SENATE STANDING COMMITTEE ON COMMUNITY AFFAIRS

LEGISLATION COMMITTEE

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

SUBMISSION

SUBMISSION NUMBER: **14**

SUBMITTER

Spirit Pharmaceuticals Pty Ltd

spirit pharmaceuticals

20th October, 2010

TO: Members of the Senate Community Affairs Legislation Committee

RE: Inquiry into the provisions of the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

We wish to express our deep concern regarding the changes to the Pharmaceutical Benefits Scheme (PBS) and its administration proposed under the Memorandum of Understanding developed with Medicines Australia (MoU) and the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 (the Bill).

Spirit Pharmaceuticals Pty Ltd is headquartered in the Sydney CBD, with offices in Melbourne and Brisbane, and currently employs 10 highly qualified staff across a range of scientific and management disciplines. Founded in May 2004, Spirit received its first TGA approval later that year. As of September 2010, Spirit has over 20 products approved by the Australian TGA, and another 15 products under evaluation.

Spirit specialises in the commercialisation of high quality, cost effective, generic prescription pharmaceuticals for the Australian retail and hospital markets. In particular, Spirit is focused on those products that require specialised technical, regulatory or clinical support to meet the strict requirements for TGA approval. Spirit aims to provide cost effective alternatives in traditionally high cost areas such as oncology, controlled delivery analgesia and sophisticated injectables.

We support the Government's objective to achieve an efficient and sustainable PBS and, whilst we are not currently a member of the Generic Medicines Industry Association (GMiA), we fully endorse their efforts to engage with government and to contribute to policy discussions in this area. It is a great disappointment to Spirit, and to the generic pharmaceutical industry in general, that the MoU and the proposed Bill have been developed following close consultation with Medicines Australia (MA), to the

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exclusion of other stakeholders. The companies supplying generic medicines represent a critical segment of the Australian Pharmaceutical Industry and it is extraordinary that representation from such a major contributor should not be included in these significant policy discussions.

The consequence of this flawed process is a set of proposals that will pander to a powerful and vocal sector of the pharmaceutical industry, compromise the development of a healthy, competitive and diversified pharmaceutical industry in Australia and not achieve either substantial cost savings or improved health outcomes. In these regards, we concur with the views expressed in the GMiA submission made on behalf of its members to the Senate Community Affairs Legislation Committee Inquiry into the provisions of the Bill.

The attached submission further details our specific concerns, which we trust will be given due consideration through this process.

Yours sincerely

Gary J. Waters
CEO, Spirit Pharmaceuticals Pty Ltd

cc Helen Wray (Manager, IP & Health Economics, Spirit Pharmaceuticals Pty Ltd)

Submission to the Inquiry of the Community Affairs Legislative Senate Committee into

NATIONAL HEALTH AMENDMENT (PHARMACEUTICAL BENEFITS SCHEME) BILL 2010

SPIRIT PHARMACEUTICALS PTY LTD

This submission is made in response to the Community Affairs Legislative Senate Inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010.

Spirit Pharmaceuticals Pty Ltd (Spirit) is headquartered in the Sydney CBD, with offices in Melbourne and Brisbane, and currently employs 10 highly qualified staff across a range of scientific and management disciplines. Spirit was founded in May 2004 and received its first product approval later that year. As of September 2010, Spirit has over 20 products approved by the Australian Therapeutic Goods Administration (TGA), and another 15 products under evaluation.

Spirit specialises in the commercialisation of high quality, cost effective, generic prescription pharmaceuticals for the Australian retail and hospital markets. In particular, Spirit is focused on those products that require specialised technical, regulatory or clinical support to meet the strict requirements for approval by the TGA. Spirit aims to provide cost effective alternatives in traditionally high cost areas such as oncology, controlled delivery analgesia and sophisticated injectables.

Whilst Spirit is not currently a member of the Generic Medicines Industry Association (GMiA), we concur with the positions articulated in the GMiA's submission to the Senate Committee; however we wish to reinforce the following areas of concern:

1. **We do not believe the 2010 Bill and the associated reforms are necessary and have not been justified.**

   Spirit 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. We also understand that these objectives need to be delivered in the context of a health system focused on the provision of high quality care and optimised health outcomes for all Australians.

   The PBS reforms introduced in 2007 were designed to assist government in meeting these objectives and were initially anticipated to deliver $3 billion in savings over 10 years. The 2007 reforms delivered a $274 million reduction in PBS outlays in 2008-9 from the statutory price reductions associated with both the F2T and F2A formularies alone.

   Our own, recent experience of the impact of price reductions is evidenced through one example from the most recent round of "Price Disclosure Related Reductions" that will be effective 1 April 2011. Spirit's product "Gemcite" (gemcitabine, chemotherapy agent) will undergo a 37% price reduction on 1 April 2011.

   This demonstrates how the 2007 reforms continue to deliver savings to the PBS within the current framework. The PWC "Report to Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007" estimated that;

"The total savings to Government from the reforms will be in the range of $3.6 billion to $5.8 billion to 2018"

This 10 year savings estimate can be roughly compared with the estimates from the 2010 reforms, which are that they will provide $1.9 billion in savings over 5 years. It is of concern to us that no comparative analysis has been provided to demonstrate that the reforms proposed in the MoU and the Bill will have a positive, incremental effect over and above the policies currently in place. It seems to be quite possible from the above figures that this may not be the case.

