BCAC Submission to the Health Select Committee re: Terre Maize petition for funding of Ibrance and Kadcyla

4 March 2019

Contents

Breast Cancer Aotearoa Coalition

1. The Breast Cancer Aotearoa Coalition (BCAC) is a coalition of more than 30 breast cancer-related groups, and is an incorporated society with charitable status run by breast cancer survivors, established in 2004. BCAC's mission is to make world-class detection, treatment and care accessible to all those affected by breast cancer in Aotearoa, New Zealand; to provide information and support to empower those with breast cancer to make informed choices about their treatment and care; and to provide a voice for New Zealanders who have experienced breast cancer.
2. BCAC's activities include distributing 1,400 Step by Step support packs each year to New Zealanders diagnosed with breast cancer; providing information on diagnosis, treatment and recovery via our website (www.breast.cancer.org.nz), delivering up-to-date breast cancer news, research results and events on the website and via facebook, twitter and an e-newsletter, and providing technical support for the Metavivors online community for those with advanced breast cancer.
3. We are strongly committed to taking an evidence-based approach in all that we do. We facilitate our members' education by helping them to attend international breast cancer research and peer support meetings. Our members serve on numerous government and NGO committees, providing consumer input, and we meet regularly with clinicians, researchers, DHB and Ministry of Health staff, and other stakeholders in breast cancer in NZ. Organisations we interact regularly with include: Breast Cancer Cure (charity, research), Breast Cancer Foundation NZ (charity), Breast Cancer Trials (Australia and NZ breast cancer clinicians and researchers), Breast Screen Aotearoa (government), Breast Special Interest Group (breast cancer specialists' professional body), Clinical Trials NZ (research), DHBs, Health Quality and Safety Commission (government), Medicines NZ (industry), Ministry of Health, Patient Voice Aotearoa (NGOs), PHARMAC, and Sweet Louise (charity). We provided consumer representation on the working groups that developed the Management of Early Breast Cancer: Evidence-based Best Practice Guideline (2009) and the Standards of Service Provision for Breast Cancer Patients in New Zealand (2014). We provide an annual briefing on breast cancer-related issues to the Minister of Health, and to other members of parliament with interests and responsibilities in health.
4. The issues we raise are based on direct communication from our members about their current concerns. As New Zealanders who have personally experienced breast cancer, we are uniquely placed to provide an authentic consumer voice on the subject, to identify possible solutions to issues, and to help with their implementation.
5. BCAC is not a wealthy charity and relies heavily on gifts of volunteer time and expertise. We employ two part-time staff and have total annual expenses of $60-70,000. BCAC's activities are funded by donations and grants from individuals, businesses, other charities, NGOs and government entities, bequests and interest on savings. We do not charge a fee for membership or any of the services and goods we provide. We do not have a vested interest in the outcomes of our activities other than a desire to improve the lives of all New Zealanders affected by breast cancer.

Why we are making this submission

6. BCAC has received a strong message from members that the issue currently causing the greatest distress and hardship to breast cancer patients is the lack of access to effective medicines. BCAC has a deep understanding of this issue. Three of our current committee members have advanced breast cancer and we have previously lost three committee members and many close friends to the disease.

7. The fact that many New Zealanders must personally pay to gain access to cancer medicines that are evidence-based and recommended by their oncologists is creating a two-tiered health system in which those who can pay will live longer (1). Families are forced to cash in retirement savings, sell properties, set up 'Give a Little' pages and fundraise to gain benefits in quality of life, progression free survival and overall survival offered by modern medicines.

8. Studies using data from New Zealand's comprehensive Breast Cancer Registers published by researchers based at the University of Waikato have demonstrated serious socio-economic inequities in access to breast cancer detection treatment and outcomes (2). Further analysis presented by the Breast Cancer Foundation NZ (3) reveals ethnic inequities in the number of treatments provided to Māori women with advanced breast cancer and their survival.

9. Recent research has shown alarmingly poor survival for all New Zealanders with advanced breast cancer, compared to those in other countries (3). In New Zealand the median survival is 16 months, compared to 29.4 months in the Netherlands, 36.8 months in Germany, 25 - 54 months in the USA, 23.1 months in France, and 33 months in Sweden (3). Overseas expert, Dr Fatima Cardoso, Chair of the ABC Global Alliance and co-author, of ESMO guidelines for treatment of advanced breast cancer (4), confirmed our fears about New Zealand's poor outcomes for breast cancer patients by referring to the 'worrisome case of New Zealand' and stating that the outcomes were 'not like those of a developed country' (Cardoso presentations, Auckland, 29 January 2019 and Wellington 'Cancer Care at a Crossroads' conference, 1 February 2019).

10. BCAC acknowledges that improving breast cancer outcomes involves a wide spectrum of activities, from better risk assessment, targeted screening, earlier detection, greater public health literacy, prompt access to surgeons, radiation oncologists, medical oncologists, imaging and pathology services, as well as the facilities, staff and training needed for these. However, access to new medicines can, to a large extent, account for major improvements in breast cancer survival in the developed world over the last 40 years (5). As research continues to reveal the multiplicity of sub-types of breast (and other) cancers, the ongoing discovery of new medicines to target each type more precisely is leading to more effective treatments, better quality of life and longer life for cancer patients.

BCAC's experience with PHARMAC

11. PHARMAC and the Ministry of Health play critical roles in determining New Zealanders' access to medicines. The Health Select Committee has already received submissions from each, describing their perspectives on the Terre Maize petition. BCAC's specific comments on these submissions are appended to this submission.

12. On 13 February 2019, the Health Select Committee heard PHARMAC and the Ministry describe the processes used to make decisions about public funding of cancer medicines in New Zealand. This of course was an internal perspective on their own work. BCAC has engaged with PHARMAC many times over the last 14 years, and wishes to offer the Committee an evidence-based, authentic, patient-centred perspective on this organisation and its processes.

13. BCAC first met with PHARMAC in June 2005, and raised with them matters relating to proposed changes in the pharmaceutical treatments schedule, provision of medicines under exceptional circumstances, and in particular the need for subsidies for taxanes, aromatase inhibitors and trastuzumab (Herceptin®).

14. At that time, taxanes (e.g. docetaxel) had been available in the USA since 1999, funded in Australia since 2001 and recommended as a high priority for NZ patients by PHARMAC's Cancer Treatments Subcommittee (CaTSoP) in 2004. Taxanes were finally funded in NZ in 2007. Aromatase inhibitors were subsidised for some uses in breast cancer in NZ, but scientific evidence for their effectiveness in a wider range of patients had been accumulating since about 2000 (6). Between 2007 and 2009, wider access to these medicines was finally granted by PHARMAC. Trastuzumab (Herceptin®) was registered rapidly by Medsafe in March 2006 and first examined by PHARMAC in December 2005. Australia provided funding for this breakthrough medicine in August 2006 but the evidence-based 12-month treatment was not added to the Pharmaceutical Schedule in NZ until 2010. The government made the decision to fund this treatment in November 2008 but was forced to provide a separate Ministry of Health fund for this as PHARMAC refused to fund. NZ was the last of the OECD countries to fund Herceptin®.

15. Since 2005, BCAC has used PHARMAC's consultation process to provide feedback on any proposals to fund medicines for breast cancer (this consultation occurs at the very last step before a medicine is approved for funding - see process description below), has contacted and met with PHARMAC staff at regular intervals. BCAC has participated at every opportunity as consumers commenting on PHARMAC's policies and processes (e.g. 2008 Terms of Reference and Appointment Protocols for PHARMAC's Pharmaceuticals and Therapeutics Advisory Committee, 2009 Consumer Engagement consultation, 2010 consultation on Consumer Advisory Committee Terms of Reference, 2011 consultation on PHARMAC's Exceptional Circumstances funding, 2012 PHARMAC's Operating Policies and Procedures, 2016 Trans-Pacific Partnership consultation, 2018 Consumer Voice review). We note that from a consumer perspective very little has changed as a result of these consultations. One of our members served on PHARMAC's Consumer Advisory Committee between 2010 and 2013, but there are currently no members of this committee with direct experience of breast or any other cancer.

16. BCAC corresponds directly with PHARMAC regarding widening access to breast cancer medicines, such as pertuzumab (Perjeta®) (7, 8, 9) and, since 2018, BCAC has applied directly to PHARMAC for listing of four medicines to treat advanced breast cancer: fulvestrant (Faslodex®) (10), nab-paclitaxel (Abraxane®) (11), everolimus (Afinitor®) (12), and palbociclib (Ibrance®) (13).

17. Our observations and interactions with PHARMAC over the last 14 years have led us to conclude that, despite changes in leadership, PHARMAC consistently shows a deplorable lack of urgency in granting access to medicines for NZ cancer patients (see Table below), is insular in its thinking and has a culture of secrecy, has failed to plan for future health needs of a steadily increasing number of NZ cancer patients, denies any responsibility for poor health outcomes and has failed to respond to consumer input.

Summary of issues with PHARMAC

18. Medical care for people with breast cancer in New Zealand has fallen far behind world's best practice (as defined by evidence-based practice guidelines) in the area of availability of proven medicines. This is reflected in the poor outcomes particularly for people with advanced disease.
19. PHARMAC is simply far too slow in giving due consideration to life-saving and life-extending treatments. This includes delays (for no justifiable reason) in referring applications to their clinical advisers. The publication of minutes of meetings is also unacceptably slow.
20. PHARMAC's internal processes are far from robust with applications not being included in the application tracker – in one case for nearly a year.
21. PHARMAC is too focussed on delaying or denying treatment access 'dressed up as' reducing the risk of funding ineffective medicines whilst not giving adequate attention to the impact of failing to provide access to proven effective medicines.
22. PHARMAC's decision-making is veiled in secrecy (there are no published minutes of the meetings where medicines are ranked and funding decisions are made). The basis for particular decisions, let alone the ways in which PHARMAC's Factors for Consideration are applied, is opaque.
23. There is no opportunity for consumers or the public to have any meaningful input into PHARMAC's decision-making processes.
24. BCAC is concerned that the impact over time has been a trend in reduction in medicines choice because sponsors are not willing to 'navigate the New Zealand system' because of the low probability of success and protracted delays to funding. Unless the system changes, we are destined to fall further behind world's best practice.
25. BCAC is also concerned that New Zealanders' participation in clinical trials (an important means for some patients to gain access to new medicines and to contribute to research) is being stifled. Without the treatments that are the current international standard of care, we are excluded from trials aimed at testing the addition of a new treatment (i.e., we cannot participate in the control arm of the study let alone the experimental one).
26. The longer we fail to deal with these issues the more people will die prematurely or have their quality of life severely compromised. This deeply affects patients, families, whānau and wider society.

Outline of PHARMAC's process for listing medicines

27. The steps involved in listing a medicine on the Pharmaceutical Schedule (i.e. government funds or subsidises cost to patient) are as follows:

    - Application to PHARMAC (for each particular use of a particular medicine, both clinical and financial applications are required)
    - Medsafe approval (also known as 'registration') will be required as well, but application for this may or may not have been filed at this stage. Medsafe ensures that particular medicines meet safety, quality and performance standards' and perform as claimed by the manufacturer (https://www.govt.nz/organisations/medsafe/).
    - Receipt of application acknowledged by PHARMAC

- Referral to the Pharmacology and Therapeutics Advisory Committee (PTAC) or one of its sub-committees - in this case the Cancer Treatments Subcommittee (CaTSoP). CaTSoP comprises clinicians representing various cancers, bringing their own expertise to the room, but they are not required to consult more widely with others in their field if further expertise is required. There is one breast cancer specialist on CaTSoP at present. The committee is appointed on the basis of their clinical expertise and ability to appraise scientific evidence from clinical trials, but when making their recommendations they often also take financial cost into account, although they have no particular expertise in economic assessment (e.g. CaTSoP minutes September 2018, published December 2018; https://www.pharmac.govt.nz/assets/ptac-cancer-treatment-subcommittee-minutes-2018-09.pdf).
- PTAC or CaTsoP minutes produced, giving the committee's recommendation, with a priority ranking (low, moderate, high or decline).
- Referral back to PTAC, if the recommendation was from CaTSoP.
- PTAC minutes produced, giving the committee's recommendation. PTAC meets 4 times per year.
- If the recommendation is positive, then the medicine (for the use ('indication') described in the application) goes onto a list to await prioritisation by PHARMAC staff.
- The prioritisation process takes place at an unspecified time, involving unspecified PHARMAC staff, using PHARMAC's decision-making framework, which includes measuring each recommended medicine against the Factors for Consideration, except that PHARMAC states that 'The Factors are not weighted or applied rigidly, and not every factor is relevant for every funding decision PHARMAC makes. …. the context within which decisions are made is constantly changing.' (https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/factors-for-consideration/). These meetings occur 3 or 4 times per year.
- There are no published minutes of these meetings.
- PHARMAC issues a proposal to list the medicine on the Pharmaceutical Schedule and seeks feedback from the public (about 2-3 weeks are allowed for input).
- The PHARMAC Board (the Chair of PTAC attends as an observer) makes the final decision on listing the medicine (unless it has delegated this to the CEO of PHARMAC). https://www.pharmac.govt.nz/assets/pharmac-board-governance-manual.pdf
- Decision to list is notified.

Time taken to fund currently available breast cancer treatments

28. BCAC has calculated the time from initial application to PHARMAC to listing (funding) of currently available breast cancer medicines on the Pharmaceutical Schedule, using PHARMAC's Application Tracker (see Table below). There are 11 products with 23 indications (particular uses) listed. The average time from application to listing was 1032 days (34 months) and the median time to listing was 912 days (30 months). As these are all standard, accepted, evidence-based treatments, one

can only wonder how many people could have been effectively treated during these protracted periods of 'decision-making'.

Currently Funded Treatments and the Time taken					
Treatment	***Indication***	***Application***	***Pharmac Listing***	***days***	
Anastrozole	Widening 1st line ABC	Oct-01	Jun-05	1339	
Anastrozole	Third line	Feb-97	Dec-98	668	
Anastrozole	After 2 years tamoxifen	Oct-02	Dec-08	2253	
Anastrozole	Second line	Oct-01	Sep-02	335	
Aromatase inhibitors	Widening of access	Aug-07	Nov-08	458	
Aromatase inhibitors	Include Stage IIIc	Jul-07	Aug-08	397	
Capecitabine	ABC after failure of 2 prior chemotherapies	Mar-00	Nov-02	975	
Docetaxel	Adjuvant treatment in breast cancer	Sep-04	May-07	972	
Docetaxel	EBC contraindicated anthracycline treatment	Feb-10	Jun-11	485	
Docetaxel	Early breast cancer	Nov-09	Jun-11	577	
Exemestane	Widened access	Jan-04	Jun-07	1247	
Gemcitabine	MBC	Feb-12	Nov-12	274	
Lapatanib	First line HER2+ MBC	Nov-10	Feb-12	457	
Letrozole	First line EBC	Feb-06	Aug-08	912	
Letrozole	Third line	Apr-98	Dec-98	244	
Letrozole	Post-menopausal women	Jan-02	Jun-05	1247	
Letrozole	First line ABC	Jan-02	Sep-09	2800	
pertuzumab	HER2+ MBC - treatment naïve	Nov-13	Dec-16	1126	
trastuzumab	HER2+ EBC 12 month regimen	Dec-05	Jun-10	1643	
trastuzumab	HER2+ MBC retreatment	Apr-10	Sep-11	518	
trastuzumab	HER2+ EBC 9 week regimen	Dec-05	May-07	516	
zoledronic acid	EBC	Oct-14	Dec-17	1157	
zoledronic acid	Prostate, breast and multiple myeloma	Jan-03	Oct-14	4291	
			average	1032	days
			median	912	days
			low	244	days
			high	4291	days

Source: Pharmac's Application Tracker, accessed 29 February 2019.

