Petition of Terre Maize: Fund Kadcyla and Palbociclib for breast cancer sufferers

Report of the Health Committee

July 2019

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Louisa Wall
Chairperson

Petition of Terre Maize: Fund Kadcyla and Palbociclib for breast cancer sufferers

Recommendation

The Health Committee has considered the Petition of Terre Maize—Fund Kadcyla and Palbociclib for breast cancer sufferers—and recommends that the House take note of its report.

Request to fund breast cancer medicines

The petition of Terre Maize was presented to the House on 16 October 2018. It requests:

> That the House of Representatives urge the Minister of Health and Pharmac to fund Kadcyla and Palbociclib for breast cancer sufferers, and note that 33,971 people have signed online petitions requesting the Minister to provide this funding.

Advanced breast cancer (ABC)

Advanced breast cancer (ABC) is cancer that has spread from the breast to other areas of the body. It is also known as metastatic, secondary, and stage 4 breast cancer.

We heard evidence from the petitioner, Terre Nicholson (formerly Terre Maize). Ms Nicholson belongs to a group of about 200 New Zealanders with ABC, who call themselves "metavivors". We heard that 36 metavivors died in 2016 and 2017 and at least 12 died in 2018.

We received evidence from other submitters, including metavivors, the Breast Cancer Aotearoa Coalition (BCAC), pharmaceutical companies, the Ministry of Health, and Pharmac.

We heard that metavivors are often younger than the publicly funded breast-screening age (45 years) when they first discover that they have breast cancer. We heard how devastating it can be to fight breast cancer for years, to finally believe that you are in remission, only to discover, often suddenly, that the cancer has spread and you now have advanced breast cancer.

Treating advanced breast cancer

Several medicines can be used to treat ABC. They include the two listed in the petition:

- Kadcyla is the brand name of Trastuzumab emtansine (also known as T-DM1). It is an endocrine (hormone) therapy for patients with "HER2 positive" cancer. They comprise about 20 percent of ABC patients.
- Palbociclib (brand name Ibrance) is a second-line treatment for those with "oestrogen-receptor (ER) positive" breast cancer. They comprise about 70 percent of ABC patients.

It was submitted that access to these medicines is likely to extend the lives of metavivors by slowing or stopping the cancer's progress.

Submitters told us that several other medicines should also be funded, including trastuzumab (Herceptin) as a later line of therapy, the hormone therapy fulvestrant (Faslodex), and the chemotherapy treatment nab-paclitaxel (Abraxane).

According to a paper published in September 2018 by the Breast Cancer Foundation New Zealand,[1] the median survival time for New Zealanders with ABC is 16 months. This compares with three years in other developed countries.[2]

The petitioner told us that, although neither Ibrance nor Kadcyla represent a cure for breast cancer, they have been shown to slow progression of the cancer. She commented also that experience in the US has found that Ibrance "doesn't work long-term for everyone".

BCAC submitted that new medicines, to a large extent, "account for major improvements in breast cancer survival in the developed world over the last 40 years".[3]

BCAC submitted that New Zealand has created a two-tier health system in which those who can pay live longer. This is because many New Zealanders must pay privately for cancer medicines that are evidence-based and recommended by their oncologists.

Pharmac's process

Applications to publicly fund medicines are considered by Pharmac's Pharmaceutical Therapeutic Advisory Committee (PTAC). The PTAC can seek advice from a subcommittee. After the PTAC has made a recommendation, Pharmac assesses the relative value of the application in the context of other funding applications.[4]

There is no fixed time frame for Pharmac's final decisions. Pharmac said that this is because "the priority of funding for a medicine compared with other medicines can change over time. Decisions about the next medicines to be funded take into account many factors including the health benefits they offer relative to other possible choices, new and updated clinical evidence, the amount of funding available and the price we have negotiated with suppliers".[5]

Concerns about Pharmac's process

We heard various concerns about the application process for funding a medicine. Many submitters commented that it takes too long. BCAC calculated that it takes a median of 912 days between the lodging of an application to fund a breast cancer medicine and funding becoming available for it.[6]

