

13 July 2011

Senate Finance and Public Administration Committees  
PO Box 6100  
Parliament House  
Canberra ACT 2600

Dear Committee Secretary,

**RE: Senate Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme (PBS)**

Thank you for the opportunity to comment upon the administration of the Pharmaceutical Benefits Scheme.

Research Australia is the nation's largest alliance working to make health and medical research a higher national priority. Research Australia is a united voice from across the Australian community that is supported by 170 partner organisations including industry, hospitals, philanthropic groups, research institutes and universities.

*Submission Background*

The Pharmaceutical Benefits Scheme (PBS) provides the Australian community with affordable access to over 740 medicines (marketed as over 3,500 brands).<sup>1</sup>

Pharmaceutical companies apply to the Pharmaceutical Benefits Advisory Committee (PBAC) to have their medicines listed on the PBS. The PBAC is an independent, expert committee comprised of doctors, health professionals and consumer representatives.<sup>2</sup>

The PBAC considers new applications for PBS listing by objectively reviewing the clinical effectiveness and value-for-money of the new medicine, in comparison with other available treatments. The same requirements for listing new medicines on the PBS are applied in all cases to ensure consistency and fairness in the listing process.<sup>3</sup> No new medicine can be listed unless the PBAC makes a positive recommendation.<sup>4</sup>

Recently, the Government deferred the listing of the following seven new medicines after receiving positive recommendations from the PBAC, noting that they will be "reconsidered for listing when circumstances permit"<sup>5</sup>:

1. Invega Sustenna® (manufactured by Ortho-McNeil-Janssen Pharmaceuticals) - a long-acting medicine given by injection once a month to

<sup>1</sup> Submission of the Australian Government Department of Health and Ageing, 9 April 2010, Senate Community Affairs References Committee, Inquiry into Consumer Access to Pharmaceutical Benefits, pp 5-6.

<sup>2</sup> <http://www.pbs.gov.au/info/industry/listing/participants/pbac>

<sup>3</sup> Submission of the Australian Government Department of Health and Ageing, 9 April 2010, Op Cit, pp 5-6.

<sup>4</sup> <http://www.pbs.gov.au/info/industry/listing/participants/pbac>

<sup>5</sup> The Honourable Nicola Roxon MP, Minister for health and Ageing, Media Release, Benefits from new medicines listed on the PBS & NIP, 25 Feb 2011.

- treat symptoms of schizophrenia, a treatment option especially for those who have a hard time remembering to take a pill every day<sup>6</sup>;
2. Targin® (made in the UK and supplied in Australia by Mundipharma Pty Ltd) - to relieve moderate to severe persistent pain when other forms of treatment have not been effective and to bring relief from constipation which is a typical side effect of treatment with opioid analgesics<sup>7</sup>;
  3. Duodart® (supplied in Australia by GlaxoSmithKline Australia Pty Ltd) - for men who have benign prostatic hyperplasia (BPH) which is a non-cancerous enlargement of the prostate gland that causes urination complications<sup>8</sup>;
  4. Symbicort® (supplied by AstraZeneca Australia) - for the treatment of asthma for people whose doctor has determined that their asthma is not well controlled with a long term asthma control medicine, or whose asthma is severe<sup>9</sup>.
  5. Fragmin® (supplied in Australia by Pfizer Australia Pty Ltd) - to prevent blood clots forming in blood vessels and to treat deep vein thrombosis (DVT);<sup>10</sup>
  6. Synarel® (distributed in Australia by Pfizer Australia Pty Ltd) - to treat endometriosis in women;<sup>11</sup> and
  7. Botox® (distributed in Australia by Allergan Australia Pty Ltd) - is injected into muscles and used: to prevent headaches for those suffering from chronic migraines; to treat increased muscle stiffness for those with upper limb spasticity; to treat the abnormal head position and neck pain that happens with cervical dystonia (CD); to treat certain types of eye muscle problems; to treat the symptoms of severe underarm sweating; and cosmetically to temporarily improve the look of moderate to severe frown lines between the eyebrows.<sup>12</sup>

