Australian Greens Minority Report

National Health Amendment (Pharmaceutical and Other Benefits Cost Recovery) Bill 2008

The Australian Greens generally support a move to impose cost recovery measures in the case of high volume, commercially viable drugs.

However, the Australian Greens remain concerned that without the draft regulations the Committee is not able to fully subject the Bill to the scrutiny required, and we are not assured that our concerns will be adequately addressed in the regulations.

The Majority Report conclusion notes that 'in the absence of regulations...it has been difficult to appropriately assess the possible implications of the legislation'. The Australian Greens concur with these sentiments and, while we agree with the comments made in the Majority Report we cannot agree at this stage with recommendation (2) of the report that the Bill be passed.

As highlighted in a number of submissions to the inquiry, there is a potential that applications for low volume non-orphan drugs will be discouraged, which threatens the well being of some of the most vulnerable groups in our society. This includes palliative care patients, children and others suffering from rare cancers and other rare medical conditions. We are particularly concerned about the impact on Indigenous communities, who comprise a relatively small proportion of our population and therefore a small market population, but experience severe health disadvantage and can require access to specific medications.

A second concern explored by the Majority Report, but not addressed in its recommendations, relates to the operations of the PBAC. This Bill makes no provision for examining the efficiencies or operating requirements of the PBAC in a cost-recovery environment.

Outstanding Issues

Impact on industry and innovation

Draft regulations should be released for public review and comment before this Bill proceeds. These regulations, as pointed out in the Majority Report, should "incorporate specific measures...to ensure that there is no disincentive for companies to lodge applications to list low-volume medicines, or to change or extend the indications of listed medicines."

The regulations should also clearly state the conditions under which waivers are granted, as it is inappropriate that the waiver of fees be decided on a 'discretionary' basis.

The Australian Greens believe that fees should be fixed and linked to specific services. This would address concerns that fees (which are currently fixed only for a 2 year period) may later be inflated on high volume drugs to effectively cross subsidise fee-wavered applications. Such an action would be against the principles of cost recovery.

Sustainability of the PBAC

As suggested in the submission by Professor Allan McLean (Submission 2), the operations of the PBAC should be reviewed to ensure its continuing integrity under the pressures and constraints imposed by the cost recovery environment. This would demonstrate to industry and to the public that the independence of the PBAC will not be undermined by the move towards cost-recovery.

The cost to patients

Currently, this Bill offers no protection to patients. While the Department of Health and Ageing has provided answers to the inquiry that costs to patients will not be affected, more certainty regarding this should be provided for in the new arrangements.

Conclusion

The Australian Greens believe that these issues should be addressed before the Bill is passed.

Recommendations:

Recommendation 1

Draft regulations, incorporating specific measures to ensure that there is no disincentive for companies to lodge applications to list low-volume medicines, or to change or extend the indications of listed medicines, should be released for public review and comment before this Bill proceeds.

Recommendation 2

These draft regulations should include a schedule of fixed fees linked to specific services and clearly state the conditions under which waivers are granted.

Recommendation 3

The operations of the PBAC should be reviewed to ensure its continuing integrity under the pressures and constraints imposed by the cost recovery environment.

Recommendation 4

That the Government give an undertaking that costs to patients will not be affected by the new arrangements.

Senator Rachel Siewert Australian Greens