2. **The exclusion of the GMiA, or other effective representation from the generics industry, from the negotiations around the MoU and the 2010 reforms has led to flawed policy and the potential for adverse impacts on the pharmaceutical industry in Australia as a whole.**

   It is a great disappointment to Spirit, and to the generic pharmaceutical industry in general, that the MoU and the proposed Bill have been developed following close consultation with Medicines Australia (MA), to the exclusion of other stakeholders.

   Whilst Spirit accepts the right of Medicines Australia to advocate on behalf of its members, it is incumbent on government to consult with all relevant stakeholders. To our knowledge there was no consultation, negotiation or agreement about the MoU or the underpinning Bill with the GMiA or the generic pharmaceutical industry as a whole. Without the insight and contribution of this significant sector of the industry, both the MoU and the Bill lack balance and detail flawed and irresponsible public policy. It should not be put forward as representing an "agreement with the industry" when it clearly promotes sectional interests ahead of the interests of the PBS, taxpayers and other sectors of the pharmaceutical industry.

   The GMiA represents a critical segment of the Australian Pharmaceutical Industry (>70% by volume of generic products) and it is extraordinary that representation from such a major contributor should not have been included in these significant policy discussions.

3. **The proposed 2010 reforms place the full burden of reform on suppliers of medicines in the F2 formulary, where earlier reforms have already focused and continue to deliver savings. There is no mechanism to achieve savings in the F1 formulary.**

   All products marketed by Spirit are listed in the F2A or F2T formularies. The proposed reforms to the F2 PBS formulary are heavily weighted towards the older F2 medicines, where typically the greater market share is held by dedicated generics companies, such as Spirit. A number of these items have already undergone significant price reductions. Further statutory reductions risk many of these items becoming uneconomic. 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, who also markets a rebranded product as a generic, and there are fewer alternative sources of supply in the market.

The GMiA's analysis shows that the share of PBS receipts to the F2 formulary declined by 17.7% over the 4 years from April 2005 to April 2009. In contrast, the share of PBS receipts to the F1 formulary has increased by 35.4% over the same period. The cost to the government of the F1 formulary more than doubled between 2005/2006 and 2009/10, increasing 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. It is clear that the 2007 reforms are continuing to deliver savings and the 2010 Bill does not address the areas where expenditure is continuing to grow.

There does not seem to be any mechanism in the MoU or the Bill by which the growth of expenditure on the F1 formulary will be controlled, in fact 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 currently imposed on the more expensive F1 medicines.

4. 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 reforms have the potential to jeopardise the viability of, and fundamentally change the business landscape for, the supply of pharmaceutical products and in particular, generic medicines in Australia. At risk is:

- The development of a healthy, competitive and diversified Australian pharmaceutical industry
- Surety of competition of multiple brands of generic medicines and the associated competition that keeps prices affordable
- Paradoxical effects that emerge from restrictive pricing policy in the prescription medicine market where some suppliers of generic medicines are forced to exit the market allowing the remaining players to increase prices
- Appropriate balancing of reward for innovation against long term medicines affordability and sustainability of the PBS, without compromising health outcomes
- Active challenge of potentially weak patents leading to earlier competition and savings to government

5. Potential Adverse Impact on Sprit Pharmaceuticals

We strongly believe that the proposed 2010 Bill will have an adverse impact on our company in a number of ways, including the following:

5.1. Product viability

Whilst we do not have any intention of reviewing our current product range at this time, if the 2010 Bill is passed and further statutory reductions in price are applied (anticipated to be 23-30% across the whole F2 formulary), that may force us to assess the viability of some of our current products.

In addition, we shall have to evaluate the opportunity to introduce new products against the new, and potentially uncertain, pricing environment. This will not only reduce the

opportunities we have to grow and develop our business, but will also reduce the level of competition required to maintain a healthy pharmaceutical industry in Australia.

5.2. Administrative Burden

The proposed Bill would increase the number of items subject to price disclosure to 1600. Whilst Spirit does not currently have that many products on the market and therefore subject to disclosure, our data collection systems are manual, the pricing structures complex and the collection and reporting of data represents a disproportionately high administrative burden related to the value of the product reported. We are reliant on timely, and correct, reporting from third parties in many instances and the rapid expansion of this requirement will undoubtedly lead to reduced reliability in the data.

6. Conclusion

A weakened generic medicines sector is not in public's best interest. The proposed 2010 Bill will not bring stability to industry, rather the Bill jeopardises the ongoing viability of the generic medicines sector in Australia which in turn substantially strengthens the commercial interests of the suppliers of originator medicines in Australia at the expense of the generics sector. The proposed Bill will not deliver longer term sustainability to the PBS nor does it ensure more affordable medicines for Australians in the long term.

Spirit urges the Senate Committee to recommend further scrutiny of the Bill and full engagement with the GMiA and members of the generics industry to ensure the interests of all stakeholders are represented in future policy discussions.

Spirit strongly supports the recommendations made by the GMiA in their submission to the enquiry, i.e.

Recommendation 1: The Government should put on the public record the detailed breakdown and composition of forecast savings stemming from the proposed 2010 and the 2007 PBS reforms.

Recommendation 2: The Government should work with the GMiA to develop a reporting mechanism that enables inclusion in the Commonwealth Budget forward estimates of all savings resulting from the 2007 PBS reforms.

Recommendation 3: The presence of a generic medicines sector is already delivering and will continue to prospectively deliver substantial savings to the F2 formulary and no further reforms are necessary.

Recommendation 4: Should the Government contemplate further reforms to the PBS, all relevant stakeholders should be consulted before further reforms are drafted.

We appreciate the opportunity to make this submission and look forward to a positive, and constructive, outcome.

Spirit Pharmaceuticals Pty Ltd.