The PBS is one of the fastest-growing Government programs, in 2008-09, around 182 million PBS-subsidised prescriptions were dispensed at a cost of over \$7.7 billion (approximately 15% of the Department of Health and Ageing budget).<sup>13</sup> The growth of the PBS has averaged 9.6% over the past ten years<sup>14</sup> and is projected to grow by 2.1% per annum in real terms over the next four years. This compares with an inflation rate of 3.3% to March 2011.<sup>15</sup> Consequently, these new medicines may have been deferred as a cost saving measure. As Prime Minister Julia Gillard said "we can take these tough decisions now to bring the budget back to surplus"<sup>16</sup>.

<sup>6</sup> <http://invegasustenna.com/about-invega-sustenna>

<sup>7</sup> [http://www.betterhealth.vic.gov.au/bhcv2/bhcmcd.nsf/pages/mfctargi/\\$File/mfctargi.pdf](http://www.betterhealth.vic.gov.au/bhcv2/bhcmcd.nsf/pages/mfctargi/$File/mfctargi.pdf)

<sup>8</sup> <http://www.news-medical.net/drugs/Duodart.aspx>

<sup>9</sup> <http://www.mysymbicort.com/asthma/index.aspx?source=10>

<sup>10</sup> [http://www.betterhealth.vic.gov.au/bhcv2/bhcmcd.nsf/pages/pfcfragi/\\$File/pfcfragi.pdf](http://www.betterhealth.vic.gov.au/bhcv2/bhcmcd.nsf/pages/pfcfragi/$File/pfcfragi.pdf)

<sup>11</sup> <http://www.betterhealth.vic.gov.au/bhcv2/bhcmcd.nsf/pages/pfcsynan/%24File/pfcsynan.pdf>

<sup>12</sup> <http://botox.com/>

<sup>13</sup> Submission of the Australian Government Department of Health and Ageing, 9 April 2010, Op Cit, pp 5-6.

<sup>14</sup> Ibid.

<sup>15</sup> Noted in a speech delivered on 5 May 2011, by the CEO of Medicines Australia, Dr. Brendan Shaw commenting on Treasury's forward estimates contained in last year's Budget

<sup>16</sup> ABC news, Gillard warns of tough budget, 1 April 2011 available from <http://www.abc.net.au/news/stories/2011/04/01/3179342.htm>

### *Response to the Terms of Reference*

Research Australia would like to comment generally in regards to the terms of reference for the inquiry into the Government's administration of the PBS.

These medicines treat serious conditions ranging from schizophrenia to deep vein thrombosis. PBAC considers them to be clinically and cost effective medicines, in comparison with other available treatments. Deferring listing on the PBS carries important research and development (R&D), social and economic implications.

**R&D Implications** - The potential long term impact of PBS deferrals on the health and medical R&D sector could be exponential. Australian research discoveries leading to new medicines, cannot progress from 'bench to bedside' without the support of the pharmaceutical industry. The industry directly employs over 14,000 people in Australia; invests over \$1 billion in research and development every year; has exports totaling \$4 billion in 2009 – 2010; and supports clinical trial activity of more than \$262 million in 2008 – 2009.<sup>17</sup>

Listing on the PBS is the last link in a chain that takes research from the bench top to the consumer, ultimately improving health outcomes. If pharmaceutical companies cannot list their medicines on the PBS it could act as a disincentive for the long term investment in R&D. This could directly impact upon the future of research discoveries and the development of new medicines and is out of step with public attitudes.

