bcac breast cancer aotearoa coalition

Together we're stronger
Tangata tū pakari tonu

28 October 2016

PHARMAC TPP "Have your Say – Consultation 2016"

Breast Cancer Aotearoa Coalition's response to questions: Thank you for the opportunity to attend the preliminary consultation meeting held in Wellington on September 6, 2016 and to "Have our Say".

The Breast Cancer Aotearoa Coalition (BCAC) is driven to transform the lives of those diagnosed with breast cancer every year by seeking world-class detection, treatment and care.

Why is BCAC needed?

Compared to Australia and other developed countries, New Zealand has: poorer cancer services and delayed delivery of treatment [i], reduced access to effective treatments, especially medicines and worse outcomes and higher death rates as a result of these inadequacies. New Zealand has the seventh highest incidence of breast cancer in the world and New Zealanders are 40 per cent more likely to die than their Australian counterparts [ii and iii]. Outcomes are improving, but we are not there yet: the next ten years are critical.

Achievements

Established in 2004 we've helped to transform the breast cancer landscape in New Zealand to improve care and treatment. Some of our achievements include:

- Producing and distributing the *Step by Step* support pack free-of-charge to more than **10,000** people (1,200 packs p/a) and developing patient videos, *Kiwi Stories of Breast Cancer*, to provide information, hope and support to women experiencing breast cancer (**11,000** views)
- Engaging with PHARMAC, Minister and Ministry of Health over the public funding of a range of breast cancer medicines including taxanes, aromatase inhibitors and HER2-targeted molecules.
- Promoting: extension of the age for free breast screening to between 45 and 69; the need for fertility services for young people diagnosed with breast cancer; the need for cancer nurse navigators; the need for psychosocial support for cancer patients; reviewing the ethical status of a breast cancer clinical trial; helping to develop the *Guidelines for the Management of Early Breast Cancer* and the *Standards of Service Provision for Breast Cancer Patients in New Zealand*; providing consumer input to many expert clinical groups.

Although we have a track record of driving real and tangible change for those with breast cancer, **there is more to be done.**

PO Box 90224, Auckland Mail Centre
Auckland,1142, New Zealand
P 09 537 5227 E bcac@breastcancer.org.nz
www.breastcancer.org.nz

Ongoing commitments

- Public funding of a range of innovative and effective new breast cancer medicines, including: Abraxane, Afinitor, Faslodex, Halaven, Kadcyla and Perjeta and extending the uses of Tykerb
- The introduction of a new rapid radiotherapy intra-operative treatment in the public health system for women with early stage breast cancer
- Well-designed clinical trials to achieve increased patient access to new treatments
- Improved access to lymphoedema services throughout New Zealand
- Providing ongoing consumer input to a range of specialist meetings alongside clinical leaders
- Extending the free breast screening age up to 74
- Closing the gap for Māori and Pasifika women, who have worse breast cancer outcomes
- Providing support and information for women with secondary breast cancer
- Informing women and their families about the latest in breast cancer news and research through our comprehensive and regularly-updated website.

4.1. TPP-related consultation questions

1. How well does the proposed OPP section 2.1 reflect the proposed TPP-related changes?

We see the proposed changes as introducing an increased level of transparency for the open track model with no clear timeline while the reverse applies to the TPP track, no transparency and clear timelines. Our preference would be a single-track model where large pharma and other applicants are treated equally while managing issues of confidentiality separately from the process. We have reservations regarding the proposed 36-month timeline indicated, which seems too long in an era of increased innovation, rapid and ongoing change as a slew of new breakthrough medicines become available – some of which may work for more than one condition. We suggest a 12- to18-month timeline. We are aware that access to new drugs is slow, with the average time between registration and funding being 579 days for New Zealand, compared to 383 days in Australia and 118 days in the UK [vii]. We see benefit in striving for a shorter period.

2. How well does the proposed OPP section 4.1 (General Section) reflect the proposed TPP-related changes?

It appears to reflect the TPP requirements as we understand them.

3. How well does the proposed OPP section 4.5 (the procedure for listing a pharmaceutical on the pharmaceutical schedule) reflect the proposed TPP-related changes?

It appears to reflect the TPP requirements as we understand them. We also welcome the online open track initiative. This will make PHARMAC's processes transparent as long as they are kept up to date and accurate. We are concerned there will be no timeline for the open track process and that patients in need of a medicine may have to wait for years with deteriorating health before a decision is made – time that cancer patients may not have.

4. How workable is the proposed TPP track and what issues or concerns might you have with its implementation?

In our view the key drivers for change are transparency and timeliness.

The TPP track indicates that timeliness is achievable. We prefer to see a single track where all applicants are treated equally and the value to be gained from a timeline is shared by all.