Key treatments that New Zealanders with breast cancer are currently missing out on

Palbociclib (Ibrance®)

29. Ibrance® (palbociclib) was registered for first- and second-line use in the treatment of women with hormone receptor positive breast cancer in June 2017. This type of cancer has only two targeted treatment class options (tamoxifen and aromatase inhibitors) available funded in New Zealand. If these treatments fail, then chemotherapy remains the only funded option for New Zealand women. It is vitally important that less toxic treatments than chemotherapy are funded to extend survival and maintain quality of life in those who relapse after first line treatment or have a recurrence.

30. The sponsor of Ibrance® (palbociclib), Pfizer, applied for its listing on the Pharmaceutical Schedule in the first line setting in combination with letrozole (only 1 of the 2 approved indications) in February 2018 and it was considered by CaTSoP in September 2018. The submission by PHARMAC to the Health Select Committee states that CaTSoP advised 'while this treatment looks promising, the evidence only showed modest benefits for patients, and the price is prohibitively expensive.' This is not what is actually stated in the minutes of the CaTSoP meeting which say there was a 'relatively high price' being sought by the supplier and that 'overall there was reasonable evidence

of a modest effect' and the recommendation that it be funded with a moderate priority. Meanwhile, in New Zealand women with breast cancer are being advised by their oncologists to pay privately for treatment at a cost around $6,000 per month if sourced in New Zealand. People accessing medication from Malaysia are paying about $3,000 per month.

31. Because most women currently self-funding Ibrance® (palbociclib) are using it in the second line (or later) setting, (having exhausted available treatment options), BCAC made an application for the public funding of Ibrance® (palbociclib) in combination with fulvestrant (another unfunded treatment that is covered below) in the second line setting in November 2018. This was therefore in time for the deadline for consideration at the February 2019 PTAC meeting. The submission presented all the latest scientific evidence and also included the individual perspectives of a number of New Zealand women who provided information about their need for therapy, their response to (self-funded) therapy and their experiences in sourcing treatment from overseas (13). On 21 December 2018, BCAC was advised by PHARMAC that the application would not be considered at the February PTAC meeting. This indicates PHARMAC's lack of concern and lack of urgency in dealing with this issue, despite the desperate situation the petitioners find themselves in. (See also section below on fulvestrant registration and funding).

Trastuzumab emtansine (T-DM1, Kadcyla®)

32. Kadcyla® (T-DM1) has been registered in New Zealand since 2013. The first application was made by the sponsor for funding in August 2017. It was considered by PTAC in November 2017 and subsequently by CaTSoP (most recently in September 2018) and given a medium priority for funding. It has been funded in Australia since July 2015, and was recommended by NICE (UK) in 2017. BCAC wrote to PHARMAC subsequent to the CaTSoP minutes being published supporting the recommendation for access to Kadcyla® (TDM-1) for patients with metastatic breast cancer previously treated with trastuzumab and/or a taxane i.e. as second line therapy (14). This is consistent with international guidelines' recommendations. However, BCAC contends that the proposal to deny access to patients with symptomatic brain metastases should be reconsidered. The Subcommittee also recommended that trastuzumab emtansine (Kadcyla®, TDM-1) for the treatment of HER2 positive metastatic breast cancer patients who have previously received trastuzumab (Herceptin®) in combination with pertuzumab be deferred pending further evidence to support its use in this setting. BCAC has provided PHARMAC with 8 published clinical papers that support its use in this setting. Furthermore, international guidelines such as those of ESMO and ASCO (American Society of Clinical Oncology) endorse such use. ESMO Guidelines (4) state that after first-line, trastuzumab-based therapy, T-DM1 (Kadcyla®) provides superior efficacy relative to other HER2-based therapies in the second line (versus lapatinib + capecitabine) 'and beyond' (versus treatment of physician's choice). (Level of evidence: 1A). As shown above, New Zealanders do not even have access to lapatinib and capecitabine in the second line setting. The need for Kadcyla® to be funded for patients with advanced breast cancer is urgent and should be implemented without further delay.

Fulvestrant (Faslodex®)

33. Fulvestrant is used to treat hormone-receptor positive advanced breast cancer in postmenopausal women with disease progression following anti-oestrogen therapy. This product was first registered by Medsafe for breast cancer in 2006 and applications were made to PHARMAC by the sponsor (AstraZeneca) for funding in August 2006 and Dec 2007. It was considered by PTAC in Dec 2006, March 2008, and July 2008 and by CaTSoP in March 2008 and recommended for decline. The sponsor subsequently let the Medsafe registration lapse. The product is currently available in New Zealand under Section 29 of the Medicines Act. New data at a higher dose indicate significant

benefits in women with hormone-receptor positive breast cancer. Fulvestrant is included in the approved indication for Ibrance® (palbociclib) in the second line setting.

34. Based on requests from oncologists and their patients, BCAC made an application for the listing of fulvestrant on the Pharmaceutical Schedule in May 2018, which was referred to CaTSoP in September 2018 (10). CaTSoP recommended funding with a medium priority for hormone-receptor positive advanced breast cancer. BCAC is awaiting an update from PHARMAC on the next steps that will be taken to subsidise this medicine as this recommendation should be implemented as soon as possible. Furthermore, this treatment will be needed for use in conjunction with Ibrance® (palbociclib) in the second line setting, as indicated above.

Nab-paclitaxel (Abraxane®)

35. This is a chemotherapy formulation which, according to feedback from medical oncologists, is needed in New Zealand particularly for people who are intolerant of the commonly used formulation, which contains a toxic solvent. It is also needed for people with other cancers who have similar intolerance and need taxane treatment. It was registered by Medsafe in 2010. The sponsor (Specialised Therapeutics) made applications for reimbursement in August 2010 and April 2013. It was considered by PTAC in Nov 2010, Feb 2011, Aug 2013, Feb 2014 and Aug 2014. It was considered by CaTSoP in Nov 2010, Sep 2013, and Mar 2014. It was recommended for listing "if cost neutral" to the older (more toxic) formulation. On the basis of requests from clinicians, BCAC made a further application for its listing for the select group of patients who cannot tolerate paclitaxel in the current formulation in February 2018 (in time for the May 2018 PTAC meeting deadline) (11). BCAC was subsequently advised by PHARMAC that this would not go to PTAC in May 2018 or CaTSoP in April 2018. The reasons given were that 'we have a lot of applications and don't have the capacity to consider all of them at our next meetings' and 'we want to consider all the breast cancer medicines at the same time'.

36. Not having seen any minutes relating to this application from the September 2018 CaTSoP meeting, BCAC followed up PHARMAC and asked whether this submission had been considered and why it had not been included in the 'Application Tracker' on the PHARMAC website. BCAC was informed by PHARMAC 'Unfortunately, the application for nab-paclitaxel that was submitted by BCAC was not considered at CaTSoP in September. There were a number of applications for consideration at this meeting, including several for breast cancer treatments, which meant that choices had to be made about which ones to immediately progress for clinical advice. I note that nab-paclitaxel for the treatment of metastatic breast cancer has previously been considered by our committees and has been recommended only if cost neutral; and so is an option for investment should this level of pricing be achieved. We are currently considering whether information provided in your application would change our assessment of cost-neutrality and whether further clinical advice should be sought. I note that the next CaTSoP meeting is scheduled for early April 2019.'

37. This further demonstrates the lack of urgency and complete lack of regard for needs of clinicians and patients when a submission made in February 2018 will not be referred to a clinical advisory committee until April 2019. BCAC is also concerned that it took nearly a year for this application to be included in the 'Application Tracker' on PHARMAC's website. This treatment has been funded in Australia since May 2009 – i.e. for nearly 10 years! It is also used to treat patients with other cancers, who would benefit from its availability and reduced toxicity.

Everolimus (Afinitor®)

38. Everolimus is recommended by ESMO guidelines and is reimbursed or recommended for use in Australia (since 2014), Canada, France and the UK (CDF, NICE and SMC). The sponsor (Novartis) has indicated that they will not apply for registration or reimbursement in New Zealand for breast cancer (although it is registered and reimbursed for other cancers). Based on feedback from oncologists that this treatment is needed in New Zealand, BCAC made an application for funding for everolimus in July 2018 (in plenty of time for consideration at the September 2018 CaTSoP meeting) (12). This application was not referred to CaTSoP, nor has this submission been referred to any other advisory committee as far as BCAC is aware. It is listed in the Application Tracker with no activity having been noted. Once again this emphasises the lack of regard for patient needs, lack of adherence to due process and lack of urgency on PHARMAC's part. It has been reimbursed in Australia since June 2014, was recommended in the UK in 2016 and reimbursed in Canada from 2013.

Pertuzumab (Perjeta®)

39. Pertuzumab is a targeted treatment for HER2 positive breast cancer approved by Medsafe in July 2013 for use in conjunction with trastuzumab (Herceptin®). The sponsor (Roche) made an application to PHARMAC in November 2013. It was reviewed by PTAC in February 2014, August 2014 and May 2015 and by CaTSoP in March 2014 and March 2015. At all meetings it received a low priority for funding but it was funded for treatment-naïve patients in December 2016 – over 3 years after the first application. PHARMAC proposed that funding only be available for patients who had not already started trastuzumab treatment. In response to the consultation, BCAC responded to PHARMAC that it should also be available for people who had already commenced trastuzumab (7). This group had been funded to receive treatment in Australia, on the basis that, although there was no direct clinical trial evidence in this group, there was a plausible rationale for such treatment. BCAC wrote to PHARMAC again twice January 2017 (8) and July 2018 (9) seeking funded access for this group based on results of the PHEREXA clinical trial (15). This was requested urgently given that this treatment had shown a significant impact on survival in a group of patients who had already run out of other treatment options. CaTSoP considered access by such patients again in September 2018 and recommended that these patients should have access to treatment, but only if they had had no other therapies in the meantime. This is concerning as patients only find themselves in the unenviable position of seeking other treatments because they were denied therapy from the date of implementation of funding. This example, again demonstrates unacceptable delays and lack of regard for needs of patients who find themselves in dire need of effective life-extending therapy.

40. It is unacceptable for patients forced to find alternative treatments while a new drug is moving slowly through the PHARMAC approval process to then be excluded from access to the approved drug on the grounds they received an alternative through the period of delay. This approach by PHARMAC is consistently and unacceptably reducing the number of patients gaining access to new approved medicines; it effectively punishes patients who sought an urgent alternative in the meantime.

Trastuzumab (Herceptin®), subcutaneous therapy

41. Trastuzumab (Herceptin®), the standard of care for HER2 positive breast cancer in both early and advanced disease, is now available in a formulation that may be given by subcutaneous (under the skin) administration rather than by the intravenous infusion. The first application was made by the sponsor (Roche) for funding in August 2014. It was considered in November 2014, March 2015 and

November 2015. It was given a low priority for funding by CaTSoP in March 2015 and a recommendation for funding if cost-neutral to the intravenous formulation by PTAC in November 2015. This formulation would have significant benefits for patients and the health care system in terms of reduced time taken (5 minutes every 3 weeks compared with 90 minutes for the first dose and 60 minutes every 3 weeks for subsequent doses of the intravenous formulation) and reduction in need and duration for a peripherally inserted central catheter (PICC) line or portacath and their associated complications. Clinicians have reported to BCAC that provision of this formulation would greatly relieve pressure on infusion facilities, freeing up space and staff time to allow faster treatment of other cancer patients. This formulation has been funded in Australia since April 2016.

Pegylated doxorubicin (Caelyx®)

42. Caelyx® is doxorubicin in 'pegylated liposomes' (tiny fatty spheres that are coated with polyethylene glycol). This reduces the rate at which the active substance is broken down, allowing it to circulate in the blood for longer. It also reduces its effects on non-cancer tissues and cells, so it is less likely to cause some side effects. It was registered by Medsafe in 1997. The sponsor made applications to PHARMAC in October 2006 and October 2011 and it was considered by PTAC in Nov 2006, Feb 2009, Feb 2012 and by CaTSoP Dec 2007, June 2008 and Nov 2011. It was recommended for listing with low priority by PTAC and low-moderate priority by CaTSoP. According to the PHARMAC Application Tracker it was last ranked in Feb 2012. BCAC understands that the sponsor has given up on getting this treatment funded in New Zealand. It has been funded in Australia since 2003. It provides significant benefits for some patients.

Lapatinib (Tykerb®) for second line use

43. Applications for funding of lapatinib in second line metastatic HER2 positive breast cancer were considered in 2007, 2010 and 2011. In January 2012, PHARMAC proposed funding lapatinib for first line but not second line use - outside its (then) approved indications. BCAC wrote to PHARMAC to suggest lapatinib should be available for use in the second line setting (16). This was consistent with the expert opinion of New Zealand's cancer clinicians expressed to PHARMAC in a submission from the NZ Breast Cancer Special Interest Group. Experts considered this was the area of greatest clinical need and strongest evidence for lapatinib was as a salvage therapy for those patients with metastatic HER2 positive breast cancer who progress after receiving trastuzumab with chemotherapy for metastatic disease. In 2012, PHARMAC funded lapatinib only as a first line treatment, thereby denying patients access to it as a second line treatment. It has been funded in the second line setting in Australia since May 2008. Subsequent applications for second line use were made in February 2012, February 2013, August 2013 and all were recommended for decline. Its use in the second line setting elsewhere has now been superseded by Kadcyla®. ESMO guidelines now recommend the use of the combination of lapatinib and trastuzumab in certain settings which appears to have little prospect of ever being funded by PHARMAC.

Eribulin (Halaven®)

44. Eribulin kills cancer cells by inhibiting cell division and is used to treat late stage metastatic breast cancer that is hormone-receptor-positive and HER2-negative that has previously been treated with anthracycline and taxane chemotherapies. ESMO recommend it as a choice in patients pre-treated (in the adjuvant and/or metastatic setting) with an anthracycline and a taxane, and in combination with trastuzumab. There has been no application for registration or reimbursement in New Zealand. It has been funded in Australia (Oct 2014), Canada (Aug 2012), France (Sep 2015), UK (NICE Dec 2016) and Scotland (Mar 2016). BCAC believes that the sponsor is simply not interested in negotiating the New Zealand system with so little prospect of timely funding.

