Report to Parliament on the second meeting of the Pharmaceutical Industry Discussion Group (PIDG) to identify and examine potential unintended consequences of the 2010-11 Budget Measure Further Pharmaceutical Benefits Scheme (PBS) Pricing Reform.

September 2012
LIST OF ACRONYMS

API          Australian Pharmaceutical Industries
CHF         Consumers Health Forum of Australia
DIISRTE     Department of Industry, Innovation, Science, Research and Tertiary Education
EAPD        Expanded and Accelerated Price Disclosure
F1          Formulary 1
F2          Formulary 2
GAP         Guaranteed Adjustment Proportion
GMiA        Generic Medicines Industry Association
MA          Medicines Australia
MOU         Memorandum of Understanding
NPSA        National Pharmaceutical Services Association
PBS         Pharmaceutical Benefits Scheme
PIDG        Pharmaceutical Industry Discussion Group

SCOPE OF THE REPORT

The purpose of this report is to inform the Parliament of the outcomes of the second meeting of the Pharmaceutical Industry Discussion Group (PIDG), held on 6 March 2012.

EXECUTIVE SUMMARY

The PIDG convened for its second meeting on 6 March 2012. Members provided updates on the Expanded and Accelerated Price Disclosure (EAPD) price reductions which were scheduled to take effect on 1 April 2012, reducing the price paid by the Government for 75 medicines, and the price paid by consumers for more than 60 medicines. Members also commented on the first rounds of EAPD data collection which concluded in November 2011, and the first Dispute Resolution Process which concluded in February 2012.

Similar to the first meeting, PIDG members did not report any unintended consequences of pricing reforms. The PIDG discussed the ways in which their members were preparing for the reduction day and noted the cooperation between the sectors in ensuring that there were no consumer disruptions.
The PIDG noted that the impacts on the pharmaceutical sector will continue to be monitored by the Department of Health and Ageing (the Department) after the 1 April 2012 reduction day.

BACKGROUND

The PIDG was established in 2011 to identify and examine any potential unintended consequences of, or relevant issues relating to, the National Health Amendment (Pharmaceutical Benefits Scheme) 2010, which gave effect to the 2010-11 Budget Measure ‘Further Pharmaceutical Benefits Scheme (PBS) Pricing Reform’ and commenced on 1 December 2010. The reforms include:

- on 1 February 2011, price reductions of two or five per cent for all drugs on Formulary 2 (F2) at 11 October 2010;
- increasing the price reduction that occurs when a PBS drug transitions from Formulary 1 (F1) to F2 (on the listing of the first new brand) from 12.5 per cent to 16 per cent;
- streamlining the PBS listing process, particularly for supply under section 100 arrangements;
- introducing data collection for drugs with prices below the general patient co-payment (previously only collected for prescriptions attracting Government subsidy) to address gaps in the current PBS prescription data; and
- EAPD, which extended price disclosure arrangements to apply to all non-exempt drugs on F2. The first EAPD price reductions were published in mid-December 2011 and took effect on 1 April 2012. EAPD was agreed as part of the Memorandum of Understanding (MoU) between the Department and Medicines Australia (MA) to deliver savings of $1.9 billion and provide pricing certainty to industry.

As part of the passage of the Bill, the Government committed to convene a discussion group every six months with pharmaceutical industry peak bodies. The aim of this group was to discuss the impacts of the reforms, identify any unintended consequences or relevant issues, and identify potential solutions to issues raised. The Department was required to table a report on the outcomes of each meeting.
The PIDG first met on 28 July 2011. No unintended consequences of reforms implemented were reported by the PIDG members during this meeting. It was noted, however, that there were some generic manufacturers who had concerns around the possible impact on commercial viability of the largest of the measures, EAPD.


This report noted the mechanisms already in place to ensure patient access is not interrupted; and that sectors of the pharmaceutical industry are being supported to ensure smooth transition through the changes. The PIDG recommended that the Department continue to work with peak bodies in order to manage the potential impacts of EAPD, and to monitor the sector in the months after the price reductions come into effect.

MEMBERSHIP OF THE PIDG

The PIDG consists of representatives from the Department and the following industry peak bodies:

- AusBiotech, representing Australia’s biotechnology industry;
- Australian Pharmaceutical Industries (API), a wholesaler servicing more than 4000 independent pharmacies in Australia;
- Consumers Health Forum of Australia (CHF), representing healthcare consumers;
- Generic Medicines Industry Association (GMiA), representing generic drug suppliers, with nine member companies;
- MA, representing the discovery-driven or ‘innovator’ pharmaceutical industry, with 52 member companies;
- National Pharmaceutical Services Association (NPSA), representing pharmaceutical wholesalers; and
- The Pharmacy Guild of Australia (the Guild), representing community pharmacy.

The Department also provides Secretariat support for the PIDG.
OUTCOMES OF THE SECOND PIDG MEETING

In the second meeting, the PIDG members provided updates in regard to the upcoming EAPD price reductions scheduled to take effect on 1 April 2012, continued to discuss any potential issues relating to the April reductions, and proposed mechanisms for ongoing monitoring on the progress of the EAPD program.

This report provides an overview of:

1) status of actions arising from the first PIDG meeting;
2) the PIDG discussions of the outcomes and impacts of the first Main Cycle and the First and Second Transitional Cycles of EAPD; and
3) other business.

