

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

About Cancer Voices Australia

Cancer Voices Australia is the national consumer organisation representing Australians affected by cancer. It aims to ensure the voices of people affected by cancer are heard at a national level and to effect improvements in cancer treatment, care and support by contributing to national cancer policy, program development, management and evaluation

Submission

Cancer Voices Australia (CVA) welcomes the opportunity to provide a submission to this Inquiry. We commend The Senate for establishing this inquiry.

Our submission reflects CVA's key areas of interest – and the impact the decisions have on the cancer community.

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

The recent decision by Cabinet not to list on the Pharmaceutical Benefits Scheme (PBS) medicines recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) is a major concern for CVA.

CVA believes that this decision if continued will have considerable impact on the approval and listing process in relation to future drugs proven efficacious in the treatment of cancer/s.

The PBAC is internationally recognised and its current Chair, Emeritus Professor Lloyd Sansom AO has promoted and achieved transparency in its operations over the years with open dialogue and engagement with interested parties. A major development is the introduction of the Patient Impact Statements designed to provide the PBAC (during its deliberations) of the impact that the drug under consideration will have on the patient and their family if not listed.

As the independent expert authority established by government to assess applications for medicines to be included on the PBS, the PBAC is in the best position to determine and recommend which medicines should and should not be recommended for inclusion on the PBS. In reaching its decisions, the PBAC is required to consider the efficacy and cost-effectiveness of new medicines, and also whether the proposed medicine meets a need

CVA contends that the previous approvals' process, which provided for Federal Cabinet approval of medicines over a threshold of \$10 million per annum, was an appropriate process that worked in the interests of both government and health consumers. With increases in the cost of drugs/medicines now may also be an appropriate and opportune time for Government to review this amount

2. Any consequences for patients of such deferrals

As a peak consumer organisation for people affected by cancer, CVA believes that Australians affected with cancer should have access to the latest most effective treatments and that cancer patients should be able to access the medicines that best suit their individual needs.

Decisions by Cabinet to defer the listing of medicines on the PBS can severely restrict peoples' access to important drugs. CVA cites, by way of example, the bowel cancer drug Erbitux. Erbitux was deferred by Federal Cabinet in July 2010. It is a medicine that can extend the lives of people with late stage bowel cancer, but its cost puts it out of the reach of many who need it. While we acknowledge that the Minister for Health and Ageing announced in June 2011 that Erbitux will now be listed, the listing does not take effect until 1 September 2011, leaving many patients unable to access the recommended drug for now **over 15 months!**

We strongly support cancer patients being able to access, through the PBS, the medicines that their health professionals recommend, that are supported by the best evidence, as the best option/s for them.

In addition to the cost of medicines, cancer patients face a heavy financial burden with:

- out-of-pocket expenses for surgery, radiotherapy, tests and other medical and allied health procedures
- travel expenses, especially for rural patients and
- loss of income.

It is important that cancer medications are subsidised by government so that all cancer patients can access them, not just those patients who can afford to do so. For many people affected by cancer and surviving on low incomes, even relatively inexpensive medicines become a significant financial burden.

3. The criteria and advice used to determine medicines to be deferred

CVA 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, and the Therapeutics Goods Administration (TGA), CVA would like to know where Government is obtaining its expert advice and on what criteria and evidence it is basing its decisions regarding new listings.

CVA is very concerned that decisions regarding the listing of drugs may be made on the basis of their cost to the Australian Budget, rather than the health benefits to Australian people who are in need of and will benefit from them.

CVA cites the following example which involves a drug that can be prescribed for cancer patients –

In public documents available on the TGA website there is a statement in relation to both Clexane (already listed on the PBS and Fragmin – was recommended for listing by the PBAC but rejected by Cabinet on unknown grounds and for unknown reasons.

