

**SENATE STANDING COMMITTEE ON
COMMUNITY AFFAIRS**

LEGISLATION COMMITTEE

**Inquiry into the National Health
Amendment (Pharmaceutical Benefits
Scheme) Bill 2010**

SUBMISSION

SUBMISSION NUMBER: 25

SUBMITTER

Lundbeck Australia Pty Ltd

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Senator Moore
Chair of the Senate Community Affairs Legislation Committee
Att. Committee Secretary Naomi Bleaser
PO Box 6100
Parliament House
Canberra, ACT 2600

Sydney, October 20th 2010

Lundbeck Australia Pty Ltd writes in support of the current legislative proposal for amendments to the National Health Act as agreed between the Australian Government and Medicines Australia.

Lundbeck Australia is a research based pharmaceutical company with a number of innovative products listed on the Pharmaceutical Benefits Scheme for the treatment of mental and neurological disorders. In addition, Lundbeck has a number of new products under development where there is a high unmet clinical need and a significant burden to society..

As an R&D based company Lundbeck invests up to ten years in advance in high risk clinical projects in anticipation of a financial return after a sustained period of significant losses. We rely on a stable and predictable environment as well as a reasonable period of exclusivity to recoup losses accumulated in the lengthy period leading up to commercialisation. In that period we are able to build in a margin that is a buffer to manufacturing costs and thus secure a return on investment which allows us to reinvest in new innovative therapies. Ultimately we expect market competition to force prices closer to a return that solely supports the manufacturing and distribution costs of a particular product. This is an internationally recognised operating environment for pharmaceutical companies and allows most developed countries a continuous flow of new innovative medicines as well as an efficient supply of older medicines. In Australia the 2007 PBS reforms set out to ensure that the Australian Government would obtain more efficient supplies of generic medicines. The MoU negotiated between the majority of the suppliers to the PBS and the Federal Government ensures that the reforms will be realized and that Government will be in a position to bank the savings in the forward fiscal estimates.

The MoU legislation is now at a critical point. We would encourage Members of Parliament to stay focused on the objective: to deliver efficient health outcomes to patients through a sustainable PBS. Without an implemented MoU the government will unfortunately not be able to source appropriately priced generic medicines-even though these are supplied by the Generic Manufacturers at efficient prices to Pharmacists. The inefficiencies have always rested with inability of government to limit trading terms and discounts supplied to pharmacist. The additional costs in the supply chain have been at the expense of the government. In many instances the Australian Government pays more than twenty times the acquisition cost for the same medicines as overseas European markets.

Failure to implement the MoU as it has been negotiated will remove the innovative medicines industry's incentive and ability to deliver much needed new treatments to patients in a range of critical disease states. Without the certainty that the MoU provides Lundbeck will not be able to invest in treatments that may relieve thousands of patients with mental health and neurological disorders.

In the short to medium term it will result in an unsustainable PBS which ultimately will be unable to afford to supply new innovative medicines. There are clear lessons from the experience in New Zealand where pricing policy has seen very few innovative products listed and direct consequences for the health of the national population with declining cancer survival rates.

Lundbeck Australia is a locally operating company investing strongly in local research however an uncertain local environment will force the company to downscale its operations in favour of other geographical areas where conditions are more predictable and attractive.

I am personally troubled that the generics industry has attempted to derail a carefully considered and beneficial plan to secure certainty for research-based medicines companies in Australia and urge you to support the legislation in the future interests of patients.

Best regards

Klaus Abel
Managing Director, Lundbeck Australia Pty Ltd