Submitters also commented that the Pharmac application process should be more open. It was suggested that Pharmac publish its committee and subcommittee minutes sooner and

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1 https://www.breastcancerfoundation.org.nz/what-we-do/advocacy/abc-report

2 Referred to in submissions from Breast Cancer Aotearoa Coalition, supp 1, p 4, and Dr Fatima Cordoso, p 1.

3 Submission from Breast Cancer Aotearoa Coalition, supp 1, p 4.

4 See the submissions from Pharmac, supp 4, p 4, and the Breast Cancer Aotearoa Coalition, supp 1, pp 6–7.

5 Pharmac, supp 3, p 3.

6 For more details, see the submission from Breast Cancer Aotearoa Coalition, supp 1, p 10.

make public the information used in decisions. It was also said that Pharmac should seek the public's views throughout the consideration process, and that consultation should be transparent.

Pharmac's action plan

Pharmac told us that it has an action plan to help it deliver faster, simpler, and clearer decisions and better engage with and include consumers. Key activities in the action plan are to:

- implement a new, easy-to-use online application system that can track the status of applications
- publish recommendations within 12 weeks by appointing additional staff solely to assess applications and produce recommendations
- ensure certainty about decision making by closing applications if Pharmac is no longer actively considering them, instead of its current system of leaving applications open (but inactive)
- work to increase consumer involvement in Pharmac's funding process[7] through initiatives such as the Consumer Voices public consultation.

Early access schemes

Although early access schemes were not included in the petition request, we received correspondence from the ministry on early access models in foreign jurisdictions which include access to cancer-related treatments. The ministry noted that these schemes can come with significant costs. For example, in the UK, the NHS cancer drug fund went significantly over its budget. This resulted in the fund being redesigned.

Many different kinds of early access schemes are used internationally. The schemes are usually either financially based with a focus on cost containment, or outcome-based with a focus on value for money and reducing uncertainty about costs or benefits. The schemes vary depending on how much cost is carried by the Government, the patient, or the manufacturer. Some schemes involve reimbursements for treatments by the manufacturer where the patient has not responded to the treatment. This model has been used for just over 50 percent of schemes in Italy. The OECD noted that there have been disputes over the performance of treatments or slow recovery of data about them, which often make it hard to recoup funds.

The ministry noted that early access schemes change rapidly and are often confidential between the parties involved. This makes it difficult to access information about these schemes and to know whether they are successful.

The ministry also noted that early access schemes are complex and come with a high cost, not only for the pharmaceuticals, but for the administrative and implementation costs involved. This would require funding that could have an alternative use, such as in prevention and early diagnosis.

[7] Pharmac submission, supp 2.

The Minister of Health stated that he has asked Pharmac and the ministry to investigate early access schemes. They will provide the Minister with advice on possible ways to improve access to innovative medicines in New Zealand.

Palbociclib (Ibrance)

Ibrance is registered with MedSafe and is available privately at a cost of about $6,000 a month.

Ibrance as a first-line treatment

In February 2018, the pharmaceutical company Pfizer applied to Pharmac to fund Ibrance as a first-line hormone treatment for advanced breast cancer. In September 2018, the Cancer Treatments Subcommittee reported evidence of "modest" benefit from using Ibrance in combination with a non-steroidal aromatase inhibitor, such as letrozole. The subcommittee recommended that Pharmac fund Ibrance for ABC patients who have not already received a hormonal treatment, with medium priority.[8]

The PTAC considered the subcommittee's advice in February 2019.

Ibrance as a second-line treatment

In November 2018, BCAC applied to Pharmac to fund Ibrance as a second-line treatment, for patients who have already received a hormonal treatment. Pharmac told us that it had asked the supplier for more detailed evidence about the use of Ibrance for people who have already received a hormonal treatment. The subcommittee was due to consider that application in April 2019.

Pharmac told us that the PTAC would review the applications for Ibrance for both first-line and second-line treatment in May 2019, with recommendations to be published in mid-August 2019.

