



26 February 2010

BCAC RESPONSE TO REVIEW OF ACCESS TO HIGH COST, HIGHLY SPECIALISED MEDICINES IN NEW ZEALAND

The Breast Cancer Aotearoa Coalition (BCAC) is pleased to respond to the Review of Access to High Cost and Highly Specialised Medicines in New Zealand.

BCAC is a collective of more than 28 breast cancer-related groups as well as individual members working to ensure that world-class detection, treatment and care is available to all those with breast cancer in Aotearoa, New Zealand.

Since its inception in 2004, BCAC has had years of experience interacting with PHARMAC and other stakeholders in the process of medicines funding including high cost and highly specialised medicines as well as others. In illustrating particular points we will use recent examples where appropriate.

Our overwhelming concern in relation to the Review is the absence of a consumer voice reflected in the Recommendations.

In Recommendation No. 1, the Review suggests that there is no particular need for a separate process of assessment and decision-making for high cost or highly specialised medicines. In general, we agree that these medicines should be able to be accommodated within a process which is adequate for all medicines being evaluated.

The problem is that the current processes have major flaws which must be addressed. These flaws are general rather than being specifically related to the processes for high cost or highly specialised medicines.

The main concerns we have relate to the current processes for both assessment and decision-making about which medicines should be subsidised in New Zealand. As the Review and its recommendations deal mainly with the general processes, our subsequent comments also address these.

Topics are in the order of discussion as laid out for the recent consultative FORUM convened by the HCHS Panel in Wellington.

Making a difference together

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1. Extension of PHARMAC's Role to Purchasing in Other Areas of Pharmaceuticals and Health

We can see the logic of evaluating other areas of health to ensure value for money. The Review proposes that this be done by PHARMAC extending its role to assessing and purchasing in other areas such as hospital pharmaceuticals (for inpatients) and other health technologies (presumably this would include not only products but also evaluating practices such surgical techniques etc.).

However, given the significant issues around the way PHARMAC processes and structures currently work, as outlined in Section 3, below, this is unsupportable.

If PHARMAC's processes of assessment and decision-making could be modified to the degree needed in the following areas:

- **Active and meaningful consumer involvement in clinical and economic assessment and decision-making,**
- **Timeliness of decision-making,**
- **Independence and competence of clinical and economic assessments and**
- **Transparency;**

only then would BCAC support this approach.

There would be significant negative consequences if the current flawed model was extended to other areas of health care. Therefore, we cannot support Recommendation 12 without major process changes having been fully implemented and evaluated.

2. Budget Setting for Medicines on the Pharmaceutical Schedule

PHARMAC have publicly stated that it is not their responsibility to advocate for more funding for pharmaceuticals. The current situation is therefore about face. There are medicines that have been identified, evaluated etc. and are considered to have a high priority for funding by PHARMAC's advisers, yet they are not funded until PHARMAC can afford them from within their budget. They may not be funded at all, funding may be delayed for years or they may be funded for inadequate duration/dose just to save money.

The budget should be set so that these medications can be funded within a reasonable time frame from being recommended for listing. The budget for community pharmaceuticals has increased only marginally since the inception of PHARMAC.

PHARMAC may be doing a great job at managing expenditure to budget, but this means that literally thousands of New Zealanders are not able to access medications that they need, that their doctor considers appropriate, that is considered efficacious safe and of sufficient quality by MEDSAFE and that PTAC has advised should be funded. This situation is simply ludicrous and nothing to be proud of.

Furthermore, delaying access or funding treatment for inadequate duration (e.g. 9 weeks Herceptin) is cost saving but simply a waste of money if the treatment is not effective. Spending on pharmaceuticals is not just about the total upfront cost is but whether they are effective or not. Failing to effectively treat disease has longer term costs to the community. In the case of Herceptin, the treatment duration (9 weeks) was considerably less costly than the approved regimen of 52 weeks. However, MEDSAFE declined to approve the regimen PHARMAC funded, because they did not consider the evidence of efficacy adequate.

The budget needs to be set with clearly defined needs in mind. It should also take into account a significant element of forward planning for medications which are likely to become available in the future.

The Review considered that medicines in the future are likely to become more costly and specialised (p24 – the pipeline). It does not address how the future should be planned for to address this issue.

3. Current Processes for Assessment and Decision Making

This section outlines issues with the current processes and provides the rationale for why we cannot support Recommendation 3 until there is major change in the current processes.

Need for Societal Values to be Reflected in Decision-Making

The document discusses the need for society's values to be included in decision-making but fails to address the issue of whether the current decision-making processes result in decisions which reflect society's views.

We maintain that although the Decision Criteria may be intended to reflect the societal viewpoint, the reality is that PHARMAC's decision making does not adequately represent the societal viewpoint.

To reflect society's view would require a broader range of stakeholders to be involved in the both of the assessment processes (clinical and economic) and decision-making.

We believe that meaningful involvement of a broader range of stakeholders, including consumers, would be beneficial to the funding processes, would improve their outcomes

and generate greater societal acceptance of decisions. In particular, we have addressed consumer involvement in our 2009 submission to PHARMAC which is attached.