We see value in the open track as a means of gaining transparency. We do not see a need to trade transparency for confidentiality and feel that issues of confidentiality can be managed separately from the process. In addition, we would want new indications that have been the subject of a previous application considered within a timeframe and not on an open-ended basis.

We see no reason for PHARMAC which is in control of its committee dates including PTAC to introduce delays to the proposed time driven process. We see this as reducing the value of what is proposed and putting the overall timeliness at risk. We are concerned that the proposed timeframe of 36 months is too long.

5. How reasonable is 36 months as the proposed timeframe within which PHARMAC should make its Final Determination for TPP track applications?

As highlighted above we see this timeframe as being too long. In an era of increased innovation, rapid and ongoing change, a faster response time is needed to rapidly provide medicines that deliver greater length and quality of life, especially to breast and other cancer patients.

Given the speed of drug development a slew of new breakthrough medicines will become available in a short timeframe – some of which may work for more than one condition. The US FDA has a rapid approval process for promising medicines and we propose that a similar process be introduced for New Zealand to ensure that breakthrough medicines reach patients while they can be helped to improve or retain health and life.

6. How reasonable is the proposed period of grace of 10 working days within which supplier TPP track applications may be amended?

We see the 10-day grace period as workable.

7. What level of detail would it be reasonable to publish following a TPP Review?

Information relevant to the decision made.

The question PHARMAC has to answer is, “Is it fundable and if not why not?” This is generally an issue of prioritisation and competing needs rather than a second review of the drug’s efficacy.

For example, when PHARMAC does accept the strength of data provided, they may still give a medicine low priority because of insufficient funds in the medicines budget. Many of the breast cancer medicines we want funded are fully backed by strong data and are the standard of care in Australia and other countries. If or when PHARMAC declines funding we want it

made clear that it is as a result of a lack of funds and other competing needs and when PHARMAC agrees to fund, its priority against other competing needs, should be made clear.

In our view if New Zealand's medical regulatory body Medsafe has already registered a drug, then we do not see it as helpful that the Pharmacology and Therapeutics Advisory Committee (PTAC) review the medicine again. We understand why they may be led to justify their decision in this way, however as consumers we find new and sometimes derogatory information from PTAC regarding a drug unhelpful. The drug will have been registered and considered by Medsafe. Why ask these questions again, why have two regulatory bodies performing the same tasks? Communicating derogatory information about a new drug successfully being administered in other developed countries, in our view, unnecessarily colours the reason for the decision and creates unnecessary stress for patients, frustration for clinicians and acrimonious public argument. We believe that increasingly the key reason for a decision is a lack of funding.

A more objective view would be obtained on any given medicine if the function of analysis of efficacy was separated from the body charged with funding medicines (PHARMAC). Independent cost-benefit analysis would provide more credible outcomes from the consideration processes.

We are also aware that the Factors for Consideration although broader are of necessity narrowed as they relate to PHARMAC's statutory objective and as a result all decisions are made within the context of a capped fund. They are generally qualitative in nature which means transparency is harder to achieve.

We support the Cancer Society's view in its position statement on breakthrough therapies, that a robust system like ESMO Magnitude of Clinical Benefit scale – like a Drug Scorecard (a standardised, generic, validated approach to stratify the magnitude of clinical benefit that can be anticipated from anti – cancer therapies: the European Society for Medical Oncology Magnitude of Clinical Benefits Scale) should be considered [iv].

8. What other thoughts do you have on the proposed OPP changes?

Breast cancer is **not** one of the eight diseases identified as a priority for Māori and yet for Māori breast cancer patient's outcomes and quality of life are particularly poor. For example, there is a major disparity in female breast cancer incidence and mortality between rural Māori and non-Māori populations in New Zealand.

In 2010 the age-specific registration rate of breast cancer was 60% higher in rural Māori compared to non-Māori women, and the mortality rate in Māori was almost twice that of non-Māori for this disease [v]. While Pasifika women have the highest mortality.

Are these factors being taken into account when reviewing breast cancer medicines? It is clear that late diagnosis and suboptimal access to treatment remain the focus for poor outcomes so stage of cancer, survival gaps and treatment differences are all important. If late diagnosis and or more aggressive cancers at an earlier age is an issue for rural Māori, **then the availability of new breakthrough treatments is vital.**

We know that patients who have been diagnosed with primary breast cancer have a greater risk of being diagnosed with secondary breast cancer (30%) therefore optimal treatment options for early breast cancers will reduce the risk of advanced breast cancer. **Is this being taken into account?**

Patients with advanced breast cancer may live for many years with the disease and will require treatment and support to live as long and as well as possible, managing their cancer effectively as a chronic condition. **We want a focus on both quality of life and length of life in making decisions regarding treatment options.**

5.4. Other consultation questions

9. What comments do you have on the proposed new funding application website?

The new website will improve transparency and timeliness in the provision of information. In addition, it should make PHARMAC's processes visible.