Denosumab (Xgeva®) for prevention of skeletal related events in metastatic breast cancer

45. Denosumab (Xgeva®) is approved by Medsafe (but not marketed) for the prevention of skeletal related events (SREs) in patients with bone metastases from solid tumours (including breast cancer). It has a different mechanism of action to zoledronic acid, can be given to patients with renal impairment and is given by subcutaneous injection, rather than intravenous infusion. A recent Cochrane Collaboration meta-analysis of 3 randomised clinical trials comparing denosumab with zoledronic acid in women with metastatic breast cancer with bone involvement found that denosumab reduced the risk of developing an SRE compared with bisphosphonates (zoledronic acid) by 22% (RR 0.78, 0.72 to 0.85; P < 0.001; 3 studies, 2345 women) (17). No application has been made to PHARMAC for funding of denosumab for prevention of skeletal related events in New Zealand, although a clinician applied for funding for hypercalcaemia of malignancy in 2018. Denosumab has been funded in Australia for breast cancer patients since 2011 and was recommended by NICE (UK) in 2012.

Trastuzumab (Herceptin®) – Treatment beyond progression

46. Survival of patients with HER2 positive metastatic breast cancer in New Zealand is 62% (95% CI 55-68%) at 1 year and only 10% (95%CI 7-15%) at 5 years (18). Given these low survival rates, there is a need to urgently increase availability of extended trastuzumab therapy. This is supported by the Breast Cancer Special Interest Group. A US study (19) reported median survival of 3.5 years (95%CI 3.0-4.4 years) from time of initiation of therapy with trastuzumab in metastatic breast cancer patients. The median number of trastuzumab-based therapies received was three (range 1 – 12) and 34% of patients had received four or more lines. In New Zealand trastuzumab can only be used once, until disease progression and not thereafter. The median survival after diagnosis for all New Zealand patients with HER2+ metastatic breast cancer (including Luminal B and HER2 enriched subtypes) is only 18.3 months (95% CI 15.5-22.9 months) (18).

Impacts of PHARMAC's performance in funding breast cancer medicines on New Zealand's health system and society

47. The above examples demonstrate how far New Zealand has fallen behind the rest of the developed world in the treatment of breast cancer. Failure to fund a wide range of proven medicines demonstrates the dysfunctional nature of PHARMAC's processes and the woefully inadequate level of medicines funding. Our poor survival statistics are testament to the cumulative impact of so many negative decisions and delays.

48. PHARMAC justifies their protracted processes by inferring they are saving the money that would be wasted on 'ineffective' drugs, should they make a bad decision. Nobody (least of all cancer patients) wants to see PHARMAC funding ineffective treatments. What BCAC has consistently requested is timely access to proven, evidence-based therapies that do make a difference in the lives of patients. BCAC would like to see some analysis of the impact of PHARMAC's delays in granting access to treatment. These delays in making proven treatments available to New Zealanders have added up to many lives cut short prematurely or significantly reduced in quality. For example, aromatase inhibitors, capecitabine, docetaxel, lapatinib, pertuzumab, trastuzumab and zoledronic acid, all of which are standard treatments in breast cancer with strong evidence for their effectiveness, had prolonged times to reimbursement in New Zealand compared with similar countries. How many lives of New Zealand people with breast cancer were lost prematurely as a consequence of these delays? How many New Zealand people experienced significant reduction in their quality of life during treatment because proven treatments were not available to them?

49. Independent economic analysis (20) has also shown that these delays are costly to our health system. NZIER points out that PHARMAC makes claims about 'savings' on the medicines it purchases (based entirely on reductions in the purchase prices), but does not take into account the health system costs of failing to fund cost-effective medicines in a timely manner. A major reason for funding medicines is the reduction in health service utilisation that is expected as a result of reduced pain, better symptom control, slowed or prevented progression of disease, reduced infection rates, and reduced adverse effects. All of these considerations apply to patients with advanced cancer. Failing to fund cost-effective medicines results in health system costs such as hospitalisations, as well as higher mortality, more productivity loss, and greater loss of quality of life.

50. The Terre Maize petition now before the Health Select Committee, and the request from Malcolm Mulholland for a review of PHARMAC, result directly from the delays and negative decisions from PHARMAC that are outlined above. Similar calls from those representing other diseases suggest that this situation is not unique to breast cancer, or even all cancers, but is an issue for many New Zealanders who need access to the medicines they could expect to receive if they lived in other comparable nations (see 21, and https://www.priorities.nz/).

51. The real-life impacts on New Zealanders of PHARMAC's failure to fund Ibrance® treatment are starkly conveyed in the patient perspectives supplied by BCAC to PHARMAC and attached to this submission (Appendix 1).

BCAC's rebuttal of statements made in PHARMAC's submission to the Health Select Committee

52. PHARMAC stresses its role as defined in the Public Health and Disability Act and the 'fixed budget' from which it must provide 'the best health outcomes… reasonably achievable… from within the amount of funding provided' (page 2). However, despite its protestations PHARMAC actually has a large say in the size of its budget. PHARMAC submits a joint bid for the Combined Pharmaceutical Budget with the DHBs to the Minister of Health. The Minister's principal sources of advice on this matter are the bidders themselves – the Ministry of Health and PHARMAC. Notwithstanding any input from the Health Select Committee, or independent advice sought by particular Ministers of Health, the setting of this budget would seem to be a rather closed loop. This fixed budget is used throughout PHARMAC's submission to excuse itself of any responsibility for New Zealand's low access to medicines. Even the Ministry of Health admits that this is the case in their submission where they state: 'Whilst NZ might not have the same breadth of access to some medicines as other comparable countries, our health outcomes for cancer are comparable' (page 4 of MoH submission). BCAC agrees with the statement that New Zealand does not have the same breadth of access to new medicines as comparable countries. However, it is not correct to say that outcomes for cancer are comparable (as outlined in paragraph 9, page 2 above).

53. If PHARMAC has considered 'need' (impact of disease) on 'the individual', 'on family, whānau and wider society' (page 3), then why are we still hearing desperate personal stories from New Zealanders with advanced cancer, why are people signing petitions asking for better treatment, why do we regularly see cancer patients seeking crowd-funding for medicines, and why do New Zealanders with advanced breast cancer have such poor survival compared to those in other countries? This status quo seems to be acceptable to PHARMAC, but is it acceptable to our society?

54. PHARMAC states that 'there is always a greater demand for funded medicines than the available resource' (page 3). We are puzzled as to why this statement is presented as a universally accepted truth, when in fact it is simply the result of a political choice. BCAC hears the often-expressed

opinion that pharmaceutical companies are to blame because medicines are just too expensive. Intensive care of patients who have had accidents is expensive, however the Minister of Health correctly does not suggest turning accident victims away at the door. It is an accepted part of meeting the health needs of our society just as it must be for those suffering and dying of this disease. The 103 new medicines recommended by PHARMAC's own experts but not funded (22), are clearly not a wish-list, but vital treatments that are being withheld.

55. PHARMAC describes how it uses a framework to make decisions (page 3). However, on its website PHARMAC explains that these factors are 'not weighted or applied rigidly, and not every factor is relevant for every funding decision PHARMAC makes. This is because the situation for one assessment may require quite different considerations compared with another. Funding decisions are made relative to other options, and the context within which decisions are made is constantly changing.' This suggests that the framework is not necessarily applied consistently, and that other unspecified factors can come into play. How is the performance of this decision-making framework audited? Why are evaluation and monitoring not part of this process? Why are there no minutes produced from the prioritisation meetings where this framework is used?

56. PHARMAC "seeks to achieve 'best health outcomes'" (page 3). Why are 'best health outcomes' presented here in quotes? How does PHARMAC measure its success in achieving these? BCAC contends that the numbers of New Zealanders accessing medicines and numbers of prescription items (page 4) tell us nothing about health outcomes. As PHARMAC itself states on page 8, 'a simple count of funded medicines won't show you how successful a health system is' – BCAC agrees. Why is there no benchmarking against other countries? Other measures of NZ's performance, like the CPI and GDP, are internationally recognized and routinely compared across countries, as a way of ensuring that NZ is functioning in the way its citizens expect.

57. In its own briefing to the incoming Minister of Health (23), PHARMAC presented data showing that of 29 OECD countries, only Mexico spends less per capita on pharmaceuticals.

58. PHARMAC lists its 2017/18 achievements on page 4. How do the metrics given for cancer medicines compare to those in other countries? Is 0.6% of prescription items being for cancer medicines and $220 million gross expenditure on cancer medicines a good, average or poor achievement? The fact that the expenditure was more than last year tells us only that it was worse last year, not that it is adequate this year. Furthermore, gross expenditure ignores the fact that there are substantial confidential rebates on many cancer medicines and the actual spend is much lower. Therefore, we have no way of knowing the actual spend, let alone whether this is adequate.

59. We do know that of 20 OECD countries compared, New Zealand ranks 19th in access to new medicines (these are innovative pharmaceuticals that contain a molecule first registered in any of the compared countries between 2012 and 2017) (24). New Zealanders have funded access to only 23.5% of these medicines, compared to 46.4% in Australia, 84.3% in Great Britain, and 94.9% in Japan.

60. Economic analysis by NZIER (25) points out that investment in medicines has fallen year on year from 8.1% in real terms in 2007 to only 4.7% in 2017/18. It identifies a $375 million investment gap in government-funded medicines made available through the public health system in New Zealand, in order return to the 2007 level of the Combined Pharmaceuticals Budget. Budget documents indicate that overall expenditure on pharmaceuticals will reduce and widen this gap further. NZIER suggests a corrective 'real terms adjustment' (taking into account population growth and inflation) to maintain stability in pharmaceutical investment relative to other investments.

61. Describing zoledronic acid as a 'new cancer medicine' is far-fetched (page 4). It was first registered in the USA for treatment of osteoporosis in 2001, in 2003 it was shown in a Phase III trial to be effective for use in metastatic breast cancer (26), and in 2010 shown to be effective in treating early breast cancer (27). Here is its history as a breast cancer treatment in NZ:

    - Zoledronic acid (any use) application to Medsafe - June 2002
    - Medsafe approval - April 2004
    - Application to PHARMAC for use for bone metastases in advanced breast cancer - Jan 2003
    - Approved for this use by PHARMAC Board - Oct 2014 (i.e. 11 years and 8 months from application to approval)
    - Application to PHARMAC for use with early breast cancer (the indication referred to in PHARMAC's submission to the HSC) - October 2014
    - Positive recommendation from Cancer Treatments Sub-Committee - Mar 2015
    - Pharmacology and Therapeutics Committee (PTAC) recommendation - Nov 2015
    - Approved for this use by PHARMAC Board - Dec 2017 (i.e. 3 years and 2 months for from application to approval).
    - Therefore zoledronic acid for breast cancer provides an example of protracted and unacceptable delay rather than something we should be proud of.

62. In response to the question: should the budget be increased to purchase more cancer medications (page 5)? PHARMAC responds that it has increased the amount spent on these by 50% over the last 8 years, but there is no evidence given to show that this meets the needs of the New Zealand public. Survival figures for New Zealanders with advanced breast cancer (3), inequities in outcomes for different ethnic groups (e.g. 28, 29) and for those being treated in public or private practice (1), and frequent calls from members of the public for change (e.g. see submissions from Metavivors to this Committee) suggest that it is not.

63. There is an incorrect statement in relation to trastuzumab emtansine (Kadcyla®) (page 6). Roche applied for this drug to be used as a second-line treatment for metastatic breast cancer after treatment with trastuzumab and a taxane in August 2017, not 2018.

64. BCAC agrees that it is unfortunate that PHARMAC cannot provide a timeline for making a funding decision, if any (page 6). We understand that the process used by PHARMAC to make these decisions is complex and requires input not only from the expert advisory committees PTAC and CaTSoP, but also from the suppliers, as well as a consideration of a large number of other factors (shown in their framework diagram). We also understand that a further layer of complexity is added as each medicine is ranked against the others under consideration. However, we are surprised that there is no public record of these proceedings, let alone any detail of the factors considered in any particular decision such as cost-effectiveness and how it was derived. There is no record of who participates in these meetings and no record of how each medicine scores against the multiplicity of factors against which each is judged. We understand that there could be good reasons for keeping pricing information confidential, but not why we cannot know who attends those meetings or how, for example palbociclib's impacts on an individual and their family, might have been assessed. Presumably, some information is distilled into the reports that the staff will prepare for the Board, and possibly this could be obtained by OIA. The information contained in the documents that PHARMAC releases for public comment on each medicine that is

recommended for subsidy do not contain such details (BCAC routinely receives these for comment.)

65. Minutes from meetings of PTAC, its sub-committees and its Consumer Advisory Committee are available from the PHARMAC website, why not the real decision-making meetings and the detail of considerations in decision making as well?

66. In relation to PHARMAC's statement that 'in the case of breast cancer survival the most important intervention [for Māori] is finding breast cancer at an earlier stage before it becomes advanced' (page 7), BCAC wishes to point out that finding breast cancer early does not preclude its recurrence or progression to a more advanced stage. Around 30% of all breast cancers will recur. The majority of people with advanced breast cancer have already been treated for early breast cancer. Only around 5% of all people diagnosed with advanced breast cancer in New Zealand have de novo metastatic disease (i.e. this is their first breast cancer diagnosis) (3). The survival statistics of concern are those describing the subsequent fates of all those diagnosed with advanced breast cancer: after 5 years 5% of Māori are still alive, compared to 15% of NZ Europeans. This petition concerns the treatment of those who have already received a diagnosis of advanced breast cancer and need help now, not every person who potentially could have breast cancer.

67. PHARMAC's assertion that New Zealand's performance in providing access to medicines does not need to be benchmarked against other countries is both disappointing and, we believe, a dangerous one. Arguing that the New Zealand health context is somehow fundamentally different in unspecified ways from other countries, such that comparisons are impossible, is deeply concerning. Breast cancer survival statistics can and have been compared across countries, and show that New Zealand's performance is poor (3). 'Meaningful benefits' (page 8) should be similar across different countries – we have no reason to think that a New Zealand breast cancer patient's experience of length and quality of life should be any different from those of someone living in another country. Given that the only options for treatments for advanced cancer are radiotherapy and systemic therapy with medicines, and occasionally surgery, it is not too far-fetched to think that access to medicines has a significant role in determining health outcomes for this group of New Zealanders, and that comparing access to medicines is a pertinent measure of the relative experiences of breast cancer patients in different countries.

68. Contrary to statements made by PHARMAC (https://www.pharmac.govt.nz/about/our-history/the-envy-of-nations/), the NZ system is not the 'envy' of other countries. Patients and clinicians in other countries simply cannot believe the situation that NZ patients find themselves in, for example, advanced cancer patients having to fundraise in their communities to fund their own survival.

69. PHARMAC's 'Mind the Gap' study (page 8) (30) was rebutted by experts, including Australian and New Zealand cancer specialists (31, 32).

70. PHARMAC argues that other countries go ahead and approve and fund medicines foolishly, before 'meaningful' health gains have been proven, citing the Kim and Prasad 2015 (33) study (also used by the Ministry in their submission) (page 8). This USA study reviews FDA approvals of 36 cancer medicines between 2008 and 2012. However, the FDA assesses only the safety and efficacy of medicines. It does not look at cost-effectiveness or make funding decisions; it is equivalent to Medsafe in NZ. To imply that the FDA has made unwise funding decisions compared to PHARMAC is misleading. The American system of public funding of medicines is completely different from that of any other country.