Other evidence about palbociclib

We received evidence from Dr Fatima Cardoso of the European School of Oncology. Dr Cardoso submitted that drugs such as palbociclib have led to some improvement in progression-free survival. However, the overall survival benefit has not yet been clinically proven. Despite this formal lack of evidence, Dr Cardoso said that the world has accepted these medicines as standard therapies and "is now moving on to testing the next generation of new drugs or combination therapies".[9]

Dr Cardoso also submitted that medicines such as palbociclib extend the length of time before chemotherapy is needed. Further, as oral medications, they are easier to administer than infusions. They also have lower toxicity than most chemotherapy agents, meaning that patients are more likely to be able to continue working.

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8 Submission from Pharmac, p 6, and Pharmac supp 3, p 2.

9 Dr Fatima Cardoso, p 5.

Trastuzumab emtansine (Kadcyla)

In August 2017, the pharmaceutical company Roche applied to Pharmac to fund Kadcyla as a second-line treatment for HER2 positive ABC patients who had already received Herceptin and another medicine, taxane. In November 2017, the PTAC recommended it for funding, with low priority.

Pharmac told us that, in September 2018, the Cancer Treatments Subcommittee advised it that the evidence about Kadcyla was weak, poor quality, and not relevant to New Zealand patients because it "did not assess the use of Kadcyla after treatment with pertuzumab (Perjeta)".[10] Pharmac has funded Perjeta for certain patients since 1 January 2017. The subcommittee recommended that Kadcyla be funded, with medium priority, for those who had not been treated with Perjeta. Pharmac's submission estimated the number of patients to whom this applied to be fewer than 100 people.

Trastuzumab (Herceptin) as a second-line therapy

Dr Cardoso submitted that it is good practice for ABC patients who are HER2 positive to take trastuzumab (Herceptin). She said that trials designed to establish whether Herceptin should be taken after cancer progresses were stopped early on, because it was considered unethical to not provide the medicine after cancer had progressed. However, Herceptin is not funded in New Zealand as a second-line therapy. We were informed that the standard treatment in Europe and the USA now is to continue Herceptin "for several lines of therapy, in combination with different chemo or endocrine therapy agents".

Fulvestrant

BCAC said that it applied in May 2018 for the hormone therapy fulvestrant (Faslodex) to be funded. Several years earlier, Pharmac had declined a Faslodex funding application from the pharmaceutical company AstraZeneca. We heard that the subcommittee recommended funding, with medium priority, for patients with ER-receptor positive ABC.

At the same time as the Ibrance application in November 2018, BCAC applied for fulvestrant to be funded as part of second-line treatment.

Dr Cardoso expressed surprise that fulvestrant is not funded. She submitted that it has "been around for a long time", is efficacious, is not very expensive, delays the use of chemotherapy, and is well tolerated.

Emphasis on early detection

Pharmac and the Ministry of Health told us about the importance of improving the early detection of breast cancer. The Government aims to increase breast screening rates, especially of Māori women, whose screening rates are lower. The ministry said that 72 percent of women aged 50 to 69 were screened in 2015. The rate was 65 percent for Māori women.

[10] Submission from Pharmac, p 6.

However, we note that many of the metavivors were diagnosed with breast cancer before they were 50 years old. Also, BCAC submitted that, although finding breast cancer early is important, it "does not preclude its recurrence or progression to a more advanced stage". It said that around 30 percent of all breast cancers will recur and that 95 percent of those diagnosed with ABC have had an earlier breast cancer diagnosis. Further, we were told that, 5 years after ABC diagnosis, 5 percent of Māori are still alive. This compares with 15 percent of New Zealand Europeans.

Funding for medicines

BCAC and others submitted that New Zealand should spend more money on medicines. It was submitted that New Zealand spends less than many comparable countries, and has spent relatively less each year since 2007. Submitters told us that although more medicines are available each year, this indicates that the situation "has improved relative to what it once was", but not in comparison to other wealthy countries.