For other suggestions on this see International Comparisons (Section 4, below) where NICE in the UK's model integrates public and patient viewpoints as a matter of course and as a matter of principle. The Australian system also integrates a broader range of stakeholders in decision making.

Role of consumers or patients in the processes and decisions

The preliminary report gives no emphasis to the issue of meaningful consumer involvement in the processes of clinical assessment, economic assessment and procurement decision making.

In our experience, consumer involvement in any of these aspects is either absent or has only marginal impact on decision-making. We attach our response (dated 30 November, 2009) to Pharmac's consultation on how it could improve consumer involvement.

In our view, consumer involvement must occur in all the processes and there are clear examples of how this can work from elsewhere.

- Clinical assessment currently does not solicit the perspective of those affected by the disease. For example, this is done by NICE in the UK where consumer perspective and information on the effect on people's lives of the disease or treatment being evaluated is actively sought during the clinical (and economic) assessment.
- Economic assessment as currently carried out by PHARMAC does not use patient perspective in outcome valuation. For example, in preparing the economic analysis of Herceptin in early breast cancer, PHARMAC staff assigned the quality of life weighting associated with various health states in the modelling of the Quality of Life without input from patients.
- Decision making at PHARMAC does not appear to meaningfully involve consumers at all. It is significant that consumers are not represented amongst the decision makers (e.g. Pharmac Board or the organisation itself). The processes are supposedly in place to consult with consumers (and others). However, we do not believe this occurs in reality in any meaningful way. The Judicial Review of the Herceptin funding decisions found the lack of consultation on the decision to decline funding of Herceptin was inadequate (Gendall Judgement 2008). As far as the consultations which do occur go, we have found little evidence that consumer response to these consultations impacts on decision making.

PHARMAC's Role in Clinical and Economic Assessments from Procurement Decisions and Processes

We believe it to be vitally important that the clinical and economic assessments are not influenced or manipulated by the procurement decisions and processes. Indeed for the integrity of the system as a whole these assessments should be completely independent from the purchasing processes.

There is currently legitimate concern over PHARMAC's ability to carry out clinical and economic assessments in a competent and unbiased manner.

We would support the PTAC and its subcommittees having a wider membership and more input from a variety of stakeholders (Recommendation 10) and this should include public and patient input to assessments. This may require support for consumers being educated to fulfil the requirements of this role. In addition, in order to ensure high quality, well-informed decision making, independent expert clinical opinion should, as a matter of course, be sourced from outside PTAC for assessment of particular medicines.

Current Issues around Timing of Decision-Making and Restrictions on Access

The Review has clearly looked at the issue of availability of funded medicines in NZ versus Australia (and perhaps elsewhere). The issue they do not appear to have fully appreciated is that access in New Zealand is often delayed (i.e. a product may eventually become available but only years later than in other countries) or access is more severely restricted. Examples are the use of aromatase inhibitors in early breast cancer and taxanes for early breast cancer. These treatments were under consideration by PHARMAC for literally years and received only partial funding up to 5 years later than in Australia in some cases, despite being recommended by PTAC.

From the patients' perspective there is often a limited window of time in which treatment must be initiated (e.g. adjuvant therapy for early breast cancer) and therefore a delay serves to deny them appropriate treatment i.e. it has the same outcome for the patient as funding being declined. For this reason, we agree that timely decision making is absolutely essential.

For this reason we support Recommendation 6 – processes need to result in effective and timely decision making.

Restriction of Therapeutic Choice for Patients and Prescribers

As the committee has identified, restriction to only one treatment per class or a sole supply tender for a particular drug can result in the lowest possible price because one supplier has the whole market.

Although this may make sense economically, it does not take into account that people are different, their response to medication is different and that one choice of medication for a particular condition means that many patients are left with inadequate treatment or must fund their own medication. It is simply no comfort to the person who does not respond as the majority do, to be told of all the savings which accrued to the tax payer through having no choice.

Therefore, where alternatives are available, patients must be able to access them funded. This could be appropriately restricted – i.e. using the special authority system or under exceptional circumstances (provided this is simplified and shown to provide successful results to a greater number of patients than at present).

Exceptional Circumstances Schemes

The issue of therapeutic choice is also related to the exceptional circumstances (EC) schemes. Because there is currently such limited therapeutic choice, the number of exceptional circumstances schemes has grown. If there was more therapeutic choice, then these schemes could be simplified. Some of the complexity associated with EC seems purely in place to be a bureaucratic barrier to having patients' access medication via these schemes.

The simplification of the current schemes as proposed (Recommendation 2) is supported. From the patient perspective, it is important that decisions to approve access or deny access to treatment be made in a timely, consistent and transparent manner.

The current rule in the Cancer EC that medicines under evaluation by PHARMAC cannot be funded under EC is completely unfair to patients who would otherwise qualify for treatment and should be abolished.

Arrangements to Improve Availability of “Orphan” Medicines

There should be special arrangements in place to encourage the availability of medicines which are not commercially viable otherwise. MEDSAFE fees could be waived or reduced. Simplification of the EC schemes would also facilitate the funding of these medications.