71. When overseas commentators state that new cancer medicines 'do not always do what it says on the tin' (surgeon Prof. R Sullivan, Cancer Care at a Crossroads conference, January 2019, Wellington), they are not referring to the medicines that are the subject of this petition. Medsafe, which is charged with 'making sure medicines meet safety, quality and performance standards' (https://www.govt.nz/organisations/medsafe/), first approved palbociclib in November 2016 and trastuzumab emtansine in December 2012. Other breast cancer medicines approved by Medsafe but not yet funded for all appropriate breast cancer indications in New Zealand include everolimus (first approved by Medsafe for other applications in July 2012), fulvestrant (May 2006), nab-paclitaxel (July 2010), pegylated doxorubicin (1997), lapatinib (2012), pertuzumab (2013) and sub-cutaneous trastuzumab (October 2014). These could hardly be described as 'new'. It was disappointing to hear Steve Maharey, Chair of PHARMAC, repeating Prof. Sullivan's phrase to New Zealand media as a convenient soundbite with which to defend PHARMAC's performance.

72. Although noting that 'later evidence often shows that these medicines do not in fact offer meaningful benefit in overall survival' (page 8), neither PHARMAC nor the Ministry mention the cancer medicines which have fulfilled the promise of early data and resulted in significant health gains for cancer patients, e.g. trastuzumab (Herceptin®) and pembrolizumab (Keytruda®). Notably, both these cancer medicines, which are repeatedly cited in PHARMAC annual reports as being very expensive (and are also very effective), obtained their funding approvals in New Zealand only as a result of extensive public lobbying. Other countries funded these on the strength of evidence earlier than New Zealand did, and history shows they were right to do so.

73. PHARMAC's statement that 'Many new medicines are launched and registered for sale in NZ without clear evidence that they will work as well as pharmaceutical companies claim' (page 9) is alarming (and not supported by any examples or evidence). Medsafe's role is to ascertain the safety and efficacy and quality of medicines and it should not be registering any medicines which do not meet 'performance standards' or where the evidence does not support the claims made by the manufacturer.

74. The New Zealand women with advanced breast cancer who have contacted BCAC are asking for medicines that have been recommended for them by their oncologists. They are not emotionally grasping at straws, and neither are their clinicians. PHARMAC's statement that it 'understands that patients, their families and whānau and clinicians want the latest medicines in the hope that they will provide the best possible health result' (page 9) is condescending and implies that these clinicians (the self-same 'experts' on whom PHARMAC relies for advice) are not equipped to determine where there is an unmet health need for their patients.

BCAC's rebuttal of statements made in the Ministry of Health's submission to the Health Select Committee

75. This submission does not address the topic of the petition (access to life-extending drugs for breast cancer) but instead looks at the 'whole spectrum of care' for breast cancer in NZ (page 1) and argues that early detection will somehow eliminate any need for improvements in advanced breast cancer care (page 2).

76. While admitting that 'Access to medicines is an important building block of a high quality health system, and a key intervention for improving breast cancer survival' (page 1), the Ministry states, without supporting evidence, that 'New Zealanders have very good access to medicines' and that 'Our goal is for breast cancer to be diagnosed and treated early, when it is curable, before it has the opportunity to become advanced'. This suggests that the Ministry has no interest in improving

treatments for those with advanced breast cancer. Furthermore, it is patently untrue that New Zealanders have very good access to medicines; for example, between 2011 and 2017 Australia had three times the number of new medicines funded, almost twice as fast as New Zealand (34) and New Zealand ranks 19th out of 20 OECD countries for access to new medicines (24).

77. The Ministry states that 'NZ has very high breast cancer survival rates' (page 2), citing age-standardised five-year net survival of 87.6% for NZ women diagnosed with breast cancer from 2010-14, compared to an OECD average of 85%. Of course, this is for every diagnosis, and tells us nothing about the fates of those with late stage or advanced breast cancer (as noted by members of the Health Select Committee during the Ministry's presentation on 13 February).

78. BCAC agrees that early diagnosis is important, but we should not focus on that to the exclusion of improving treatment of those with advanced disease.

79. The Ministry then makes comments which seem designed to shift the blame for any shortcomings in breast cancer statistics to Māori women: 'Differences in screening coverage for Māori women exist, with only 65% screened in 2015' (page 2). BCAC notes that the latest figures from BreastScreen Aotearoa show that, in 2018, 66.3% of eligible Maori were screened (35). Both figures exceed the OECD average of 61% cited by the Ministry. Even so, they state that 'reducing the equity gap between population groups remains a key focus'. This is not the subject of the petition.

80. The Ministry states that 'It is unclear whether access to a greater number of medicines alone contributes to improved cancer outcomes' (page 2). To support this statement, they cite a 2017 Global burden of disease study which shows that 'NZ's general health loss from cancer is reducing over time' at a rate similar to the UK, which publicly funds more cancer medicines than NZ, and a JAMA study (probably Kim and Prasad 2015 (33)) which showed only 5 out of 36 cancer medicines approved in the US 2008-12 improved survival rates when reviewed 4 years later.

81. Ibrance® (palbociclib) and Kadcyla® (trastuzumab-emtansine) are not among the drugs examined in the JAMA study, which included only four breast cancer drugs – bevacizumab, everolimus, lapatinib and pertuzumab. The study does not identify the five drugs which passed the authors' evidence test of significantly improving overall survival. Since PHARMAC now funds lapatinib and pertuzumab, although only for limited applications, we can only presume that these two drugs can deliver the stringent survival benefits that PHARMAC demands for breast cancer medicines to be funded.

82. BCAC notes that breast cancer data presented in BCFNZ's 2018 report (3) shows a direct relationship between the number of lines of treatments administered to advanced breast cancer patients in Auckland and Waikato and their survival (Figs. 33 -35, BCFNZ, 2018).

83. BCAC notes that the Ministry makes direct criticism of the methodology used in BCFNZ's ABC report (3). We also note that BCFNZ has robustly responded to this criticism in their own separate submission to the Health Select Committee, and we endorse the points that they make.

84. Under the heading 'Accountability of PHARMAC', the Ministry states that 'As the environment in which we purchase pharmaceuticals changes PHARMAC will need to adapt in order to meet challenges and take opportunities' (page 3). BCAC agrees – in fact this 'future' is here already and PHARMAC should be adapting right now. NZIER's report (20) identifies the costs to the health system of missed opportunities to fund cost-effective available medicines.

85. The Ministry explains that PHARMAC is ultimately accountable to the Minister of Health, and that the Minister is accountable for the public resources allocated. PHARMAC's objective, stated in the

NZ Public Health and Disability Act 2000, is 'to secure for eligible people in need of pharmaceuticals the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the funding provided' (page 3). However, it is hard to find any performance measures applied to PHARMAC that relate in any sensible way to health outcomes. This year's annual report (36) has the usual financial measures and also numbers of prescriptions, numbers of medicines, and estimates of numbers of people benefiting from medicines. The only measure which might be used to assess their performance in relation to New Zealanders' health is 'QALYs achieved per $1 million spent'.

86. The Ministry states that 'PHARMAC is also accountable to clinicians and consumers', and goes on to say that 'when making funding decisions, it takes advice from clinical experts, conducts economic assessments, and seeks the public's views' (page 3). BCAC would like to point out that seeking input is not the same as being accountable. Furthermore, the public is consulted only after PHARMAC has got to the very end of its protracted processes for the very few medicines it decides to fund and is given only two weeks to comment. BCAC contends that transparent consultation should occur throughout the consideration process. BCAC also notes that the clinical advice used by PHARMAC is received only from a limited number of PHARMAC-appointed clinicians, not from wider groups representing clinical disciplines with expertise in the diseases for which medicines are being considered, such as New Zealand's Breast Special Interest Group.

87. Under the heading 'Funding of PHARMAC', the Ministry explains that the budget for PHARMAC is agreed with the Minister of Health, after advice from DHBs and PHARMAC itself (page 3). As BCAC has noted above, this appears to be a closed loop – it's the Minister's decision but he takes PHARMAC's advice. Thus PHARMAC has a pivotal role in determining the size of the pharmaceuticals budget, but when challenged about the size of it, it can defer to the Minister, who is 'responsible'.

88. The Ministry states that PHARMAC 'has been able to buy more medicines and improve people's access to medicines year after year' (page 4). No evidence for this assertion has been given. However, this simply tells us that our situation has improved relative to what it once was; it does not take into account the continued poor access that New Zealand breast cancer patients have compared to other countries of comparable wealth.

89. Under the heading 'Innovation in medicines and early access schemes', the Ministry states that 'Whilst NZ might not have the same breadth of access to some medicines as other comparable countries, our health outcomes for cancer are comparable' (page 4). No evidence is given for this statement. BCAC notes that BCFNZ's 2018 report (3) shows that the survival of New Zealand women with advanced breast cancer is significantly poorer than that of women in Germany, the Netherlands, USA, France, Sweden, and Canada.

90. The Ministry then states that 'Any investment in access to medicines must be … aimed at reducing inequities in cancer outcomes' (page 4). BCAC agrees that inequities must be addressed, but not by ensuring that a uniformly low level of care is available to all. Recent New Zealand research has shown significant inequities in breast cancer treatment pathways and outcomes for Māori and Pasifika women compared to NZ European women, for rural Māori compared to urban Māori, for breast cancer patients with or without co-morbidities (such as diabetes), and for those able to afford private care vs public care (2). BCAC notes that this research supports our perception that New Zealand's health system for cancer care has become a two-tier system, with Tin Tin et al. (1) concluding that 'Patients [who] … received public health care … had a 95% average higher risk of mortality compared to those who received private care'.

91. The Ministry notes that they and PHARMAC will need to adapt to the 'challenge' posed by genomics and other technologies allowing more accurate diagnosis (page 4). BCAC considers it telling that this is couched in terms of any development being a threat rather than an opportunity (in this case the savings that could be made by not giving people therapies that will not work for them).

92. Under the heading 'Inequity in cancer outcomes', the Ministry notes that there are differences in access to medicines between Māori and non-Māori, but then goes on to propose that the outcome differences will be addressed 'equally in finding breast cancer at an earlier stage before it becomes advanced' (page 5), thus dismissing the needs of those already diagnosed who initiated the petitions currently before the Health Select Committee. The Ministry concludes by partially quoting Tin Tin et al. (1), that 'stage at diagnosis accounted for a substantial proportion of the survival differential in Māori and Pacific women'. The authors of this research article do conclude that early detection would be a good way to improve survival, but they also present evidence that Māori and Pacific breast cancer patients receive significantly less systemic therapy than other ethnicities.

93. In conclusion, the Ministry's submission comes across as not focused on the matter at hand (the petitions) but is extremely simplistic and unambitious for NZ, basically contending that with earlier diagnosis of breast cancer in Māori women, all will be well. Additionally, the majority of their contentions cannot be substantiated as they have provided no supporting references.

Conclusion and recommendations

94. In this submission, BCAC has presented evidence of PHARMAC's shortcomings with respect to providing access to medicines considered in other countries to be the standard of care for the treatment of breast cancer. We have demonstrated also that New Zealanders with breast cancer, particularly Māori, Pasifika, and those who are not wealthy, have their quality of life reduced and their lives shortened by their lack of access to these medicines.

95. BCAC has observed that PHARMAC (and the Ministry of Health) have maintained and promulgated a 'rationing mindset' over many years with respect to medicines for cancer. PHARMAC has used its negotiating and purchasing role to justify a culture of secrecy and deliberate opacity. The positions taken by each in their submissions to the Health Select Committee on this petition reveal a willingness to gloss over the unmet needs of patients, to cherry-pick information to support their views that there is nothing wrong with the status quo, and to make unsubstantiated and repeated statements that the current system is the 'envy of the world'. By measuring their performance in terms of cost savings rather than improvements in health outcomes, they have created an environment where delays and negative decisions are the norm, such that clinicians no longer aspire to give their public patients new and promising treatments, but try to find ways to 'make do' with older medicines, where pharmaceutical suppliers limit the effort they put into introducing medicines to the New Zealand market, and where New Zealanders cannot participate in clinical trials, because we do not deliver the world-class standards of care required for the control arms.

96. We strongly encourage the Committee to watch the following video which describes the current state of play in world-class treatment of metastatic breast cancer (you will have to register with 'Practice Update' with an email in order to view it, but this does not take long): https://www.practiceupdate.com/content/metastatic-breast-cancer-later-lines-of-therapy/65993/62 This demonstrates how multiple medicines are used in various combinations and sequences to optimize quality and length of life for these patients. This is in stark contrast to the situation in New Zealand, where there are few medicines available and the sequences and patient groups in which they may be used are strictly limited by PHARMAC's decisions. The

medicines mentioned in this video are what Sarah Fitt described to the Committee on 13 February as 'me-too' medicines, implying that they all perform the same job. Her statement shows just how poorly informed PHARMAC's CEO is of modern world-class cancer care.

97. Despite PHARMAC insisting that it values consumer input, this petition and calls from patients for its review indicate that PHARMAC does not meaningfully include patient perspectives or the consumer voice in their processes and the Ministry of Health is very far from delivering the 'person-centred care' that it says it aspires to.

98. We recommend that:

    a. The budgetary cap must realistically and fairly meet the proven needs of our society

    b. It must enable comparable outcomes to other OECD countries to be achieved

    c. PHARMAC's processes be accelerated and transparent

    d. Those patients who have already been diagnosed, and may have accessed currently available treatments while awaiting the outcomes of a PHARMAC decision, be treated fairly and not excluded from funded access when the decision is made

    e. It is recognised that all New Zealanders suffering and dying have an equal entitlement to the best possible evidence-based medication and care

    f. It is recognised that although new medicines may come at an additional cost they often produce net health system and societal savings and benefits

    g. Access to medicines is provided in a manner which is equitable

    h. PHARMAC meaningfully incorporates consumers into every aspect of its decision-making processes

    i. PHARMAC's performance is measured in relation to health outcomes and that it be monitored, evaluated and publicly reported on.

99. In the interim BCAC implores the Health Select Committee to look favourably upon the petition of Terre Maize to fund Kadcyla and palbociclib for breast cancer sufferers, to investigate and independently review PHARMAC's operations, to assess its impacts on the health of New Zealanders, and to remedy, with urgency, PHARMAC's current shortcomings with respect to cancer patients.

Glossary and explanation of terms

ABC – advanced breast cancer

ASCO - American Society of Clinical Oncology

Adjuvant therapy - Additional treatment to increase the effectiveness of the main treatment, often surgery, in early breast cancer. This includes systemic therapies, such as chemotherapy, endocrine therapy, or targeted therapy, and radiotherapy. The goal of adjuvant therapy is to eliminate undetectable microscopic cancer cells that may have travelled to other parts of the body.

Aromatase inhibitors (AIs) – A class of drugs used to treat breast cancer by stopping oestrogen production in post-menopausal women. After menopause, small amounts of oestrogen are still produced with the help of an enzyme called aromatase. AIs such as letrozole, anastrozole and exemestane block aromatase, and therefore the production of oestrogen.

BCAC - Breast Cancer Aotearoa Coalition

BCFNZ - Breast Cancer Foundation NZ

BCT – Breast Cancer Trials – formerly Australia and New Zealand Breast Cancer Trials Group – Professional organisation for clinicians and researchers promoting and running clinical trials in these countries.

BSIG – Breast Special Interest Group – professional organisation for breast cancer specialists from all disciplines in New Zealand

Capecitabine (Brinov®, Xeloda®) – Cytotoxic chemotherapy drug which interferes with DNA synthesis in cancer cells.

