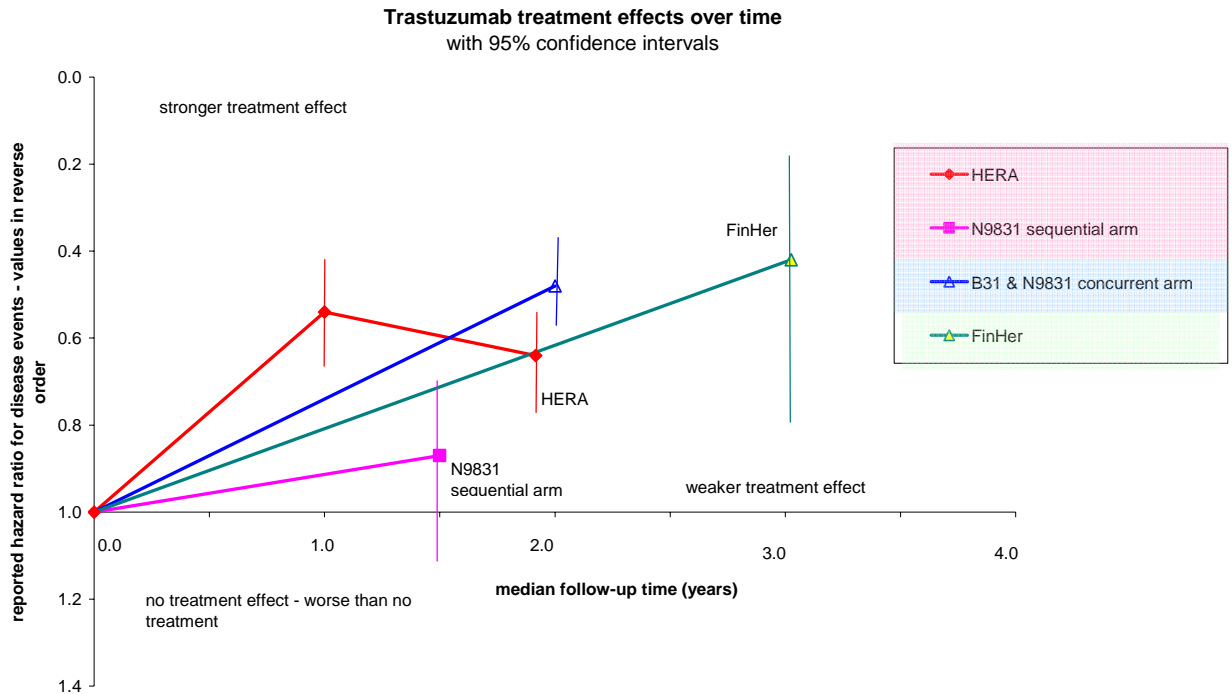
The larger studies provide greater certainty of the accuracy of the evidence, providing greater confidence in the result. Smaller studies, such as FinHer, have greater confidence intervals than larger studies, however the results are still statistically significant. The following graphs illustrate the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