



Nikki Shute
PHARMAC
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Wellington 6143

August 30, 2013

Dear Nikki,

Thank you for the opportunity to provide feedback on the proposal of May 2013 reviewing PHARMAC's Decision Criteria. This feedback is provided on behalf of the Breast Cancer Aotearoa Coalition, an organisation representing more than 30 breast cancer groups as well as individual members throughout New Zealand.

Key considerations

Patient focus

It is important that decisions made by Pharmac are consistent with a consumer-centred health care system. This concept should underpin every decision that Pharmac makes about medicines and their listing on the Pharmaceutical Schedule, and in particular, cancer treatments. In this regard, the health outcomes for patients should be the primary consideration.

To ensure this focus, greater patient/consumer engagement is needed at all levels in Pharmac's processes, including effective consultation to gain all relevant information and views well in advance of decision making.

Underlying principles and legal framework

Wider principles of equity, fairness, ethics, community values and cultural needs should be incorporated into Pharmac's decision-making processes that affect access to medicines. As a taxpayer-funded organisation, Pharmac should reflect the principles, ethics and values of the community it serves, and should continually strive to better meet the needs of New Zealand patients.

Decision processes should take proper account of the New Zealand legal framework (e.g. Human Rights obligations, the Treaty of Waitangi, New Zealand Public Health and Disability Act). Pharmac should also incorporate Government's responsibilities, policies and priorities (both health and non-health priorities) (e.g. the Medicines Strategy, Faster Cancer Treatment, the statutory obligations of DHBs) into its decision processes to ensure consistency and conformity with other elements of government and the health system.

Making a difference together

Mahia kotahi nga rerekētanga

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Consistency

Decisions also need to be consistent among treatments already listed, for potential new listings, and among patients and patient groups. Decision criteria should be applied to treatments currently listed on the schedule as well as new treatments. The current focus tends to create barriers to access to new treatments in favour of existing, often less effective, options.

While applying consistency in decisions, Pharmac should constantly strive to deliver better, more equitable health outcomes for New Zealanders.

Quality and transparency

The quality and consistency of decision-making by Pharmac needs to be independently evaluated on a regular basis and subject to audit.

There is an urgent need for more transparency around the reasoning behind each decision that is made. The current use of the Decision Criteria as a 'tick-box list' of elements considered, without explanation as to how criteria were applied or what impact the considerations had on the decision outcome, is opaque and unhelpful for those affected by decisions.

Timeliness

It needs to be recognised that for many patients affected by life-threatening diseases such as cancer and other serious diseases, who require access to treatment within a critical timeframe, the lack or deferral of a decision to either list or decline listing is in effect a denial of access to treatment. BCAC has serious concerns about the current delays in access to new cancer treatments, which can be stretched out to years. Such delays would not be tolerated with other modalities of treatment used in cancer such as surgery or radiotherapy.

Suggested Criteria

1. Clinical need for the medicine/device

To properly and fully apply the criterion of clinical need, expert clinical advice, sourced independently of Pharmac, is needed. Information and input is also needed from patients and their representatives on the impact of the disease and the treatment on patients, families and communities (see below). Key elements in assessing clinical need include the following:

- Severity of disease (impact on mortality and morbidity) in the population and within groups who currently have poorer health outcomes.
- Other treatments available – and whether/why a new treatment is needed in a population or population group.
- Urgency of need for treatment given the disease and patients' circumstances.
- Patients' perspective on how the disease and current treatments affect their quality of life, physical and psychological wellbeing, family relationships, ability to work, and impact on carers/families/whanau.
- Access to current treatments – are there significant geographical, cultural, social or other barriers to patients accessing treatments currently?
- Need to take into account the variability among individuals and the need for alternatives to be available if a patient does not respond to or is intolerant of available treatments.

- Treatments that may be preventative, curative or palliative in nature need input from those affected to assess their relative importance to the overall management of a particular condition.
- Expert clinical advice independent of Pharmac should be sought from clinicians, preferably specialist clinical groups, treating the disease for which the medicine or device is available.

2. The treatment's ability to meet patient needs and needs of others affected by the disease

Again, independent clinical and patient/consumer advice is needed to assess this criterion.

Necessary considerations include:

- Efficacy versus current treatments based on available clinical evidence.
- Safety versus current treatments based on available clinical evidence.
- Concurrent offerings, i.e. supportive materials and services, with treatment under consideration (e.g. education, patient information, administration, training and support services).
- Quality versus current treatments, including supplier, continuity of supply, ability to provide concurrent offerings with treatment, longevity, reliability and accuracy of devices etc.
- Urgency of need for new treatment.
- Patients' perspective on how the proposed treatment impacts on their quality of life, physical and psychological wellbeing, family relationships, ability to work, as well as impact on carers.
- Improvement in access to treatment and resulting health outcomes.

3. Costs and burdens associated with the disease and its treatment

- Net cost to the health care system
- Impact of disease and treatment on costs to society, including all those affected no matter who meets the costs (focus on individuals, whole of government, health system and other parties). Disease impact should include impact on quality and length of life, costs of re-treatment and palliative care if a disease is not treated effectively, loss of contribution to the workforce, impact on family, care-givers and community.

4. Cost effectiveness of treatment

- Far greater transparency is needed in all Pharmac's cost utility analyses.
- In particular, where either cost of treatment, budgetary impact or consequences for patients are considerable, cost-utility analysis needs to be more comprehensive, detailed and transparent.

5. Fairness, equity and community values

Pharmac's decisions must incorporate human impact as well as budgetary impact. Necessary considerations include the following:

- How does the decision impact on individuals and the community? Does it provide the best possible health outcomes for affected patients?

- Is the decision consistent with Government health priorities, policies and strategies?
- Is the decision consistent with the statutory requirements of DHBs, on whose behalf Pharmac purchases, i.e. does it “improve, promote, and protect the health of people; reduce health disparities by improving health outcomes for Māori and other population groups; exhibit a sense of social responsibility by having regard to the interests of the people to who it provides, or for whom it arranges the provision of, services; uphold the ethical and quality standards commonly expected of providers or services and of public sector organisations.”

Support for submissions from other groups

In addition to the points made above, BCAC is fully supportive of the response to this consultation made by the collaborative group chaired by **Medicines New Zealand**, to which BCAC has contributed.

We are also fully aware of and supportive of the patient-focused submission made by the **New Zealand Organisation for Rare Disorders**.

Yours sincerely

A handwritten signature in blue ink that reads "Libby Burgess". The signature is written in a cursive, flowing style.

Libby Burgess MNZM

Chairperson

Breast Cancer Aotearoa Coalition

www.breastcancer.org.nz