CaTSoP - Cancer Treatments Subcommittee (of PTAC)

CDF - Cancer Drugs Fund - a source of funding for cancer drugs in England.

CTNZ – Cancer Trials NZ

DHB – District Health Board

Docetaxel (DBL Docetaxel®, Docetaxel Sandoz®, Taxotere®) - Cytotoxic chemotherapy drug from the taxane group.

Doxorubicin (Doxorubicin Ebewe®, Arrow-Doxorubicin®) – Cytotoxic chemotherapy drug from the anthracycline group. Doxorubicin liposomal (Caelyx®, Doxil®) is doxorubicin in a different formulation that assists in its delivery to the cancer cells.

EBC – Early breast cancer.

ER-positive – Estrogen (oestrogen) receptor positive breast cancer is a type where oestrogen receptors can be detected in in standard histology tests. When present, it indicates that endocrine therapy, such as aromatase inhibitors, tamoxifen, fulvestrant, eribulin, or palbociclib, may be useful.

ESMO – European Society for Medical Oncology

Everolimus (Afinitor®) – A drug that targets and inhibits a protein in cells called mTOR, thus interfering with cancer cell proliferation; used in treatment of metastatic breast cancer.

FDA - Food and Drug Administration – USA regulator for medicines that evaluates new drugs before they can be sold. They ensure that drugs work correctly and that their medical benefits outweigh their risks.

First-line treatment: the first medicine or set of medicines that a metastatic cancer patient receives, after a diagnosis of advanced cancer.

Fulvestrant (Faslodex®) - A selective anti-oestrogen used in the treatment of metastatic breast cancer. Given by monthly injection.

HER2 – Human epidermal growth factor receptor 2; a protein involved in cell division. In **HER2 positive** breast cancer, the HER2 gene is over-expressed, and cancer cell growth is stimulated. Targeted therapy with drugs such as trastuzumab (Herceptin®), pertuzumab (Perjeta®), trastuzumab-emtansine (T-DM1) (Kadcyla®), or laptanib (Tykerb®) can shut down this activity.

HR-positive – Hormone receptor positive breast cancer; may be oestrogen- and/or progesterone-positive. See ER-positive.

Indication – a particular condition or disease for which a medicine may be used.

Lapatinib (Tykerb®) – A drug which is a tyrosine kinase inhibitor that interferes with the function of the HER2 receptor and interferes with the biochemical pathways that drive the growth of HER2 positive breast cancers.

Letrozole (Letrole®, Femara®) - An aromatase inhibitor used as hormone therapy to suppress oestrogen production and prevent recurrence of ER-positive breast cancer in post-menopausal women, or in combination with ovarian function suppression in pre-menopausal women.

MBC – Metastatic (advanced) breast cancer.

Medsafe - New Zealand Medicines and Medical Devices Safety Authority, responsible for the regulation of medicines and medical devices in New Zealand.

Metastasis – The spread of cancer from the part of the body where it began to another through the lymphatic system or bloodstream. The cells in the new cancer location are the same type as those found in the original site.

MoH – Ministry of Health

Nab-paclitaxel (Abraxane®) – Cytotoxic chemotherapy drug from the taxane group. This is a 'nanoparticle albumin-bound' formulation of paclitaxel, that does not contain a toxic solvent.

NGO – Non-government organization

NICE – National Institute for Health and Care Excellence. A UK organization providing guidance, advice and information services for *health*, public *health* and social care professionals.

NZIER – New Zealand Institute for Economic Research

Palbociclib (Ibrance®) – A CDK4/6 inhibitor (targeted therapy) used to treat ER positive breast cancer.

Pertuzumab (Perjeta®) – A HER2 inhibitor (targeted therapy) used for treating HER2 positive breast cancer.

PHARMAC – Pharmaceutical Management Agency; the New Zealand government's agency that decides which pharmaceuticals are publicly funded.

PTAC - Pharmacology and Therapeutics Advisory Committee of PHARMAC.

Second-line treatment: a second medicine or set of medicines used after the first line has failed, i.e. the cancer has progressed. Similarly, third- and fourth-line (and so on) treatments may be used if suitable and available.

SMC – Scottish Medicines Consortium - an independent organisation that advises the National Health Service Health Boards about medicines in Scotland.

Tamoxifen (Genox®) – A selective oestrogen receptor modulating (anti-oestrogen) drug, used to treat hormone receptor positive and oestrogen receptor positive breast cancers.

Taxanes – A class of chemotherapy drugs based on compounds originally isolated from yew trees (e.g. paclitaxel and docetaxel) that can block cancer cell division.

Trastuzumab (Herceptin®) – A drug which targets and blocks the HER2 receptor, reducing cancer cell growth in HER2 positive breast cancer.

Trastuzumab-emtansine (TDM1, Kadcyla®) – A drug which uses the ability of trastuzumab to target HER2 positive breast cancer cells to precisely deliver a cytotoxic drug, emtansine, to those cells.

Zoledronic acid (Zometa®) – A bisphosphonate (modified bone mineral). Used to reduce the risk of bone complications of treatment and/or recurrence in early breast cancer and fractures from bone secondary tumours.

References (copies can be supplied on request)

1. Tin Tin S, Elwood MJ, Lawrenson R, Campbell I, Harvey V, Seneviratne S. Differences in breast cancer survival between public and private care in New Zealand: which factors contribute? PLOS One, 2016. DOI:10.1371/journal.pone.0153206, April 7, 2016.
2. Lawrenson R, Blackmore T, Campbell I, Scott N. How to Improve Outcomes for Women with Breast Cancer in New Zealand. Health Research Council of NZ and the University of Waikato; 2018. Health Research Council Reference: 14/484.
3. BCFNZ (Breast Cancer Foundation New Zealand). "I'm still here" – insights into living – and dying – with Advanced Breast Cancer in New Zealand. September 2018. https://breastcancerfoundation.org.nz/Images/Assets/22648/1/BCFNZ-ABC-Report-2018-REPRINT-10.2018.pdf?_ga=2.107264258.1670666683.1550971843-379da0bd-d4b3-40f6-a332-776e81913f13
4. Cardoso F. et al. 4th ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 4), *Annals of Oncology*, Volume 29, Issue 8, 1 August 2018, Pages 1634–1657, https://doi.org/10.1093/annonc/mdy192
5. Sledge GW, Mamounas EP, Hortobagyi GN, Burstein HJ, Goodwin PJ, Wolff AC. Past, present, and future challenges in breast cancer treatment. J Clin Oncol. 2014; 32(19):1979-86.,
6. Altundag K, Ibrahim NK. Aromatase inhibitors in breast cancer: an overview. The Oncologist June 2006 vol. 11, no. 6 553-562. doi: 10.1634/theoncologist.11-6-553
7. Breast Cancer Aotearoa Coalition. Letter to Pharmac on Proposal to Fund Pertuzumab (Perjeta). 7 November 2016
8. Breast Cancer Aotearoa Coalition. Letter to Pharmac on Proposal to Fund Pertuzumab (Perjeta). 24 January 2017
9. Breast Cancer Aotearoa Coalition and New Zealand Breast Cancer Foundation. Letter to Pharmac regarding Pertuzumab for patients with previously treated HER-2 positive metastatic breast cancer. 24 July 2018.
10. Breast Cancer Aotearoa Coalition. Application for Listing of Fulvestrant on the Pharmaceutical Schedule. May 2018
11. Breast Cancer Aotearoa Coalition. Application to Pharmac for Listing of Abraxane (nab-paclitaxel) on the Pharmaceutical Schedule. February 2018
12. Breast Cancer Aotearoa Coalition. Application for Listing of Everolimus on the Pharmaceutical Schedule. July 2018.
13. Breast Cancer Aotearoa Coalition. Application to Pharmac for Listing of Palbociclib on the Pharmaceutical Schedule. November 2018
14. Breast Cancer Aotearoa Coalition. Response to Pharmac on September 2018 CaTSoP Meeting Minutes. February 2019.
15. Urruticoechea A, Rizwanullah M, Im S-A, Sanchez Ruiz AC, Lang I, Tomasello G, Douthwaite H, Crnjevic TB, Heeson S, Eng-Wong J, Muñoz M. Randomized Phase III trial of trastuzumab plus capecitabine with or without pertuzumab in patients with human epidermal growth factor receptor 2–positive metastatic breast cancer who experienced disease progression during or after trastuzumab-based therapy. Journal of Clinical Oncology 35, no. 26 (September 10 2017) 3030-3038. DOI: 10.1200/JCO.2016.70.6267.
16. Breast Cancer Aotearoa Coalition. Letter to Pharmac regarding Proposal to Fund Lapatanib. 7 February 2012.

17. O'Carrigan B, Wong MHF, Willson ML, Stockler MR, Pavlakis N, Goodwin A. Bisphosphonates and other bone agents for breast cancer. Cochrane Database of Systematic Reviews. 2017(10).
18. Breast Cancer Foundation New Zealand. Personal Communication Adele Gautier - survival for HER2+ patients including Luminal B and Her2 enriched subtypes. February 2019.
19. Olson EM, Najita JS, Sohl J, Arnaout A, Burstein HJ, Winer EP, et al. Clinical outcomes and treatment practice patterns of patients with HER2-positive metastatic breast cancer in the post-trastuzumab era. Breast (Edinburgh, Scotland). 2013. 22(4):525-31.
20. NZIER. PHARMAC economic analysis and "savings" claims. Background notes. Produced for Medicines New Zealand, October 2018. https://nzier.org.nz/static/media/filer_public/a0/e1/a0e1043d-93dd-491c-b8fe-f3f474acbce0/pharmac_savings_background_note.pdf
21. NZ Herald. 'Depriving sick babies of right to life' - NZORD boss blasts Pharmac decision to defer Spinraza. 28 February 2019. http://nzh.tw/12207697
22. Della Barca C. Funding medicines in New Zealand: Revision of the medicines waiting list to 30 June 2018. https://www.medicinesnz.co.nz/fileadmin/user_upload/Information_Leaflets/New-Zealands-Medicines-Waiting-List-July-2018.pdf
23. PHARMAC. Briefing to the incoming Minister of Health. 8 November 2017. https://www.pharmac.govt.nz/assets/briefing-to-incoming-minister-2017-11.pdf
24. Medicines Australia. Compare 4. Comparison of access and reimbursement environments. A report benchmarking Australia's access to new medicines. Edition 4. 2018. https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2018/10/MA_Compare-final.pdf
25. NZIER. Community pharmaceuticals. Expenditure trends. NZIER report to Medicines New Zealand. December 2018. https://nzier.org.nz/static/media/filer_public/01/08/010883de-26d3-432d-9dde-0bc0d1f59dd9/community_pharmaceutical_expenditure_nzier_to_medicines_nz_december_2018_update_final.pdf
26. Rosen LS, Gordon D, Kaminski M, Howell A, Belch A, Mackey J, Apffelstaedt J, Hussein MA, Coleman RE, Reitsma DJ, Chen B-L, Seaman JJ. Long-term efficacy and safety of zoledronic acid compared with pamidronate disodium in the treatment of skeletal complications in patients with advanced multiple myeloma or breast carcinoma: a randomized, double-blind, multicenter, comparative trial. Cancer. 2003. 8:1735–1744.
27. Delea TE, Taneja C, Sofrygin O, Kaura S, Gnant M. Cost-effectiveness of zoledronic acid plus endocrine therapy in premenopausal women with hormone-responsive early breast cancer. Clin. Breast Cancer. 2010. 10 (4): 267–74. doi:10.3816/CBC.2010.n.034
28. Lawrenson R, Lao C, Campbell I, Harvey V, Seneviratne S, Edwards M, Elwood M, Scott N, Kidd J, Sarfati D, Kuper-Hommel M. Treatment and survival disparities by ethnicity in New Zealand women with stage I–III breast cancer tumour subtypes. Cancer Causes & Control, 2017. 28(12): p. 1417-1427.
29. Lawrenson R, Lao C, Elwood M, Brown C, Sarfati D, Campbell I. Urban Rural Differences in Breast Cancer in New Zealand. International Journal of Environmental Research and Public Health, 2016. 13(10): p. 1000. https://doi.org/10.3390/ijerph13101000
30. Evans J, Laking G, Strother M, Wang T, Metcalfe S, Blick G et al. Mind the gap: An analysis of foregone health gains from unfunded cancer medicines in New Zealand. Semin Oncol. 2016;43(6):625-37

31. Zalcberg JR, Wonder M. “Mind the Gap” revisited. Semin Oncol. 2017. http://dx.doi.org/10.1053/j.seminoncol.2017.07.003
32. Cameron L, Sullivan R, Luey B, Solomon, B. Mind the Graph: Foregone Health Gains in Lung Cancer. Semin Oncol. 2018 Oct;45(5-6):316-317. doi: 10.1053/j.seminoncol.2017.11.004. Epub 2017 Dec 6
33. Kim C, Prasad V. Cancer Drugs Approved on the Basis of a Surrogate End Point and Subsequent Overall Survival: An Analysis of 5 Years of US Food and Drug Administration Approvals (Letter). JAMA Internal Medicine 2015. 175: 1992-1994. doi 10.001/jamainternmed.2015.5868.
34. Medicines New Zealand. IQVIA. Access to Medicines Report 2018. https://www.medicinesnz.co.nz/fileadmin/user_upload/ATOM_Report_2018_FINAL.pdf
35. BreastScreen Aotearoa. New Zealand All District Health Board Coverage Report for the period ending 31 December 2018. file:///E:/BCAC%202019/Screening/bsa_new_zealand_all_district_health_board_coverage_report_-_period_ending_31_december_2018.pdf
36. PHARMAC. Annual Report for the year ended 30 June 2018. https://www.pharmac.govt.nz/assets/annual-report-2017-2018.pdf

Appendix – Patient perspectives on the need for funding of palbociclib (Ibrance®)

Patient Perspective on on Palbociclib/fulvestrant funding - Denise L

My name is Denise. I am 53 years old, and was diagnosed with Breast Cancer this year in March. I had no symptoms, and had regular mammograms and screening before this.

The cancer had already moved into my liver, so it was a double blow – a de novo diagnosis.

I was given some treatment options, which included Palbocilbib. I am fortunate that my husband and myself had some insurance and some savings aside, and we decided that to give me the best option available we would fund this. We were told ‘for at least 2 years’. So I am on Zoladex, Exemestane (both funded drugs), and Ibrance at $5850 monthly. So far we have spent $35,400.

The cost emotionally is another thing. How does it feel to use the money that could benefit your children, that could impact how we live (me or him) in our retirement years. How the children feel seeing us go through this? How we go about things every day, with a smile on our faces, being happy for others in their daily successes, hoping like made that they never have to live through this… And all the while fighting to make it easier when the next person is diagnosed. Trying to make sure the right drugs are available and funded!

This choice was made given the proven track record for treatment, and the extended lifespan – with good health. So far I have minimal side effects – Hot Flushes and strange oily mouth feel. In fact, I have lost weight and changed my diet, so am probably the lightest and fittest that I have ever been! It seems that this treatment is less harsh than the traditional Chemotherapy/Radiation normally given.