Communications about Pharmac's Decision Making

Currently, PHARMAC processes applications for medicines funding by soliciting clinical assessment (from PTAC and its sub-committees) and economic assessments (in-house). The applications for new products then wait until PHARMAC Board (or the CEO under delegated authority) makes a decision to list the product or to decline listing. As earlier stated this waiting process can take literally years.

As previously stated, once the assessments have been carried out, there is no information available for consumers or clinicians during this waiting time during the process about whether they will be able to access treatment at some time in the future or not (unless funding has been definitely declined by PHARMAC). This is where the frustration about “lack of transparency” lies.

PHARMAC’s analyses are not published and are only available under the Official Information Act (OIA). We support the sharing of the clinical and economic assessments not only with clinicians (as per Recommendation 8) but with all stakeholders – especially those affected by the decisions which are often based on these assessments.

Role for an Appeals Process

Currently there is no recourse except to the courts to have a decision reviewed. This is expensive, time-consuming and burdensome for patients – who are often dealing with major health issues and do not have the resources to involve themselves in long legal battles. Furthermore, unlike consumers, PHARMAC appears to have extensive resources to enable them to defend their decisions in the courts.

Optimal and Ethical Use of Medicines

We support programs that would enhance the optimal and the ethical use of medicines provided they are patient focussed and their objective is to improve health outcomes for patients and or their families.

4. International Comparisons

The various points made above may also apply when international comparisons are made.

Societal Values and Role of Consumers or Patients

NICE in the UK has clear policy on patient and public involvement and its processes seek to involve both the public and patients affected by disease and treatments. We suggest that the committee look to this example to see how the “public” and patients can meaningfully be involved in evaluation and decision-making processes for health care technologies.

Ref:

http://www.nice.org.uk/getinvolved/patientandpublicinvolvement/patientandpublicinvolvementpolicy/patient_and_public_involvement_policy.jsp

The UK Model could usefully be adapted to the New Zealand situation.

Greater consumer involvement would need to be supported by providing the consumers involved with the necessary education, training and authority to be taken seriously in these roles.

Timing of Decision-Making and Restrictions on Access

As stated earlier, timing of listing and restrictions on access also contribute to the poorer access to treatments in New Zealand compared to Australia and the UK (as well as many other countries). Many of the newer treatments for breast cancer have been years behind Australia and the UK in achieving funded access in New Zealand.

In Australia, the PBAC generally makes decisions in a timely manner and the listings occur in a timely manner. In the UK, products are often already available funded while they are under consideration by NICE.

Australia also has an authority system whereby second line or third line treatments are available under more restricted conditions – therefore treatments may be restricted to those who will benefit most.

Therapeutic Choice for Patients and Prescribers

The Review correctly identified that there is a wider range of treatments available in Australia and the UK than in NZ and treatments for breast cancer are no exception. This includes hormone treatments, chemotherapy and therapies such as anti-nauseants and white cell factors used to treat adverse effects associated with treatment.

Some patients have actually moved overseas in order to access treatments. This option is available only for those who have the resources to travel and the right to access funded treatment elsewhere.

Communications about Decision Making

PBAC issues a “Public Summary Document” which outlines the evidence they reviewed and the reason for their recommendations. The decision maker is the Minister of Health and the Minister almost without exception takes the advice of PBAC.

NICE issues its guidance publicly with thorough reasons for the decisions. It also issues draft guidance and consults meaningfully.

In NZ, PTAC minutes are published, but PTAC are not the decision makers. Decisions are made in NZ by the PHARMAC Board or PHARMAC staff under delegated authority from the Board. Their proposed decisions are sent out for consultation, but judging from our experience, these consultations are not meaningful.

Role for an Appeals Process

Both Australia and the UK have appeal processes when decisions need to be reviewed. These should be further investigated as a model for establishing something similar in New Zealand. This would give the opportunity for review of decision-making. However, it is important that any appeals process is independent and fair and perceived to be so.

Arrangements to Improve Availability of “Orphan” Medicines

TGA (the regulator) in Australia has an “Orphan Drugs” scheme which has lower fees for medicines designated as orphan (less than a certain number of patients to be treated). This could be considered for NZ. The funding of orphan medicines in Australia goes through the same processes as other medicines. However, the PBS does have the “life saving drugs program” which the Review doesn’t seem to be aware of. This is for medicines which are not considered “cost-effective” but without which people will die. There are just a few medicines in this category.

Kind regards

Elisabeth Burgess

Chairperson, Breast Cancer Aotearoa Coalition

Summary of Views versus Recommendations

1	Yes
2	Yes
3	No – not unless there are major changes in processes
4	Yes
5	Neutral
6	Yes – strongly support improvements in timeliness of decision making.
7	Yes – provided stakeholders include consumers.
8	Yes- but needs to include public and consumer involvement.
9	Yes- but needs to include public and consumer involvement.
10	Yes – but must integrate views and values of public and consumer or those affected by disease, treatments and funding decisions.
11	Yes
12	No
13	No – not unless there are major changes in processes
14	Yes
15	Yes