**Social Implications** – Deferring listing on the PBS places important medicines beyond the reach of people who need them and can least afford them (see case study below), impacting on strongly held public attitudes that support health and medical R&D and timely access to new medicines. In fact, 89% of Australians would be willing to pay \$1 more for each prescription medicine if they knew that all the money would be spent on additional health and medical research.<sup>18</sup>

**Economic Implications** - While deferring on the PBS meets a short term deficit reduction objective, it may negatively impact upon the commonwealth budget in the long term, by increasing hospital presentations and admissions (see case study below). Furthermore, deferring listings on the PBS is inconsistent with the spirit of the Memorandum of Understanding between Medicines Australia and the Government which provided a range of benefits including savings of up to \$5.8 billion over the next ten years.<sup>19</sup> Finally, 74% of Australians see research as part of the solution to addressing rising healthcare costs.<sup>20</sup> This common sense attitude should be adopted by government also; deferring medicines that result from R&D is not necessarily a viable solution to the rising costs of the PBS.

<sup>17</sup> Research Australia, 2011, Shaping Up: Trends and Statistics in Funding Health and Medical Research, Occasional Paper Series: Two, Melbourne.

<sup>18</sup> Research Australia, National and Marginal Seats Survey, April 2011, conducted by JWS Research.

<sup>19</sup> Noted in a speech delivered on 5 May 2011, by the CEO of Medicines Australia, Dr. Brendan Shaw commenting on Treasury's forward estimates contained in last year's Budget

<sup>20</sup> Research Australia, Health and Medical Research Public Opinion Poll 2010, p 10 available from [www.researchaustralia.org](http://www.researchaustralia.org)

**Case Study**

Invega Sustenna® (one of the deferred medicines for PBS listing) is a long-acting medicine given by injection once a month to treat symptoms of schizophrenia, a treatment option especially for those who have a hard time remembering to take a pill every day.<sup>21</sup> A medical discovery of this type is important because people with schizophrenia “are prone to non-compliance with treatment, particularly when their judgment is affected by the disorder”<sup>22</sup>. “Without medication, relapse rates are about 87%”.<sup>23</sup> “Hospitalisation is necessary in acute cases of schizophrenia, with the first episode, during relapse and when risk of suicide (or risks to others) is high”<sup>24</sup>. Furthermore, people suffering from schizophrenia “tend to be socio-economically disadvantaged. Over 70% of people with psychosis in Australia do not work at all”<sup>25</sup>.

In 2001, direct health system costs for schizophrenia in Australia were \$661 million “including 60% hospital costs, 22% community mental health services, 6% medical costs (GPs and specialists), 4% nursing homes and 2% pharmaceuticals”<sup>26</sup>. Access Economics noted that without increased investment into newer improved medications and research into causes and more effective treatments direct health costs will top \$1 billion, and many people with schizophrenia will still be living on the edge of Australian society, with only limited opportunities to be healthy and participating members of the community.<sup>27</sup>

Invega Sustenna® is an example of a ‘newer improved medication’ that addresses issues associated with non-compliance, which would presumably reduce relapse rates and hospital costs associated with schizophrenia. By deferring the listing on the PBS, it could be argued that the future costs to the Commonwealth budget are likely to be higher, when hospital presentations and admissions increase.

Please feel free to contact my office on (03) 9662 9366 for any further comments.

Kind Regards,

Rebecca James  
Chief Executive

<sup>21</sup> <http://invegasustenna.com/about-invega-sustenna>

<sup>22</sup> Graham N Meadows, *Overcoming barriers to reintegration of patients with schizophrenia: developing a best-practice model for discharge from specialist care*, MJA 2003; 178 (9 Suppl) : S53-S56.

<sup>23</sup> Harry H Hustig and Peter D Norrie, *Managing schizophrenia in the community*, MJA, <http://www.mja.com.au/public/mentalhealth/articles/hustig/hustig.html>

<sup>24</sup> Schizophrenia: Costs - An analysis of the burden of schizophrenia and related suicide in Australia  
An Access Economics Report for SANE Australia 2002 available from [http://www.o2c.com.au/research/SANE-Costs\\_of\\_Schizophrenia.pdf](http://www.o2c.com.au/research/SANE-Costs_of_Schizophrenia.pdf) p 10.

<sup>25</sup> Ibid, p 4.

<sup>26</sup> Ibid, p 1.

<sup>27</sup> Ibid, p 1.