Currently I have great results, including tumours that are no longer able to be located (completely gone) and shrinkage of the main tumour. Long may it continue.

This allows me to be a productive functioning member of society. I continue to work fulltime, am a wife, mother, grandmother and auntie – and want to be able to do this as long as possible.

Also the longer I can be here there is always the hope that the changes in medicine continue to go forward in leaps and bounds, and this becomes a treatable condition, rendering it a chronic illness and not a death sentence.

It is important that palbociclib is available to all who need it. It should not be just left for those who could/could choose to fund it (some of us by mortgaging our homes!!)

Patient Perspective - IBRANCE Funding Jane R

My name is Jane R and I am living with metastatic breast cancer. My wish and desire is to live as fully as I can for as long as possible. This isn't the way my life was supposed to go, and at the age of 51 I am facing an early death and the possibility ... let's face it ... certainty of leaving my 2 children to move on into adulthood and so many crucial life events without me. It's difficult to explain how hard this is to even put in writing.

I was first diagnosed with breast cancer at the age of 39 when my children were aged just 1 and 2 years. Cancer returned in my bones 5 years later and so I have known for 6 years that I am living with an incurable disease. My "brand" of breast cancer is Hormone + and HER – and over the past 11 years I have been on so many different drugs I can't remember the names of them all.

My oncologist recommended Ibrance to me earlier this year after I had significant progression of bone metastases throughout my body. This progression happened after 2 years on Capecetabine and I knew I was in trouble when I felt like my whole skeleton just ached. I was grateful for Mary S sharing information about travelling up to Malaysia to get Ibrance for a much reduced cost. (When I say reduced it's still a staggering amount to pay. I've just sent $8380 to Malaysia for 3 months of Ibrance including postage).

I am immensely grateful and sheepishly aware of my privilege in that my mother has drawn on life savings and is paying for these drugs. It's an uncomfortable reality that the lack of funding for Ibrance puts a barrier between those of us with breast cancer who can access the outrageously expensive drugs and those who can't. It's demeaning to have to hustle and struggle for drugs such as Ibrance that promise precious time with loved ones.

Living with metastatic breast cancer is tough. I have tried to maintain a life as close to normal as possible. I work, I take my children to sports events, and encourage them with their homework. I catch up with friends, I try to be a positive partner to my loving husband, I push memories of the old me who used to be physically strong and adventurous to the back of my mind. Instead I set smaller goals and dream of all the places I want to travel to .... but because of this terrible disease my world is getting smaller now.

I urge the government to fund Ibrance and other life extending drugs for those of us living with metastatic breast cancer. I ask for empathy and imagination by funders. What if you were in this situation? What if your wife, sister or best friend were?

Patient Perspective – palbociclib funding Jo R

My name is Jo R and I was diagnosed with breast cancer in 2013 from a mammogram. My family had no history of breast or any other type of cancer. I had surgery and 6 rounds of FEC-d, followed by Tamoxifen.

In 2016 the doctor told me I was doing well and had probably beaten this thing. In June 2017, I was not feeling so well, I was working full time in a stressful job, I had a slight cough as everyone else in the office had in June. I cycled daily was fit and I thought healthy. Subsequently, test showed metastases in spine, hips, and lungs, and just to top it off my liver was full of tumours. I do not drink, smoke and was not overweight, and feel the irony of my diagnosis particularly when I hear those who say cancer is a lifestyle thing. The health system was great within a week I was on MMM chemo, but I was extremely sick on this protocol.

I had to give up the work I loved, and rearrange finances. We were extremely lucky to have had two good incomes, but our power bill skyrocketed, I lost nearly 15 kgs while undergoing chemo and was always cold, the heating was always on high. We received no financial assistance.

I had six rounds of MMM and improved to the point we were able to have a short holiday to the South Island for a ' final" visit to friends and family. Many times during that treatment, I listened to discussions on the television re assisted suicide. I have always believed there were other options, but being constantly nauseous for 6 months, despite multiple medications, vertigo and unable to eat anything but two tablespoons of chicken stock, watching your family and friends struggle with their emotions, and going from someone who was confident, totally in control, career orientated to being totally dependent is soul destroying.

It was friends, family and our local rural community who got me through with everything from food to company. I owe them so much.

I was put on Arimidex which was not effective and I then went onto weekly Paclitaxel chemo for 5 months, it halted the progression but again side effects including neuropathy and fatigue was hard.

I am now on my third cycle of Ibrance or to put it in perspective $ 17,400. I think the effect of this drug was summed up by my Oncologist after the last examination of my liver JESUS, the results have been dramatic, no side effects, I have more energy, my liver is significantly less swollen I can breathe easier and I can again feel positive, useful and independent.

Fairness, Equity and Irony:

I have worked since I was 17 years old, 36 of those with Ministry of Social Development and its predecessors. I only had 8 months off work when both my children were born. My husband works for the military and I can say we have had a comfortable but not extravagant life. The military is often a lonely lifestyle for spouses, and during his many overseas posting, I brought up our children. As a result you learn to be strong, resilient and self-reliant. Ironically he was overseas when I was first diagnosed. I dealt with that myself. We have both been heavily involved in the community, and I can say a lot of our finances went to support various organisations.

I was looking forward to retiring in a few years continuing community work, my husband loves his job and would not consider retirement. He will work til he drops.

I can't imagine his life without me. It breaks my heart when he trolls the net and comes up with stories about women living for 18 years plus with stage iv, he looks for the positive in everything, he hates seeing me in pain.

We or my children, have never received a benefit, no Working for Families, no childcare subsidy, we have never had convictions, dealt drugs or beaten each other up. My two children both went to Otago University, for three and four years respectively, they did not qualify for 'student allowance' due to our income, so we subsidised them.

My daughter was on placement a Canterbury Hospital when the Earthquake struck, and suffered for a short time from anxiety related issues. We supported her through the following months, until she went into full time employment, and developed her own life.

I believed in the welfare system in this country, so I was shocked and frustrated that this treatment I need is not funded and is available to those that cannot afford it. It's a travesty.

Yes in the short term, we can afford it, I can cash in my KiwiSaver, and my retirement savings. However to put it in perspective, my husband's full salary does not even cover the cost of this drug, well not if we want to eat and pay the electricity bill.

I grew up on the West Coast, I watch the funding available to Pike River, yet a fraction of this cost would keep mothers alive for a few years to help their children and soul mates deal with the inevitable and to let them and their families enjoy life.

I feel let down by the system. Drugs are coming on line all the time, we cannot wait 12 months or more for approval. Give medical staff the tools to do their job.

This drug works for me I will keep fighting and I want to show and teach my children that in this life you have to fight for what you need, you only fail if you give up.

Patient Perspective on Palbociclib Funding – Kate G

My name is Kate G[redacted]. I am 53. At 44, I was diagnosed with stage 2 lobular cancer with positive lymph nodes. (ER+, HER2 PR+). After mammograms, biopsies, scans, blood tests and consultations, I had a lumpectomy and shortly thereafter mastectomy, later followed by reconstruction (1 and 2). As well, I had 7 months of chemotherapy and 6 weeks of radiotherapy.

I wanted to throw everything at this disease that threatened my very being, and shook me to my core. All the above rolls of the tongue quickly and easily, but was in practice, anything but.

I immediately stopped work in my own business. I hesitated over how to tell my children and parents. My daughter, had just started boarding school at 13, my middle son was also boarding at 11, and my youngest boy was only 6.

Our lives were in turmoil. The treatments, side effects, and rehabilitation was hard work. I was bald, nauseous, in pain, fatigued and weakened. My kids came home from school on a Friday after my chemo, I was in bed sleeping through Saturday, and weak and ill on Sunday when they were about to leave again. My wee boy was confused and upset to lose his Mum to this for a year.

However, after 12 months life returned to normality with us all changed, and feeling more fragile. There were still operations for reconstruction, regular appointments and tests, and i took Tamoxifen which put me in early menopause. The anxiety around relapse and recurrence was in the background and ever-present, but faded as anniversaries came and went.

Almost 8 years to the day, I was admitted to ED in extreme pain, and underwent a series of tests etc. I was completely blindsided a week later, when the diagnosis was confirmed of Stage IV / secondary /metastatic/ breast cancer. I don't think even my GP (who read the diagnosis aloud off the computer screen with his back to me) understood in that moment what I knew. My cousin died at 45 of Breast cancer. I have always known primary BC is both common, and if caught early, could have good results. However secondary spread is a completely different beast. 30% of BC becomes secondary. There is a 15% chance of then making it to 5 years. And every day, you are only one scan away from that reality.

I have lived a very healthy lifestyle. I don't drink or smoke. I exercise. I love my life, my family and this place we live. I am active in both business and community. I have always paid taxes, had medical insurance and 'given back.'

The cancer had come back with a vengeance and it was scattered throughout my abdominal cavity - there was a large tumour wrapped around my lower bowel , with lymph nodes, uterine invasion and nerve roots involved. I was in pain, losing weight, and had extreme bowel symptoms to cope with. Once again it was a whirlwind of scans, tests, consultations, research, and decisions. Surgical removal was impossible. Radiation for 3 weeks was palliative and did give me some symptom relief.

I began taking Letrazole (an AI) and bought a month worth of Palbociclib (Ibrance). This was not an easy or quick decision. I sought a second opinion, and researched it both here and overseas. I researched clinical trials to see if there was a way I could get easier access to it. As at $5900 for a month's supply, it was a big step. We didn't just have that money sitting in a bank account. We felt desperate, and were clutching at straws, but it was the best straw on offer. And although I could put one month on our credit card, what on earth was i going to do the following month and the one after that?

The oncologist basically told me my timeframe was 10-12 months without Ibrance, and that would double to a median of 20 months. It was a no-brainer, i was not ready to die then and after 7 months, I'm no closer to being ready to die.

My kids are still young enough to need their Mum. My daughter has suffered with a mental health battle, and I wonder how much my cancer and its destabilising effect on the family contributed to that, at her vulnerable age. She still needs my guidance and support on a daily basis. My middle son became a type 1 diabetic during my first round of chemo, and has had a huge personal battle through his teenage years. Once again, he still needs my help even now at 21. (By the way, the technology to keep him well and make his management easier is also not funded, so we are really beginning to despair with NZ health system.) My youngest is sitting exams right now and he is doing Ok, but all he has really known of his Mum since 6 years old, is that fragility that cancer brings. Yes I have also taught him to make the most of every day, but there's a brittleness with that and he is a quiet worrier. I am sad for him that he makes decisions about going away with mates, or spending time with me, as he knows how limited that now is.

My working life still has 20-25 years in it, however I am having to sell the family business I built up to fund my Ibrance. But what does that mean for my 54 year old husband and his future? We have sold our house and down-sized, and I am currently earmarking the proceeds for Ibrance or future treatment.

My elderly parents don't want to bury their own daughter, and are quite traumatised by what i am going through, and I am still very involved in their care. That's the thing about a woman my age, we are so valuable, and at the crux of family life at both ends of the spectrum. We are the lynchpins of families, and all the while still productive members of society. It should be recognised our contribution and made a priority to provide better drugs.

I now go to Malaysia to get my Ibrance and I wonder how that sits with politicians and policy makers. It's cheaper there, so I spend about $3000 a month. I do have an oncologist there who hears from my NZ doctor about my scans and blood tests. There is draining travel to do, and the expense that goes with that. However, there are also options to freight the drugs to NZ. I also wonder why it's cheaper in Malaysia, and why New Zealanders should have to travel to a poorer country to receive medical care?

It hurts me, and saddens me to see how other money is spent in NZ, and I don't think it should be an either or, but this government talks about kindness and I ask where is that with this group of ladies? I also hope with all my heart when and if this particular drug gets funded, that we who are already using it don't get excluded from the funding.

My quality of life with Ibrance is fantastic- side effects are minimal and nothing given the alternative. Its worth every cent to buy me the wellness time that it is. I am ever hopeful that by the time it stops working for me there will be something else to try, although I am sure that will be expensive too I know that after say 20 months(hopefully longer) , it will stop working, the cancer will move, and that within 5 years it might all be over, but right now I am making the most of every day. I am living life and not waiting to die I wish that was available to everyone who needed it.

Kate G[redacted]

Patient Perspective Palbociclib and Fulvestrant – Lynne H

My name is Lynne [redacted] and I have been living with advanced breast cancer for 10 years. During that time I have had disease in my abdomen, spleen, and now bones. I have had chemotherapy IV, hormone therapies, chemotherapy tablet and most recently fulvestrant which I have self-funded for 2 and ½ years.

I have continued to work full time as an Office Manager. My husband is 69 and is retired. I have two children and three grandchildren and a large extended family.

I am now in need of palbociclib (Ibrance) which I expect would give me another 2 years of normal life and will allow me to continue working. If I don't have access to Ibrance, I will be forced to have chemotherapy and will have to stop working. I will have to spend time in hospital receiving treatment, will lose my hair, be exhausted for months and likely spend further time in hospital due to infections.

My family are all affected by this. The stress and anxiety felt by them has a big impact on their ability to function normally so it is not just the patient who needs medical intervention, but the whole family.

I believe that Ibrance would be far more cost effective than chemotherapy and will allow me to continue to live a normal life.

Patient Perspective on Funding of IBRANCE – Terre N

My name is Terre N[redacted] and I have advanced breast cancer. I'm one of the lucky ones; so far, it's confined to my bones and I've been stable with first line treatment (Letrozole) for six years. I work full time as a Principal Environmental Consultant, participate in a fair number of community and social activities, and live a reasonably "normal" life. However, I live my life in six month chunks of time between blood tests. I know it's not "if" my first line treatment will fail – it's "when".

If I lived overseas, Ibrance would be added to the Letrozole to extend my life and retain my good quality of life. However, in New Zealand, it's not funded. Most of the funded second line treatments in New Zealand reduce the quality of life – many of the Metavivors have had to quit work due to side effects.

Ibrance has been shown to be effective with hormone positive, HER2 negative, advanced breast cancer. The cancer I have is strongly oestrogen positive, a type that responds very well to Ibrance, so it is likely that it would help me.

My husband is retired and I am 63. I am originally from the US and am a New Zealand citizen. I plan to keep working after I reach 65; as an environmental consultant, much of my work can be done from a computer and age is no barrier. I am currently training the next generation of environmental professionals, passing on knowledge and a passion for the work. I have introduced new environmental management methods and technologies to New Zealand, making our country a safer and cleaner place to live. If my life is extended, with a continued good quality of life, I believe I can made additional contributions to our great country, including contributing to the tax base, well into my 70s.

Despite being in relatively good shape, the cancer affects every decision we make. It's always there, hanging over us. My husband suffers from chronic depression, a condition which has worsened since my diagnosis. My friends and family worry about me; if I am unwell, everyone panics. It does affect the whole family, as well as my friends and coworkers.

Realistically, despite a good salary, I cannot afford Ibrance. I would need to rely on Give a Little, cashing in my Kiwi Saver, and mortgaging our house. Leaving my husband in financial distress is not an option for me. Knowing that there is treatment available but not accessible is inhumane, especially when that treatment is likely to prolong life, with a good quality of life.

