BTAA Submission to the Senate Standing Committee on Finance and Public Administration Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme

14 July 2011

BTAA is one of 60 organisations who have joined with the Consumers Health Forum to voice the concerns of health consumers on this issue. Our comments in this submission focus on the likely impact on people with brain tumours.

Brain Tumour Alliance Australia Incorporated (BTAA) thanks the Senate Standing Committee on Finance and Public Administration Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme (PBS) for the opportunity to provide a submission.

There are around 1,400 new cases a year of malignant brain tumours and hundreds more of so-called benign brain tumours that can be just as deadly if the tumour is in a vital area.

The burden of the disease is high in terms of morbidity and mortality and survival rates are not improving. Australian Institute of Health and Welfare (AIHW) five year survival statistics show no significant change in survival between 1982–1986 and 1998–2004 (21 per cent over 5 years).

Brain tumours are not only a disease affecting older persons – 100 new cases a year of malignant tumours affect children, with a greater, but unknown number of benign tumours.

Malignant brain tumours are the most common form of childhood malignancies.

A fact sheet on brain tumours is at **Attachment** A.

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Brain Tumour Alliance Australia Incorporated (BTAA) provides information resources to newly diagnosed patients and their families. More information on brain tumours is available from www.btaa.org.au

The deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee.

BTAA is very concerned about the ramifications of the decision taken in February 2011 to change the process for the listing of medicines on the PBS to require Federal Cabinet approval. This decision undermines the work of the Pharmaceutical Benefits Advisory Committee (PBAC) and is not in the best interests of Australian health consumers.

BTAA considers there is a special case for people with brain tumours to have access to the latest, most promising treatments and that individuals should be able to access the medicines that best suit their individual needs, regardless of their means.

We are thus very concerned about the implications and precedent of this decision for the listing of new medicines into the future.

We note that in reaching its decisions, the PBAC is required to consider the efficacy and cost-effectiveness of new medicines, and whether the proposed medicine meets a need not already met by other PBS-listed medicines.

The PBAC is best placed to determine which medicines should be included on the PBS, and which should not. The PBAC considerations include the efficacy and cost-effectiveness of new medicines, and whether the proposed medicine meets a need not already met by other PBS-listed medicines.

It is BTAA's view that governments should be informed by the advice and recommendations of the PBAC.

BTAA considers the previous approvals process, which provided for direct Cabinet approval of medicines over a threshold of $10 million per annum, was an appropriate process that worked in the best interests of both the government and health consumers.

The consequences for patients of such deferrals.

Decisions by Cabinet to defer the listing of medicines on the PBS can severely restrict peoples' access to important drugs.

If Cabinet continues to defer approval of new medicines on the PBS, it may decide to defer a drug useful for brain tumours. Such a decision will result in people having to pay privately for medicines, or go without.

We strongly support people being able to access, through the PBS, the medicines that their health professionals recommend as the best options for them.

Brain tumours affect people at any age and a large proportion of those diagnosed are younger persons, many with dependants and not in a position to self-fund new drugs. Many are children with parents with other siblings to care for.

There are considerable financial implications of brain tumours for both health consumers and the health system. In addition to the cost of medicines, these already include significant out-of-pocket expenses for surgery, radiotherapy, tests and other procedures.

The prognosis for those with a malignant brain tumour is poor. Families are anxious to obtain access to any new medications that will prolong their life or quality of life.

It is important that brain tumour therapies are subsidised by government so that all people can access them, not just those who can afford to do so or who have communities willing to fund raise to assist them.

The burden of the disease is high in terms of morbidity and mortality and survival rates are not improving. Australian Institute of Health and Welfare (AIHW) five year survival statistics show no significant change in survival between 1982–1986 and 1998–2004 (21 per cent over 5 years). Brain tumours are the eight highest cancer causes of burden of disease, for both males and females[1].

Brain tumour patients have the second longest average length of hospital stay (12.5 days) in 2008-09[2].

Brain tumours are not only a disease affecting older persons – 100 new cases a year of malignant tumours affect children, with a greater, but unknown number of benign tumours. Malignant brain tumours are the most common form of childhood malignancies.

Brain (and other central nervous system[CNS]) tumours accounted for more than 5,000 hospitalisations in 2008-09.

Health policy for CNS tumours (including brain tumour and other central nervous system) should take account of brain tumours:

- not being amenable to initiatives to increase earlier detection through public education about screening programs, preventative health nor self-examination or recognition of symptoms;
- but being amenable to more effective treatments, including ensuring equity across the states and territories and access to high quality treatment for those in regional and rural areas.