Submissions from "metavivors"

We heard oral submissions from 19 women suffering from metastatic breast cancer. Many women spoke of the effect their cancer and inability to afford treatment had had on their mental health and their struggle to maintain their dignity. We heard that some metavivors felt their mana had been lost as their health deteriorated. In addition, many submitters had decided to attempt to self-fund the drugs through seeking donations on websites like Give A Little. Submitters spoke about the trauma of having to make themselves vulnerable by seeking donations from the public and publishing their medical information online. One submitter who had received donations to cover much of the cost of the drugs acknowledged her privilege in having the skills, knowledge, and connections to gain the donations she needed. However, she noted the injustice for many of her fellow metavivors in being unable to secure the donations they needed to afford the drugs.

Several submitters mentioned the fact that they can travel to countries like Malaysia, and receive Ibrance for approximately $2,500 per month, less than half the cost in New Zealand. They can legally bring three months' supply of the drugs into New Zealand each time they visit. We asked Pfizer, which produces Ibrance, why the cost variance is so great across jurisdictions. Pfizer listed "local health needs, economic situations and pricing and reimbursement policies" as being variables that can affect the price it sets for drugs in each country. Pfizer pointed out that, under its compassionate access scheme in New Zealand, patients only have to pay for their first 11 months of Ibrance treatment before it becomes free.

We thank the metavivors who talked to us, and particularly note the courage and strength they have shown in publicly telling their stories. We acknowledge the stress and trauma that these patients have suffered.

Our response to the petition

We note that the petition specifically requests that Parliament urge the Minister of Health and Pharmac to fund Kadcyla and Palbociclib. We greatly respect the courage shown by the petitioner, and the efforts she has gone to in presenting this request to Parliament.

However, we also respect the independence and impartiality that are governing principles of Pharmac. Its decision-making process is robust, and evidence-based. We do not believe that Parliament should attempt to influence Pharmac towards funding particular medicines.

Many of the metavivors who submitted to us, including the petitioner, indicated that they want an inquiry into Pharmac, with a focus on its purchasing model and funding decisions. While we were unable to agree to recommend or initiate an inquiry, we would like to see Pharmac continue to improve its action plan to promote the transparency and timeliness of its decision making.

A large number of innovative pharmaceuticals are coming onto the market. However, these pharmaceuticals have significant costs and limited long-term outcome data, making it difficult to establish their benefits. We heard from the Minister that Pharmac and the ministry are investigating early access schemes. This will inform the Minister about possible proposals for improving access to innovative treatments and the consideration and analysis of policy choices. Due to the importance and complexity of this work, we believe it should be completed before we make any recommendations about implementing an early access scheme in New Zealand.

We welcome the exploration of early access schemes for new and innovative pharmaceuticals and expect that the issues raised by many of the submitters will be considered during this process. We think this would include:

- the experiences of other countries that operate early access schemes
- whether early access schemes have affected timeliness or transparency in funding new medicines
- whether early access schemes provide cost-effective and improved clinical outcomes for patients
- the way that Pharmac considers new and innovative pharmaceuticals.

Appendix—Committee process

Committee procedure

The petition was referred to us on 16 October 2018. We met between 4 December 2018 and 31 July 2019 to consider it.

We received written submissions from Terre Nicholson (formerly Terre Maize) and 51 others, including breast cancer sufferers and their families, the Breast Cancer Aotearoa Coalition, pharmaceutical companies, Dr Fatima Cardoso, the Ministry of Health, and Pharmac.

We heard oral evidence from 26 submitters, including the petitioner, the Ministry of Health, Pharmac, the charity Sweet Louise, medical oncologist Dr Anne O'Donnell, and the pharmaceutical companies Pfizer and Roche.

Committee members

Louisa Wall (Chairperson)
Hon Maggie Barry (from 22 May 2019)
Dr Liz Craig
Matt Doocey
Hon Ruth Dyson (from 24 July 2019)
Jenny Marcroft
Dr Shane Reti
Hon Nicky Wagner (until 22 May 2019)
Angie Warren-Clark (until 24 July 2019)
Hon Michael Woodhouse