Patient Persepctive on funding of IBRANCE– Tracy B

My name is Tracy [redacted]. I was born to Kiwi parents in Vancouver Canada and returned permanently to the Bay of Plenty in 1998 for the "good clean NZ lifestyle"; I'm 48 and live with my

husband Dean in Tauranga Bay of Plenty. My story starts in 2012 at 42 years old when upon self-examination of my breast I felt the dreaded lump! My mother had had breast cancer 15 years earlier so I wasn't all that surprised when I found the lump; she had sailed through her treatment and is now 21 years clear, so I figured I'd be the same – right? My initial cancer was low grade stage 1 grade 1 – you can't get anything less significant than that. So I had the lumpectomy, lymph nodes out followed by 4 weeks of radiation and the usual course of tamoxifen which I managed for 2.5 years. I went on my happy way living my life and not even giving the cancer a second thought – after all, I was cured right?

In May 2017 I started feeling pain in my shoulder which jumped around to my ribs, hips and finally tailbone - to which I was told I must have a prolapsed disc due to the pain I was having. I asked if it could be related to my breast cancer almost 5 years ago and was reassured it was not but had to wait 3 months for a specialist appointment and MRI scan to confirm the prolapse and a course of treatment. I was in severe pain and had multiple trips to ED over that period. Finally on October 13th 2017 I had my MRI and was diagnosed with Stage 4 Metastatic Breast Cancer that was highly invasive of my spine and lungs …. The cancer lit up the MRI and we were all in shock. To say I was angry is an understatement – I had done all the right things, looked after myself, don't drink, don't smoke, eat well, exercise regularly and had annual mammograms – this wasn't meant to happen!

My husband has a small upholstery business that he runs from home and I'm an administrator who has ALWAYS worked and been in employment. We contribute to the community pay our taxes and look after ourselves in not having ever needed government support. To now find that we are completely at the mercy of the NZ health system and Pharmac in deciding if I get to extend my life or not is unbelievable and a situation I never dreamed I would find myself in. (but who does?) NZ looks after it's people – don't they?

My parents are still living and are now in their mid-70's, but as I'm an only child it comes down to me to look after them as their health declines in their later years and it breaks my heart to think that I might not be there to do that! My husband would be stuck with the burden of not only burying his wife but of having to look after his in-laws once I'm gone. Or even for them to become dependent on the government for support that I would normally be there to give. It's a situation that I can't bear to think about …. Or the thought of them burying their daughter before they leave this earth themselves – it's heart-breaking and torturous!

So, what are our options? Currently my cancer is stable after 5 months of chemo therapy and now 7 months on letrozole – but one day that is going to change and we will be out of options that are currently funded by the health system. So, do we increase our mortgage to fund drugs on our own? But then I'd be leaving my husband with a debt to pay long after I'm gone. Do I start up a Givealittle page (like everyone else!) but Givealittle is NOT the new health system! I have Kiwisaver which I have used a bit of to fund integrative therapy that also isn't funded by our health system. And then again, nothing left for my family after I'm gone. My family say use the money – we want you with us at any cost, but the thought of leaving an extra burden to them after I'm gone is unthinkable. Or do I just accept fate and let it all take it's course? I'd accept that if I was in my 60's or 70's but I'm only 48 – I'm not even 50 and still have so much to do and live, contribute to society and spend time with my family.

As my cancer is highly oestrogen positive and HER-2 negative I am likely to have a very good response to Ibrance and living a long productive life. This drug is the one shining light that we have in getting me to see out my parents' final years, spending time with my family making memories and continuing to work and contribute as a tax payer to the community. Having Ibrance available but not funded I feel is inhumane and quite frankly discrimination against Advanced Breast Cancer patients where other countries are funding this for their citizens. If we had AIDS and other countries were funding lifesaving/extending drugs but not NZ one wonders what the response would be? Women in their prime of life are having their lives cut short and families torn apart because of this horrible disease – NZ is better that this!

Patient Perspective on Advanced Breast Cancer and Palbociclib and Fulvestrant – Christine R

I have ER+, PR+, HER negative metastatic breast cancer diagnosed 3 years ago. Since then I have been on anastrozole for 20 months, tamoxifen for approximately 6 months and am now self-funding palbociclib and fulvestrant. I have multiple lung metastases and have been lucky enough to be able to live a full and active life with practically no symptoms since my metastatic diagnosis. My initial prognosis was 2-3 years.

My husband retired at 70yrs old earlier this year and I am 64yrs old, we have worked hard during our working life to ensure we had savings for our retirement. We even paid medical insurance which I have never tapped into and have since cancelled as it did not cover non Pharmac funded medications. We are lucky that we are in a position to be able to self-fund palbociclib and fulvestrant which so far has cost us $56,000.

We have adult sons 30 and 32yrs. I would dearly love to be around to see them find partners and have children but realistically I know that is probably a pipe dream. I will never know my grandchildren. My mother at 91 years may outlive me. I would at least like to know my husband is not going to be financially stressed in his retirement as a result of my ill-health.

We live in a state of limbo never being able to plan the next holiday too far in advance, always having to be ready to change plans, working our lives around oncology appointments. We have both been active members of the community, I have been involved for years in volunteer work in the past, paid taxes all our lives, never been on a benefit and yet when we need to health system to come to the fore it has let us down.

I have been taking palbociclib and fulvestrant for the last 8 months and this has meant I have been able to delay chemotherapy enabling me to continue working as nurse specialist and continue to pay taxes. I experience minimal side effects on this treatment.

The alternative for me if I wasn't on Palbociclib would be chemotherapy which would almost certainly cause debilitating side effects resulting in my having to take frequent sick leave and certainly impacting negatively on my quality of life and my ability to work as nurse specialist. I may even have had to quit my job. In the 3 years since my diagnosis I have only taken 5 days off work due to sickness. As I enjoy my job I had always intended to continue working till my late sixties. Sadly this will probably no longer be an option.

Patient Perspective – Claudine J

Hello,
I am Keziah's mother,
I am Imogen's mother,
I am Lucy's mother,
I am Olivia's home-for-life mother,
I am Kane's home-for-life mother.
I am Stuart's wife. I am Claudine.
I may be nothing to you but to them I am the world!
I am the Mum who gives them cuddles when someone is mean at school.
I am the Mum who reads them books at night trying to get to the point of reciting my part of the 3 bears sort of like Lucy has hers.
I am the Mum who watches them play sport encouraging them in areas I have no skills.
I am the Mum who packs beautiful lunches that they barely eat.
I am the Mum who cooks healthy dinners when they'd prefer sausages and chips.
I am the mum who sat there confronting my 3 year old's abuser.
I am the Mum who insists that they do their homework even though watching my little pony or playing fortnight is more fun.
I am the Mum who cleans them up when they vomit in the night.
I am the Mum who "sleeps" in a chair all night because my vomiting child wants to sleep on the couch not her bunk.
I am the Mum who loves my children more than anything in the world.
I am the Mum who is loved by her children more than anything is the world, even when I am being the meanest Mum in the whole wide.

I am the Mum who after months of misdiagnosis was finally told my early fears were correct and that I indeed have breast cancer.
I am the Mum who was laughed at by doctors for "google doctoring" only to be proved right.
I am the Mum who wishes I'd been wrong.
I am the Mum whose cancer spread before the experts listened.

I am the Mum who might see her 4 year old start school but with the medications currently funded in New Zealand who won't see her start high school.

I am the Mum who with Pharmac's help can be a Mum to my children for longer. I can continue to be here to read, cook, cuddle, protect and love for longer. I can have more time to prepare my babies to face the world without their Mum.

I may be nothing to you but to Keziah, Imogen, Lucy, Kane and Olivia I am the world. Please help keep their world together longer.

Patient Perspective on Palbociclib funding – Elisa W

My name is Elisa [redacted], and I am 50 years old. I was first diagnosed with hormone receptor positive HER2 negative breast cancer in 2013, and underwent a full mastectomy and chemotherapy treatment. I was prescribed Tamoxifen, but was unable to tolerate the side effects. After treatment I got back to life, with my husband, Leon, and children Josh, Luke and Māia. I completed my PhD, although it was interrupted by treatment and recovery for 18 months, and returned to work as a clinical psychologist working with people who are affected by serious brain injury. In April of this year, I finally took on the job that I had always wanted as Director of Rehabilitation at the leading provider of post-acute brain injury rehabilitation.

Three months ago, I was told that the breast cancer had returned and metastasised. There was a large tumour that had taken over my lymph nodes under my arm, another lymphatic one near my clavicle, and evidence of activity in my hip and two areas on my spine. I have had surgery to remove my lymph nodes and ovaries, but the surgeon was unable to locate the tumour near the clavicle. I have just completed radiation to the area where the lymph nodes were and to the clavicle. As a result of the radiation, I am writing this while dealing with a surprising level of pain, and painkillers – I'm told that radiation combined with my fair Pākehā skin can result in particularly nasty burns.

I optimistically expected to take sick leave for my surgery, and then return to work. As the reality of surgery, radiation and the impact of bone-strengthening medication became apparent (the side effects of the funded one can be pretty harsh), I realised that I would have to resign from my dream job. I could not do justice to the clients and families that I have sought to serve, at the same time as striving to live well for as long as possible. The financial implications of resigning from this role are significant at a time when we had hoped to recover from my low earnings over the last years while I was researching and dealing with the primary cancer. My husband now carries the double burden of wanting to spend time looking after me when I'm not well, and enjoying life together when I am, while realising that we are now solely dependent on his income, just when he'd thought I could pitch in again.

As with other people with metastatic breast cancer, the oncologist told me that my condition was "treatable but not curable. He explained that treatment could, however, support me for "a meaningful duration". Our oldest boy, Josh, has just turned 21. He's launching himself out into the world following his dream of becoming a professional sailor. Luke is 16 and is a stunning young leader who's completing his Year 12 exams. Māia, is 11 years old and is a happy, friendly young girl who loves soccer. I'm amazed at how well they cope with the reality of this disease, which they know too well having been to the tangi for Leon's very special Auntie Celia, who died when she was 42 years old, and his dear cousin, Te Paeru, who died a month before my first diagnosis when she was 43. These deaths were my first experience of the harsh reality of breast cancer being less survivable for Māori women than for Pākehā. In 2013, my concern was that whānau were dying before they had even reached the age of eligibility for free screening. I realise now that inequities around screening policy are only one of many areas of concern.

While I realise that in NZ our 5-year survival rates are 15% for non-Māori and 5% for Māori (compared with 22% in comparable countries), I desperately want to be around for both Luke and Māia's 21sts, in order to raise them to adulthood and give them the grounding that they may need to do adulthood without a mother. Despite the language of oncologists, and the reality of current

treatments, in my head I refuse to accept any alternative to being around for my family, because if I did consider that alternative I just could not cope.

On diagnosis, I was immediately prescribed Letrozole and received a Zoladex injection. The oncologist explained future treatment options and the costs of these. My parents, who are in their 80s, have been devastated by my diagnosis, just as I am devastated at the thought of the pain that it inflicts on them, and on my husband and children. They have insisted that we explore all options and that they will pay for everything they can. Financially this is a huge commitment. Palbociclib (Ibrance) was recommended to me, though I was told that this is often given some months down the track, because of the cost. From my own research, I could see that in other countries Palbociclib is typically given as a first line treatment. My question to the oncologist was "if all the drugs were free, what would you recommend?" His recommendation was to commence Palbociclib immediately.

I have had one and a half cycles of Palbociclib (interrupted by radiation), and commence my next cycle this week. The cost of this is $5850 per month. With the new Patient Assistance Program, we will be paying over $64,000 for the first year of treatment. I recognise that I am in a position of extreme privilege given that my parents are covering this cost, but see no reason why I should be able to access treatment when other women cannot. I have further privilege through my education and health system knowledge and experience, which helps me to research and insist on the treatment that I need. Being able to access treatment effectively allows me the luxury of hope for a longer survival. I picture daily the pain that other women and their families must go through in realising that treatment is financially out of reach. Why become "health literate", if it only shows you what you cannot have? If we all lived in other countries, where this is funded, this would not be a case of privilege, but would be one of accessing our rights to health and family.

Through my own work and research, I am conscious of inequities within our health system. We have been painfully aware of the difference in breast cancer survival for Māori and non-Māori within our own whānau. If we want to increase survival rates for all of us, and for Māori in particular then effective treatments must be funded for all.

From Pharmac's documentation it is clear that there is a strong intention to address health inequities and uphold peoples' rights, and Pharmac's responsibilities, under Te Tiriti o Waitangi and the United Nations Declaration of the Rights of Indigeous Peoples. Pharmac recognises, via their Te Whaioranga Māori Responsiveness Strategy that there are inequities and state their "commitment to the reduction of Māori health disparities as well as the facilitation of Māori health aspirations". The Te Whaioranga Vision is that "Whānau achieve at least the same level of health outcomes through advancing Tino Rangatiratanga."

While much of Pharmac's role is in ensuring that people have equitable access to those medicines that are funded, our glaring gap in survival rates, along with Pharmac's commitment to achieve equal health outcomes, places a responsibility on Pharmac to ensure that it has adequate funding to improve health (and life) outcomes for Māori. Te Whaioranga strategies have been around for many years. Funding drugs, with proven effectiveness, that are available in most comparable countries, is a clear way to keep moving from intentions to effective actions in addressing inequity and upholding our treaty responsibilities.

Being able to take Palbociclib, gives me hope of continuing to raise my children, enjoy life with my husband, and hopefully even return, in some way to my work.

Mauri ora

Elisa [redacted]

Patient Perspective on Palbociclib – Julie B

My name is Julie B, and I am living with metastatic breast cancer. I was diagnosed six years ago, at the age of 57. It was a denovo diagnosis – metastatic from the time of diagnosis. All prior mammograms had been clear, likewise self-examinations. The initial metastases that led to diagnosis were to bone marrow; subsequent metastases have been to ribs and spine. My cancer is hormone positive and HER2 negative.

I have been treated with a series of hormonal therapies appropriate for hormone positive, HER2 negative metastatic breast cancer. From diagnosis, I was treated with letrazole for 2.5 years, followed by two years of tamoxifen, and one year of exemestane. Each treatment has been discontinued due to progression.

Since January 2018, I have been treated with palbociclib and the companion drug fulvestrant. I have self-funded both drugs. For the year 2018, I will spend approximately $63,000 to cover the costs of Palbociclib ($48,000) and Fulvestrant ($15,000).

Few people diagnosed with metastatic breast cancer are able to self-fund treatment with palbociclib.

I have chosen to self-fund palbociclib because of its demonstrated effectiveness in the treatment of ER+, HER2- metastatic breast cancer. Fulvestrant is probably the last hormonal therapy available to me, and I want to maximise its effectiveness, and delay the commencement of chemotherapies. Chemotherapies tend to have significant unpleasant (and sometimes toxic) side effects and are less effective against hormone positive metastatic breast cancer than hormonal therapies.

The longer I can stay alive and feel well, without serious treatment side effects, the longer I can participate in family life and contribute as a mother, grandmother, sister, aunt, mother-in-law. And the less worry and disruption I will cause to family members! It's also possible, if I stay alive long enough, that new medications or treatments will be developed that turn metastatic breast cancer into a chronic condition, rather than a terminal disease.

Having metastatic breast cancer has affected my health and quality of life significantly by limiting my lifespan and influencing my decisions regarding many aspects of my life, including ongoing employment. Members of my family are also affected by their concern for me, and by their awareness that I may not live long enough to participate in significant milestones in their lives.