Product Information - FRAGMIN Injection - page 5 of 18: Precautions

'At low molecular weight heparins are unique and separate entities with regard to potency, kinetics and possible modes of action, these products are not interchangeable clinically'

**Product Information – CLEXANE - page 9: Precautions
LOW WEIGHT HEPARIN PRODUCTS ARE NOT CLINICALLY
INTERCHANGEABLE**

They differ in their manufacturing process, molecular weights, specific anti-Xa activities, units and dosage. The biological activity of different low molecular weight heparins cannot be expressed in a test allowing for a sample dose comparison. Different low molecular weight heparins may not be bioequivalent in terms of their labelled anti-Xa activities and alternative products should not be introduced nor interchangeable during a course of treatment.

So this is the published information for these medicines and in essence means that the Cabinet is rejecting the clinical evidence as recognised by another independent authority the TGA.

4. *The financial impact on the Commonwealth Budget of deferring the listing of medicines*

CVA is aware of the current fiscal restraints on the Government following the Global Financial Crisis, and the recent spate of natural disasters to befall this country, but this decision we believe places the Cabinet in the position of making clinical and cost effectiveness decisions – decisions already canvassed by the PBAC during their deliberations. It is of great concern to CVA and its many members that the recent decision of Cabinet to change the PBS listing process:

1. Lacks transparency
2. Dismisses the excellence and calibre of the long standing expert government committees involved in making recommendations to government about the most cost effective therapies available to Australians, and more importantly

3. Will impact other parts of the health system – an element often overlooked in discussions
4. May not reflect the current evidence, and
5. Politicises the decision regarding drug approvals

In assessing applications for PBS listings, the PBAC considers the cost-effectiveness of the proposed medicine. The poorer health outcomes that do result from people not being able to access the best treatments for their condition may also lead to increased health costs, through more visits to health professionals, more requirements for medications and more hospitalisations.

6. The consultation process prior to a deferral;

The Department of Health and Ageing in collaboration with Medicines Australia jointly hold a two day conference bi-annually where health policy, the PBAC, the PBS and pharmaceutical company issues are discussed in open forum. This is definite evidence of the openness and transparency displayed by all parties -where the good and collaborative intent of the Government is openly displayed.

Each year, representatives from the Department of Health and Ageing, Medicines Australia, the PBS, the PBAC and consumer groups convene at a meeting hosted by the Medical Oncology Group of Australia (MOGA) meet to also discuss issues pertinent to cancer medicines. It is an open and frank discussion but again demonstrated the intent of Government to engage with relevant stakeholders.

CVA is concerned that this current decision and lack of consultation appears on the surface to run contrary to the Government's openness in this matter.

Conclusion

It is CVA's strong view and contention that the 'new process' for listing medicines on the PBS, whereby Federal Cabinet approval may be required for all new listings, is not in the interests of Australian health consumers.

We are deeply concerned that medications that can provide patients with proven substantial health benefits are not being listed on the PBS and that, as a result, some Australians will not be receiving the best possible proven treatment for their medical condition.

CVA would respectfully suggest that the Federal Cabinet is not in the best position to make decisions about which medicines should or should not be listed on the PBS.

We believe the Australian Government should revert to the previous proven and beneficial listing process, and that it should accept the recommendations of its own independent expert authority, the PBAC.

As we have maintained - having Federal Cabinet make the decisions on all new listings reduces transparency, and with no consumer input to this process we must question the evidence of their decision.

What however, is of major concern to CVA is that no information is publicly available on the criteria Cabinet uses to reach its decisions. As the Government itself maintains – *‘we are an evidence based Government and will make policy backed by the evidence.’*

CVA is one of 60 consumer health organisations to have joined with Consumers Health Forum of Australia to voice the concerns of Australian health consumers about this very important issue.

We thank the Committee for the opportunity to make this submission on behalf on cancer patients.

For further information on our submission, please contact John Stubbs, Executive Officer, on (02) 8063-4191 or at john.stubbs@cancer.org.au

CVA is would be pleased to meet with the Committee in person to discuss our submission further.

Yours sincerely

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