The criteria and advice used to determine medicines to be deferred

BTAA questions the criteria and advice used by Federal Cabinet in making its decisions about which medicines should be listed on the PBS and which should be deferred.

Given that Cabinet appears not to be following the advice of its own expert authority, the PBAC, BTAA seeks a better understanding what criteria it is basing its decisions regarding new listings.

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[1] Cancer in Australia, An overview , AIHW, 2010, pg 61

[2] *Ibid*, pg 68.

BTAA is concerned that decisions about listing of drugs may be made on the basis of their cost to the Australian Budget, rather than their health benefits to people who are in need of them.

BTAA is also concerned by the transparency given the confidentiality of Cabinet considerations. We are concerned that having Federal Cabinet make the decisions on all new listings reduces transparency, with no consumer input to this process and no information publicly available on the criteria Cabinet uses to reach its decisions.

By contract there is transparency in the PBAC's processes, with opportunities for consumer input and to make submissions on the listing of particular medicines, and the availability of online publishing of the PBAC Public Summary documents providing advice on meeting outcomes. Indeed, BTAA has previously participated in these processes.

For example the PBAC made a decision relating to access to a drug, Avastin (bevacizumab) for relapsed glioblastoma, that offered hope to brain tumour patients that was disappointing to many in the brain tumour community. BTAA had supported its inclusion.

The decision by the PBAC not to recommend the subsidisation of Avastin for recurrent glioma brain tumour patients was seen as unfortunate by BTAA.

But at least the reasons for the decision were transparent. See here for PBAC decision:

http://www.health.gov.au/internet/main/publishing.nsf/Content/pbacrec-nov10-first-time-rejections

In this particular case the PBAC made its decision on the basis of *'uncertain clinical benefit and an unacceptably high and uncertain incremental cost-effectiveness ratio'*.

In the USA the equivalent body, the FDA, has approved Avastin for this same indication but the European equivalent regulatory agency has not. This has complicated the situation.

The therapy is particularly relevant for those diagnosed with the most lethal of the primary malignant brain tumours glioblastoma multiforme grade IV, which is what Professor Chris Obrien, journalists Matt Price, Andrew Olle and the late Senator Edward Kennedy had. People diagnosed with this particularly aggressive tumour have very few treatment options.

But medications do make a difference. Aggressive treatment has enabled some active members of BTAA Inc to have a good quality of life well beyond the usual life expectancy, and indeed given them additional months and years. What price on that?

In a submission to the PBAC prior to its evaluation BTAA supported subsidisation because there is very little else on offer to patients whose malignant primary brain tumour progresses after standard therapy. At the same time BTAA expressed a wish that the Roche company's patient access scheme should be more generous.

We understand that the Roche Company, despite this negative decision, has continued its patient access scheme and will continue its dialogue with the PBAC. Both these decisions are good news for patients although BTAA repeats its request for the access scheme to be more generous. The scheme requires patients pay the first $20,000.

As this example illustrates decisions on a drug like Avastin for brain tumour patients and the associated cost benefit analysis is both complex and emotive.

Transparency is important and enables health consumer organisations like BTAA inc who field queries from the families of those living with brain tumours about the availability and costs of emerging technologies and treatments.

Transparency has been a key benefit of our drug approval system over recent years. This is consistent with moves to increased transparency with other key government functions, such as the Therapeutic Goods Administration.

The financial impact on the Commonwealth Budget of deferring the listing of medicines

Like other consumer health organisations BTAA understands that the Government is looking to reduce costs across all areas of government. We believe that assisting with access to medicines that can make a difference to people's quality of life is an appropriate role for government and is most cost effective in the medium to long term.

We are not convinced that deferring the listing of new medicines will save the government significant funding in the short term.

While we appreciate the budgetary pressures on the government and its stated objective of bringing the budget back to surplus in the face of worsening economic conditions globally and the challenges of a patchwork economy domestically.

However we do not believe that deferring from the PBS medicines that are recommended by the PBAC is the best way to bring about fiscal discipline given its impact on the health of Australians.

In assessing applications for PBS listings, the PBAC considers cost-effectiveness of the proposed medicine. By not listing these medications and so denying people access to them through the PBS, doctors are forced to prescribe other medicines that may even be more expensive but already subsidised through the PBS. Or they prescribe other medicines that are less efficacious, or with undesirable side effects.

In the long-term, this could lead to increased costs for government and a great burden through increased visits to health professionals and more hospitalisations.

Conclusion

The decision to delay listing of drugs which have been through the PBAC process can only be seen as poor policy.

