SENATE STANDING COMMITTEE ON COMMUNITY AFFAIRS

LEGISLATION COMMITTEE

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

SUBMISSION

SUBMISSION NUMBER: **20**

SUBMITTER

Hospira Pty Ltd

Submission to Senate Community Affairs Legislation Committee Inquiry into the provisions of the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

20 September 2010

Hospira Pty Ltd

Level 3, 390 St Kilda Road

Melbourne Victoria 3004 Australia

T: 1300 046 774

F: +61 3 9868 0111

www.hospira.com.au

Hospira

Hospira Australia (incorporating the former Mayne Pharma Ltd and BresaGen Ltd).

Hospira is a global specialty pharmaceutical and medication delivery company dedicated to Advancing Wellness™ by developing, manufacturing and marketing products that help improve the productivity, safety and efficacy of patient care. With over 70 years of service to the hospital industry, Hospira's portfolio includes one of the industry's broadest lines of generic acute-care injectables, which help address the high cost of proprietary pharmaceuticals; integrated solutions for medication management and infusion therapy; and the leading U.S. injectable contract manufacturing business. Headquartered north of Chicago in Lake Forest, Ill., Hospira has approximately 15,000 employees and 17 manufacturing facilities worldwide.

In Australia Hospira is the leading supplier of injectable generic pharmaceuticals to Australian hospitals, selling over 85 active drug substances. Hospira has sites in Victoria, New South Wales and South Australia and employs over 1000 people nationwide.

Submission

Hospira welcomes the opportunity to submit to this inquiry being conducted by the Senate Committee and strongly recommends that the new reforms to the PBS as proposed under the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 ("the Bill") require further scrutiny and revision. Hospira thinks the impact these changes will have on the pharmaceutical industry have not been fully explored or appropriately resolved by Government at this time.

Of greatest concern are the Government's plans to increase and accelerate Price Disclosure. Hospira's administrative burden will be substantially increased if price disclosure is expanded across the entire F2 formulary. Increased and accelerated price disclosure is of far greater concern to generic suppliers like Hospira than originator companies - who have drafted with Government the MoU upon which the Bill is based. This is due to the fact that generic manufacturers may have many dozens of different prices for each of their products whereas originator brands only tend to have one price. The volume of data generated because of these additional prices is exponentially greater.

As the Governments engagement with generic companies regarding the implementation of increased and accelerated price disclosure was very brief, Hospira do not feel that it is sufficiently prepared for the volume of data that is going to be generated under the current proposals. Government have yet to resolve how this data will be processed, analysed or validated. As price disclosure will most likely lead to price cuts Hospira feels it is inappropriate to pass an amendment that will enable price cuts until such times as all of the procedural methodologies are completed and all stakeholders have also had input.

Hospira support the Government's objectives to achieve a more efficient and sustainable Pharmaceutical Benefits Scheme (PBS), better value for money for Australian taxpayers and policy stability for the pharmaceutical sector. The PBS reforms introduced in 2007 were designed to meet these objectives and were forecast to save about $3 billion over ten years. Three recent and separate analyses – including the Government's own – show the savings will be about double that.

Currently, the PBS provides good value for money, costs are not out of control and the ten-year reform process that began in 2007 ensures that the PBS will remain sustainable. The proposed 2010 reforms will jeopardise the ongoing viability of the generic medicines sector and more broadly the pharmaceutical industry, Australia's leading exporter of manufactured goods. In other countries it has been the market competition produced by generic companies launching subsequent brands which has driven down prices and created market places with affordable medicines for all. Yet these new reforms seem to penalize mainly generic manufacturers in Australia, which seems contradictory as it is generic manufacturers who are helping to reduce the price of pharmaceuticals. The result of this penalty may be that global generic companies may find Australia an unattractive market to operate in and withdraw entirely.

Hospira agree with and support the submission made to the Senate Committee by the Generic Medicines Industry Association (GMiA). The main points of which were as summarized by the bullets below:

- Hospira supports the Government's objectives to achieve a more efficient and sustainable Pharmaceutical Benefits Scheme (PBS), better value for money for Australian taxpayers and policy stability for the pharmaceutical sector.
- The PBS reforms introduced in 2007 were designed to meet these objectives and were forecast to save about $3 billion over ten years. Three recent and separate analyses – including the Government's own – show the savings will be about double that.
- The reforms proposed under the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 ("the Bill") are unnecessary and the additional savings proposed are not justified.
- The proposed 2010 reforms will jeopardise the ongoing viability of the generic medicines sector and more broadly the pharmaceutical industry, Australia's leading exporter of manufactured goods.
- The proposed Bill will cut $1.9 billion out of the F2 formulary (generic medicines) over 5 years when the cost to Government of the entire F2 formulary fell by 21.4 per cent between 2005/06 to 2009/10 from $2.8 billion to $2.2 billion

(Government annual contribution).

- Conversely, the Bill does not address the growth of the F1 formulary (originator medicines) that has more than doubled over the same period from $2.8 billion to $4.8 billion (Government annual contribution) and the increasing costs of the F1 formulary will be the key growth driver to the PBS in the future.
- Sectional interests have been promoted through the exclusive nature of the MoU and the reform is piecemeal, threatening the optimal functioning of the PBS. As such, the Bill fails to provide for balanced reform to the PBS:
  - The reforms to the F2 PBS formulary are heavily weighted towards the older F2 medicines, where typically the greater market share is held by members of GMiA. The reforms have a much smaller impact on the medicines more recently added to the F2 formulary, where typically the greater market share is held by the originator sponsor.
  - The reforms do not address growth of the F1 PBS formulary (originator medicines) which will be the key driver of growth of PBS expenditure in the future.
  - The elimination of reference pricing outside of therapeutic groups has imposed a significant cost impost on the PBS as there are no demand side limitations concurrently imposed on the more expensive F1 medicine.

- The Bill does NOT deliver longer term sustainability to the PBS nor does it ensure more affordable medicines for Australians in the long term.
- Future growth of the PBS will be driven by growth of the F1 formulary – the burden of PBS reforms falls SOLELY on the suppliers of medicines in the F2 formulary