10. *What information should be published and why?*

The date of application, the name of the medicine and the use for which it is being applied for. The process to be undertaken by PHARMAC, the findings at each step, relevant deliberations at each step. We would also appreciate knowledge of indicative timeframes even if extensions may be necessary.

11. *What comments do you have about the processes for publishing information?*

We would like:

- Indicative timelines provided alongside the process steps to provide maximum transparency
- Determination of efficacy separated from cost benefit analysis given the analysis of safety and efficacy already undertaken by Medsafe prior to registration of a new medicine
- Broader quantitative data as well as qualitative data.

12. *What is your view on the proposal to distinguish a decision to "Decline" from a decision to "Decline as Proposed"? How useful would you consider such a distinction?*

We would see this as useful as long as the reasons for declinature are made clear and are relevant. "Declined as proposed" suggests further opportunity for consideration of a medicine whereas "declined" suggests the door is closed on further proposals. For this reason "declined as proposed" is a preferable response to an application.

13. *What other general comments do you have regarding this consultation?*

New Zealanders deserve better access to medicines

Our women are dying earlier than they should. Within five years of diagnosis, for every 7 Australian women who die, 10 New Zealand women will die, so we have a 40% higher death rate than Australia [iii].

Recent research has shown that if our 5-year survival rate was the same as Australia's, 529 New Zealand women who died from breast cancer between 2006 and 2010 would still be alive [iii]. Across all cancers 3,631 New Zealanders would still be alive if they had been diagnosed and treated in Australia.

A number of factors are thought to contribute to New Zealand's higher death rate for breast cancer including later diagnosis, **slower access to treatment** and less effective therapy than in Australia. In New Zealand, Māori and Pacific women have significantly worse survival than other ethnicities, with the strongest reason for this being later diagnosis, when the cancer is at a more advanced stage [v].

Key statistics

New Zealanders' lack of access to new medicines is stark when we compare ourselves with other OECD countries. Some key facts about medicines access in this country:

- Between 2009 and 2014, across all diseases only 14 new medicines[vi] were publicly funded in New Zealand while 59 were funded in Australia and 131 in the UK [vii].
- **New Zealand had the lowest access to new medicines of all 20 OECD countries compared [vii].**
- New Zealanders were given access to only 13% of the new medicines registered as safe and effective by New Zealand's regulatory body Medsafe, compared to 39% in Australia and 80% in the UK [vii].
- Access to these few drugs was also slow, with the average time between registration and funding being 579 days, compared to 383 days in Australia and 118 days in the UK [vii].
- There are currently **five (**Perjeta, Kadcyla, Abraxane, Afinitor and Halaven) breakthrough breast cancer medicines funded in Australia to give longer, healthier lives to women with different types of breast cancer, but none of these is provided to New Zealand women [viii].
- New Zealanders with breast cancer are 40% more likely to die than Australians [vii].
- Australia spends $435 per person on medicines, but in New Zealand we spend a mere $180 per person [xi].
- In the UK, 80% of approved new medicines are publicly funded, in Australia 39%, but in New Zealand it's only 13% [vii].

BCAC wants to see some of these appalling statistics change to ensure our women and men get the best possible treatments available.

Access to new drugs would extend both quality and length of life for New Zealanders with breast cancer and would give oncologists additional options for treating different sub-types of breast cancer.

The impact of New Zealand's lack of access to new medicines

While effective new medicines remain unfunded, patients and their families are forced to pay high prices to gain access to these innovative drugs, or go without. This creates significant social inequity as some can afford to pay, some are forced to sell or mortgage their homes and others miss out entirely.

It is not only patients who will benefit from greater access to new cancer medicines. There are benefits to the health system in particular and society as a whole. Innovative cancer therapies deliver on every measure. They:

- deliver longer, better lives for patients
- save our health system resources
- reduce hospital stays
- keep people working
- reduce palliative care and
- keep families together.

They are economically as well as socially beneficial [ix]. New Zealand needs to catch up with the rest of the world.

Two breast cancer charities that are members of BCAC, Breast Cancer CURE and the New Zealand Breast Cancer Foundation along with the Health Research Council of New Zealand are building on and increasing our capability to develop prognostic tests to test the efficacy of drugs and develop new targets for those they are ineffective for. One project nearing completion is doing exactly that for the drug Tamoxifen and another project to develop such a test for Kadcyla, not yet available in New Zealand [xv].

This demonstrates that breast cancer charities are not standing idly by and only asking for more but are also trying to strategically improve treatment outcomes and the economies of such outcomes.

New Zealand's rigid pharmaceutical system

One of the reasons for our low and slow access to medicines is that, unlike other OECD countries, PHARMAC has a capped pharmaceutical budget. This means there is a fixed amount of money available for PHARMAC to invest in medicines, so for a new medicine to be funded, cost savings must be made elsewhere, often by removing funding for another medicine. This makes our funding system rigid and unresponsive when a breakthrough new treatment becomes available [x].