BTAA is concerned that the new process for listing medicines on the PBS, whereby Federal Cabinet approval is required for all new listings, is not in the interests of Australian health consumers. Nor is the decision in the best interest of Australians generally given it ties Cabinet up in considerations outside its immediate expertise without access to the broadest range of advice.

We are concerned that medications that can provide brain tumour patients with substantial health benefits either for treating their condition or managing debilitating side effects will not be listed on the PBS and that, as a result, some Australians will continue to not receive the best possible treatment for their medical condition. And we are concerned that the reasons they are not listed will not be transparent.

We believe the Australian Government should revert to the previous listing process, and that it should accept the recommendations of its own independent expert authority, the PBAC, which is best placed to do so.

While no brain tumour drugs have yet been affected by the new listing process, we are concerned that new medicines that could make a substantial difference to people's lives, and recommended for inclusion on the PBS by the PBAC, could be deferred by Cabinet.

Thank you for the opportunity to contribute to the Committee's Inquiry. BTAA welcomes the opportunity to engage in further consultations.

For further information on our submission, please contact Susan Pitt, Vice Chair, on 1800 857 221 or email vicechair@btaa.org.au.

Yours sincerely

Susan Pitt
Vice Chair
On behalf of
Brain Tumour Alliance Australia Inc.
vicechair@btaa.org.au

Attachment A

Brain Tumour Facts

Diverse

- Three main categories of brain tumours (central nervous system tumours): primary, 'benign' and brain metastases (or secondary brain tumours, arising from a primary cancer elsewhere in the body).
- There are over 120 different types of brain tumours alone, of which some 40 are classified as malignant.[3]
- The location of the tumour (area of brain, spine or meninges), grade, and the type of treatments undertaken and a range of other factors influence the impact on the patient, their abilities and prognosis.
- They are the only cancer to directly affect both the mind and the body.

Cause unknown

- Causes are unknown, not preventable by any known lifestyle changes.
- Early detection not possible at this time.
- Symptoms may include some of the following: headaches (that wake you up in the morning), seizures in a person who does not have a history of seizures, cognitive or personality changes, eye weakness, nausea or vomiting, speech disturbances, or memory loss.

Treatment and support

- Cause complex health issues and may require intervention from numerous specialities.
- Better treatment leads to longer life expectancy and better neurological outcomes.
- Critical shortages in health professionals best able to manage health of brain tumour patients.
- Brain tumours (and treatment side effects) can impair decision making and judgement and compound the challenge of treatment.
- Low level of understanding in the community about brain tumours and the enormous impact they have on individuals and their families.
- Although around 70% of children will survive, they are often left with long-term side effects.

Summary statistics

- Around 1,400 new cases of primary (malignant) brain tumours in Australia each year, including 100 in children.
  - This number excludes an estimated 2,000 so-called benign brain tumours that may cause disability or (rarely) death. [4]
  - Second highest cause of death for children aged 0 – 14 years from all causes – second only to accidental drowning/immersion[5] and highest

3 World Health Organization (Furnari et al. 2007). The most common primary intrinsic brain tumors are the gliomas for adults and medulloblastomas for children.

4 Based on ratio for primary brain tumours in the USA according to CBTRUS www.cbtrus.org/factsheet/factsheet.html

3 AIHW, unpublished data

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cause of death in this age group from cancer – an average of 33 deaths per year (2003-2007).[6]
    - Highest cause of death from cancer in people aged 0–39 (average of 120 deaths per year in 2003-2007).[7]
- No significant change in five-year relative survival between 1982–1986 and 1998–2004 (19%).[8]
- Largest lifetime financial costs faced by households of any cancer type, at $149,000 per person, and highest lifetime economic cost of any cancer type, at 1.89 million dollars per person.[9]
- More than 5,000 hospitalisations, 12.5 days average length of stay in hospital (2008-09).[10]
- Brain tumour research funding is low in relation to the burden of the disease – along with lung cancer and mesothelioma, bladder cancer, pancreatic cancer, lymphoma and cancers of unknown primary site.[11]

For more information see www.btaa.org.au

6 Leukemia and myeloproliferative and myelodysplastic diseases – average of 27 deaths per year for the period 2003-2007, unpublished data (AIHW).

7 AIHW, unpublished data

8 Cancer research in Australia: An overview of cancer research projects and research programs in Australia, 2003 to 2005, Cancer Australia, pg2.

9 Cost of Cancer in NSW. 2005, Cancer Council NSW, prepared by Access Economics, 2006.

7. AIHW Cancer in Australia 2010: An overview; pg177 hospitalisations, pg 80 length of stay.

8 Cancer research in Australia: An overview of cancer research projects and research programs in Australia, 2003 to 2005, Cancer Australia, pg2

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