Treatment with palbociclib (in combination with fulvestrant) has been effective in keeping my cancer stable, which has delayed the onset of chemotherapy treatment. Generally, I have felt well during this treatment and able to participate normally in family and community life.

I'm strongly supportive of funding palbociclib as a first-line treatment for metastatic breast cancer in New Zealand. But palbociclib and fulvestrant also need to be available as a later-line treatment in New Zealand, as many people currently diagnosed with metastatic breast cancer will not have had access to palbociclib as a first line treatment. For some (like myself), this is because palbociclib was unavailable at the time of first diagnosis; for many, the current prohibitive cost of Palbociclib will have removed it from consideration at the time of first line treatment.

Patient Perspective on Funding of Palbociclib and Fulvestrant – Paula N

I was under the care of a breast specialist for a year before my cancer was detected on mammogram and ultrasound. I had dense fibrous breast tissue and was told on two occasions that I did not have breast cancer, just lumpy dense young healthy breast tissue. Since being diagnosed with Stage IV hormone positive breast cancer in 2010 (de novo) at age 43, I have had the following treatments: initially right skin sparing mastectomy with tram flap reconstruction followed by 5 months of chemo and radiation. A scan then confirmed metastases in my spine. I received tamoxifen and Aredia to stabilise my bones bones. When tamoxifen failed it was followed by letrozole and Zoladex. Zoladex failed to work so I had my ovaries removed. Next was exemestane and a switch to denosumab for bones. After further progression of boney metastases to skull I was switched to cabecitabine at the beginning of this year.

My next option when this treatment fails is Ibrance plus Fulvestrant, both unfunded.

I have two young teenage boys who were 6 and 8 when I was diagnosed. They probably don't remember me not having cancer as they are now 15 and 17. I feel blessed to have seen them reach puberty, something I grieved for in the beginning as I thought I would not get to see my babies reach that milestone or experience the joys and challenges of raising the young men that they are becoming. I want to continue to be their mother, to help my 15 year old with ADHD achieve his potential without the trauma of losing me at such a crucial developmental age. I want to build resilience and strength in my sweet, caring, compassionate, sensitive 17 year old so he can cope one day without me.

My grandmother didn't get that chance with my father as she died of breast cancer at 42 when he was 9. My great aunt on my mother's side died at 32 of the same disease after being diagnosed when she was pregnant. Her husband wouldn't let her have treatment fearing it would harm the baby. She died not long after he was born and tragically he died in infancy. I was more aware than most of this disease but my own vigilance did not save me. I was failed by the limitations of the screening currently available. My cancer was slow growing and had been there for some time according to my surgeon.

I still cry a little most days over my situation. I also laugh, find joy each day and try to stay in the moment. My oncologist said to me last time that to look at me you would never know! I said I hide it well! The ongoing cycle of scan, treat, repeat is emotionally and physically exhausting, but when I feel I can't do it anymore, I look at my husband and sons and suck it up. Since having the radiotherapy on my skull and having to be clipped to the table in a mask I have become quite claustrophobic. Just one more thing to overcome.

Each day I put one foot in front of the other, for my family, for my grandmother and great aunt I never met, for the friends that I have made and lost, their families, for the women I can offer advice and support to travelling the same road, for those yet to be diagnosed, in the hope that these medicines will keep being developed and made available at a reasonable cost, that one day in my lifetime there will be a cure and I will die of something else at a ripe old age with lots of wrinkles and grey hair!

Patient Perspective on funding of Ibrance – Rachel B 2018

I am 44, and a single mother of two children (aged 5 and 7). I was diagnosed in July of this year with (de novo) metastatic hormone positive breast cancer. I initially had a mastectomy and am undergoing chemotherapy at present. The plan is to commence endocrine therapy in the New year.

I am currently trying to balance parenting and full time work with all the side effects that come with surgery and chemo. These are not just the physical changes, nausea and fatigue, but the mental struggles that come with a stage 4 diagnosis, particularly at my stage in life. This has had a massive impact on both me and my children.

While the cost of Ibrance is prohibitive, the potential for an increase in length of remission and therefore the chance for more quality time with my children, for me means I (and my extended family) will be doing what we can to pay for it.

While I understand the inherent difficulty in the necessary cost benefit analysis undertaken by both the Ministry of Health and Pharmac in any funding allocation decision, my hope is that greater assistance can be provided to those women and men like myself who are dealing with this incurable, life limiting and quite frankly horrible disease.

Patient Perpsctive on Palbociclib Funding – Sue W

My name is Sue [redacted], and I am a Metavivor. I walked to Parliament on 16th October to present two petitions to Parliament requesting funding for two life extending cancer drugs.

That day I met many women who I had only corresponded with online. I listened to their stories, step by step, and my heart broke as I heard the pain & suffering they were going through.

The physical pain & suffering – the funded drugs available which create nasty physical side effects, which everyone endures because the drugs are working (until they don't) & keeping them alive but they are toxic and impact hugely on health. The family are affected and upset as they see a loved one in pain, and knowing there is nothing they can do to help. For the patient, the inability to be as physical as they once were, and I'm not talking about old age here. It's a killer knowing there are better drugs available but out of reach because they are can't afford them.

The mental pain & suffering – the financial & emotional stress. The constant worrying about can I afford to not keep working, can I afford to live like I used too? What happens when my funded options no longer work – should I be trying to save for that day? How can I save for that day when I no longer can work? Do I re mortgage the house so I can afford a drug that will give me more time with my children, my husband? Do I use the life savings to live another year or 2 or 3? How will my

family survive after I die? Is the question their life or mine? The family should not have to ask that either, the pressure is immense to all.

No one should be in this dire situation. This drug is already funded in other countries, and New Zealand needs to step out of its third world attitude, and do the right thing. New Zealand is NOT a poor nation! But Poor decisions are being made. It is time to look after the PEOPLE!

I strongly support the funding of palbociclib as a first line, 2nd line & later line treatment for metastatic breast cancer in New Zealand. The success of this drug, and the better QOL of it gives, makes it a no brainer to fund immediately.

Pharmac, please meet your Statutory Objective: "to secure for eligible people in need of pharmaceuticals the best health outcomes that are reasonably achievable and from within the amount of funding provided".

Sue W

13 Nov 2018

Patient Perspective on Funding of Palbociclib – Mary-Margaret S - October 2018

My name is Mary-Margaret S and I'm 54 years old. I was given a Stage IV breast cancer diagnosis 27 months ago, with metastases to my mediastinum. I have the BRCA1 mutation and had my initial diagnosis in 2010 when I was 46.

At my Stage IV diagnosis, my oncologist suggested letrozole as first line treatment, but I could see from my own research that the standard of care was already letrozole plus Ibrance in my situation. On asking further I found that Ibrance wasn't available in New Zealand yet but via chains of inquiries (to Melbourne to Singapore to Malaysia) by helpful oncologists, I found that my oncologist could work with one in Malaysia, and I could get it there. I duly travelled to Malaysia and took Ibrance for 24 cycles – just under 2 years – until it stopped working. Initially I got it from there because it was not available in NZ, but after that, the greatly reduced cost ($2500 per month versus $6000) is why I continued. All up, I travelled there 7 times, and my husband twice. We spent, including travel, approximately $80,000 in that time, just over $3000 per month.

I was the first from New Zealand to travel to Malaysia for this drug and it was very stressful. Initially, I had no certainty, beyond the recommendation of my oncologist contacts here and in Australia, of the quality of care or drugs in Malaysia, and it took huge time and energy (at a time when our family was reeling from my diagnosis) to work out logistics of bringing the meds into NZ, dealing with Medsafe, and dealing with Malaysia's unfamiliar and (to me) chaotic systems. I was also recovering from the sternotomy surgery at my diagnosis, and was travelling alone as we have no family here and my husband had to stay back with our three children. Since that initial travel, I wrote up a "How to get Ibrance in Malaysia" guide to make it easier for others, which I believe has been used by at least 9 more women who have also had to travel to South East Asia so that they can afford this drug.

Ibrance for me was a miracle worker. When the cancer struck, I was teaching at Massey University, doing tertiary study myself, volunteering as an advocate for beneficiaries, teaching ECE courses, in

two choirs, on my son's school's Board of Trustees, and was chair of my church parish council. More to the point, I also had three children in high school (one who was special needs) and who all very much needed my attention and energy. While on Ibrance, I was able to carry on more or less normally for that time. I had to let some commitments lapse, but was still able to carry on as a very active member of my community and be fully present in my children's lives and see two of them through high school and into university.

Unfortunately, our financial resources were at their breaking point by the time the Ibrance stopped working. In a horrible way, it was almost a relief to find that I had progression, since we did not know if we would be able to manage to fund any more Ibrance, had it continued working for me. This saved us having to make that awful decision to just let me die sooner. We are very conscious that if Ibrance is recommended for me with fulvestrant as a later treatment, it is unlikely we will be able to afford it.

Since I stopped taking Ibrance, I have now moved onto capecitabine. It has had much harder side effects, but mostly a fatigue that has meant that I can only operate out and about for a couple of hours at a time. Instead of the cancer being there mostly in the background while I get on with life, as it was for the past two years, I feel like it is now the centre of everything. I can't make plans, I let people down, I miss my children's events and from one day to the next I don't know what, if anything, I'll be able to manage. The contrast with Ibrance couldn't be more profound and I am very grateful that I had that good two years on Ibrance, when my children were younger.

Throughout all of this, I've been so aware of how randomly lucky I have been. Because my husband and I happen to be professionals, and because I happen to be academic, we could do the research, source the funds and get the most appropriate drug for me when I needed it. Most New Zealanders don't have those options, which is horribly unfair. Every woman should have the ability to use Ibrance, not just those who are affluent.

Patient Perspective on IBRANCE - Krystal H, Niuean, 36 years old

At just the tender age of 34 I was diagnosed with breast cancer on my daughter's 13 month mark. My son was then just 2 years old. It was one of those moments where I felt like I was in a movie thinking it would never happen to me. I was at the peak of my career but nowadays my only and MOST important job in the world is trying to stay alive! So that LLM I worked so hard for 10 years became a non: issue.

I felt a lump in my breast while living on Niue so I had 2 options to either do a biopsy in Niue and send it here for testing or fly in to get tested here. We flew in 17 September 2016 and was diagnosed on 20 September 2016! Funnily enough after the initial punch biopsy as I was walking out to get a mammogram the doctor said "look Krystal if I were you I wouldn't worry too much about it". Oh how those few words gave me a glimmer of hope that the doctor thought it may be phyllodes tumour like my Dr Google research. But when I was called a second time for a mammogram, that glimmer of hope dimmed. When I got to the last test I looked at the screen and asked "is that a lymph node?" oh how my heart sank when Radiologist said yes. For I had done my homework and knew that if it was cancer and it was in my lymph nodes my chances of recovery were slim.

I was diagnosed stage 3 cancer and within 6 months it spread to my lymph nodes on the non: cancer side and I became treatable but incurable. While on chemo my breast had physical changes that were visible to the eye but oncologists couldn't quite pin it until I saw the surgeon 2 days before my bilateral mastectomy. The surgeon alerted my oncologist on the possibility of my breast cancer changing status to inflammatory breast cancer (IBC) so my scheduled bilateral mastectomy was cancelled. IBC is extremely rare that I've often wondered whether it had always been an IBC misdiagnosis. But even if it were unfortunately IBC here in NZ is treated the same as ordinary breast cancer with the focus on the hormone receptor status. In the US and Australia IBC is treated as cancer of its own.

I started off as HR+ and HER2+ and did chemo, a year of Herceptin and aromatase inhibitors but it still spread to my skin and bones. The metastases status changed to HR+ but Her2: . In April 2018 I started Capecitabine but by August it had started to show signs that it had stopped working however my oncologist knew we were a single income family since my illness so there was no way we could ever afford Ibrance. We discussed Ibrance and 2 other options but continued to gamble with staying on the same drug (Capecitabine) hoping it would work given more time but at the risk of cancer continuing to spread.

By October it was clear that I had a differential response to Capecitabine where my skin responded but not the bones. I received this news on the day the NZ Herald published our story on our appeal to the Government to fund Ibrance and Kadcyla. The next day I flew to Wellington to march for this very worthy cause and although the outcomes of our march are a long way away I felt accomplished that I have participated in something that may potentially benefit many others who like me did not have a choice but r our loved ones. I returned from Wellington feeling very desperate that my niece started a Givealittle page.

It was very hard to acknowledge that I was begging to buy more time in life yet embarrassed that it has come to this point at just 36 years old! My son Satu is 5 years old and daughter Leiola 3 years old and I owe it to them to do anything and everything I can to be here longer even if I'm begging. I am their world as much as they are mine.

In early 2017 while on chemo my 3 year old son was quite the helper always checking up on me and when I'd sleep the whole day he would whisper in my ear "Mum wake up are you dead?" and when I'd move to show him a response he would put my water bottle and medication box next to me and tell me "here's your medicine Mum". Cancer was in his vocabulary so much that his preschool teachers approached me to confirm whether he was speaking truth in talking about cancer at just 3 years old. It got to the point where I could see he would be teary when saying "My Mummy is sick she got cancer" and I knew we needed an intervention so they can be kids. So I sent both my kids to Niue after my bilateral mastectomy in May 2017 and again after my Left side total hip replacement in June 2018. Niue was a breath of fresh air for them. The freedom to run around outside, go to the beach and living the island life worked because they returned with that spark in their eyes. The very same spark which had faded with each day that they witnessed cancer turn me into a 24hour patient more often than being a mother.

My husband Ofa is my pillar of strength and I've often thought about how much life changed for him at just 29 years when our vow of "in sickness and in health" came way too early at just 4 years into our marriage. Cancer changed our status overnight from being a partner/wife to patient/carer

for the most part of the last 2 years. We struggled as the shared responsibilities for kids and household became his solely. It was and still is a big adjustment for him mentally, emotionally and physically having to care for 3 people in every way. Ofa has had to juggle between going to work for our financial support or staying home to care for us when any of us fall sick. When the kids fall sick my support is limited to giving the panadol during normal hours. Nursing them through the night is the father's responsibility in our home. I find myself always apologizing at how little input I have into our family life in comparison to the burden that I am because of cancer.

On 28 October 2018 with skin mets and bone mets to my femur, pelvis, spine, ribs and shoulder I started on Ibrance through the generous offer of help which even I found difficult to accept yet I can't accept the alternative either. My mental battles are "if Ibrance was $70/month we could afford it. If it were $700/month perhaps my family could take turns helping but at $7k/month who in my Pacific world would ever afford that?" Yesterday I read a news article that quoted "cancer is a rich man's game" that statement is very truea not only for me but for many of my Pacific sisters in this same situation. Cancer never gave us a choice we did not choose to have such an ending but Pharmac can choose to hear us and help us. Wanting to live and spend a little more time on earth is not greed when you consider the little people depending and relying on your guidance and believing in your every word to navigate life.

My plea is to please help us have equitable access to life extending drugs and equitable access for all. Please don't write us off but let us in a way help New Zealand improve cancer care for all stage 4 patients and bring us up to par with similar countries who are way ahead in caring for their people like us. Please Help!