Not only is New Zealand's medicines budget capped, but it is also very small. For the 2016/17 year it is set at $850M, representing an investment of $180 per person [xi]. In contrast, in 2015 Australia spent $435 per person on medicines [xii].

A further compounding issue is the high cost of innovative medicines. Pharmaceutical companies invest around USD $2.87 billion (2013 figure) to bring a single new medicine to market and are driven to retain economic viability and provide returns to shareholders [xiii]. Without successful pharmaceutical companies, there would be no pipeline for new medicines. It is vital that these companies collaborate with government agencies to provide their successful new products at affordable prices.

Changes are needed to New Zealand's pharmaceutical system

Following consultation, PHARMAC's criteria for deciding which medicines to fund were revised in 2015 to include not only impacts on the pharmaceutical budget but also on people, whanau and communities, as well as the wider health system [xiv]. PHARMAC's statutory obligation is to "*…secure the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided*". The problem is clearly the amount of funding provided.

New Zealanders deserve a world-class health system that supports us to live long, healthy lives. Right now our women are dying needlessly of breast cancer, other cancer patients' lives are shorter than they need to be and people with a range of diseases are suffering needlessly because they cannot access modern medicines available to the citizens of other developed countries.

We ask PHARMAC to work with the Minister of Health to show leadership in developing long-term strategic solutions, to future-proof NZ's health system and to keep pace with innovation. We see a need to bring our pharmaceutical budget in line with the rest of the OECD. Remove the cap on the pharmaceuticals budget so that we can respond to need, save lives and provide the health benefits that innovative new medicines provide. Consider the strategies that other countries have adopted, such as Early Access to Medicines Schemes and Cancer Drugs Funds.

All New Zealanders deserve a healthcare system that gives us longer, healthier lives.

References

i. Ministry of Health 2014. New Zealand Cancer Plan: Better, Faster Cancer Care 2015 – 2018.

ii. Campbell I.D., Scott N., Seneviratne S., Kollias, J., Walters D, Taylor, C, Webster F, Zorbas H and Roder DM 2014. Breast cancer survival in New Zealand women. ANZ J Surg. 2015 Jul; 85 (7-8):546-52. doi: 10.1111/ans.12851.

iii. Sandiford, P., Abdel-Rahman, M. E., Allemani, C., Coleman, M. P., & Gala, G. (2015). How many cancer deaths could New Zealand avoid if five-year relative survival ratios were the same as in Australia? Aust N Z J Public Health, 39(2), 157-161. 10.1111/1753-6405.12344

iv. http://www.esmo.org/Policy/Magnitude-of-Clinical-Benefit-Scale/Manuscript

v. Seneviratne, S., Lawrenson, R., Scott, N., Kim, B., Shirley, R. and Campbell, I. 2015. Breast cancer biology and ethnic disparities in breast cancer mortality in New Zealand: A cohort study. PLOS ONE. DOI: 10.1371/journal.pone.0123523

vi. New medicines are defined as New Molecular Entities.

vii. IMS Consulting Group 2015. Access to New Medicines: Comparison across OECD Countries. Report for Medicines Australia. (Summarised version available in Medicines Australia 2015, Compare. www.medicines.com.au)

viii. Breakthrough breast cancer medicines that improve and extend life and are funded in Australia but not New Zealand are Abraxane, Afinitor, Halaven, Perjeta and Kadcyla.

ix. Lichtenberg F.R. and Williams-Spence, J.W. The impact of pharmaceutical innovation on the longevity and hospitalisation of New Zealand Cancer Patients 1998 – 2012.

x. Wonder, M. and Milne, R. 2011. Access to new medicines in New Zealand compared to Australia. New Zealand Medical Journal Vol 124 No 1346, 12 – 28 ISSN 1175 8716 http://journal.nzma.org.nz/journal/124-1346/4966/

xi. PHARMAC NZ; Pharmaceutical Benefits Scheme, Australia; Statistics NZ; Australian Bureau of Statistics.

xii. PBS 2015 http://www.pbs.gov.au/info/browse/statistics

xiii. Di Masi, J.A. and Grabowski, H.G. and Hansen, R.W. 2016. Innovation in the pharmaceutical industry: new estimates of R&D costs. J. Health Econ. 47: 20-33. Doi:10.1016/j.jhealeco. 2016.01.012

xiv. PHARMAC 2015. Prescription for Pharmacoeconomic analysis. Methods for Cost-Utility Analysis. Version 2.2 – 2015

xv. http://www.healthresearchcouncil/newresearch targets drug resistant breast cancer 8 August 2016 and New Breast Cancer Partnership funds 3 Projects 31 March 2016