1 ACTIONS FOLLOWING THE FIRST PIDG MEETING

*The PIDG requested the Department monitor the number of new brands triggering the 16 per cent reduction and the value of the savings associated so that PIDG members may conduct further analysis if evidence suggests that the increase to 16 per cent has been a barrier to the listing of generic brands.*

The Department continues to monitor the number of off-patent and new brands of drugs that trigger the 16 per cent reduction over the next year. This is available at [www.pbs.gov.au/info/industry/pricing/pbs-items/price-reductions](http://www.pbs.gov.au/info/industry/pricing/pbs-items/price-reductions).

The Department continues to monitor the value of savings associated with the change from 12.5 to 16 per cent Statutory Price Reduction on the listing of the first new brand/move to F2.

*The PIDG requested the Department draft materials and statistics to complement its existing communication strategy for PIDG members representing pharmacies and wholesalers to distribute to members. The PIDG also requested the Guild work with its members to communicate upcoming EAPD outcomes.*

The PIDG requested the Department continue to record all delistings and provide this list to the PIDG members so that further analysis can be done by peak bodies. If this analysis suggests that there is a link between Further PBS Pricing Reform and disruption to patient access, this information should be brought back to the PIDG.

The Department will continue to record any delistings from the PBS.

To date, no disruption to patient access has been reported to the Department.

The PIDG requested the Department provide members with reports from the Department of Industry, Innovation, Science, Research and Tertiary Education (DIISRTE) to monitor job losses or factory closures in the months after the reduction date as these become available. PIDG members will also bring any issues or feedback to the attention of the PIDG in the lead up to the reduction day and beyond.

To date, no direct impacts have been reported by the DIISRTE.

The Department will continue to seek information on industry impacts from the DIISRTE as these become available.

The PIDG requested the Government continue to monitor the impacts of the Further PBS Pricing Reform measure on wholesalers and requested the Department to provide any DIISRTE reports to the PIDG as they become available.

To date, no direct impacts from Further PBS Pricing Reform have been reported by the DIISRTE. The Department will continue to seek information on industry impacts from the DIISRTE and provide these to the PIDG as these become available.
2 OUTCOMES FROM THE FIRST MAIN CYCLE AND THE FIRST AND SECOND TRANSITIONAL CYCLES OF EAPD

The PIDG focused its discussion on the price reductions scheduled for 1 April 2012, resulting from the first Main Cycle and the First and Second Transitional Cycles of EAPD.

Price reductions for more than 1400 brands and forms of 75 medicines resulting from EAPD were published in mid-December 2011, taking effect from 1 April 2012.

These medicines had weighted average disclosed prices (that is, the average price at which brands of the medicine were sold by manufacturers, with volume taken into account) at least 10 per cent lower than the Commonwealth agreed ex-manufacturer price and therefore triggered a price reduction. Reductions ranged from 10.45 per cent to 82.71 per cent (for a highly discounted product). A full list of drugs taking EAPD reductions is available on the PBS website www.pbs.gov.au/info/industry/pricing/eapd/price-reductions.

Thirteen disputes were raised by three manufacturers under the administrative Dispute Resolution Process with the following outcomes:

<table>
<thead>
<tr>
<th></th>
<th>MA – members</th>
<th>GMiA – members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>Withdrawn</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Resolved – no change</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Resolved – change</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

The PIDG noted that the forward estimate of savings for the 2010 Further PBS Reforms, of which EAPD is the majority component, remain unchanged at $1.9 billion over five years. The Department

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1 First Main Cycle of EAPD, which commenced on 1 December 2010 and ended 30 September 2011.
2 Transitional arrangements were applied to allow drugs disclosing under pre-2010 price disclosure to transition to EAPD.
3 This list was provided to PIDG members after the meeting at the request of the members.
advised the PIDG that the Guaranteed Adjustment Proportion (GAP) calculation was not applied to the price disclosure reduction cycles that were to take reductions on 1 April 2012.

The PIDG noted that EAPD will reduce the price to consumers of more than 60 drugs on 1 April 2012 when the prices drop below the General co-payment (or drugs already priced below General co-payment become cheaper). EAPD will also reduce the premium paid by consumers for 126 brands of medicine with a special patient contribution.

The PIDG representatives reported no unexpected issues from their members in the lead up to 1 April 2012 reductions. Members reported that manufacturers, wholesalers and pharmacists were working together to ensure there is no disruption to supply. Members also acknowledged the support from the wholesalers in the lead up to the reduction day. NPSA reported that manufacturers have been supportive in communicating with wholesalers regarding the April reductions.

At the previous PIDG meeting, the Department advised that the DIISRTE monitors changes to the sector over time. As of the second PIDG meeting, no direct impacts from Further PBS Pricing Reform had been identified based on DIISRTE reports.

The GMiA reported that its member companies had expressed concerns on whether EAPD might increase commercial volatility and if this might result in product withdrawals. At the same time, the CHF commented that any commercial volatility will be offset by the positive consumer impact. The PIDG requested that the Department provide members with statistics on brands delisted since January 2010.
The following list of brands delisted or changed since 1 January 2010⁴ was provided to members after the PIDG meeting:

<table>
<thead>
<tr>
<th>Month</th>
<th>Total brand deletions/changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2010</td>
<td>9</td>
</tr>
<tr>
<td>February 2010</td>
<td>17</td>
</tr>
<tr>
<td>March 2010</td>
<td>9</td>
</tr>
<tr>
<td>April 2010</td>
<td>8</td>
</tr>
<tr>
<td>May 2010</td>
<td>6</td>
</tr>
<tr>
<td>June 2010</td>
<td>16</td>
</tr>
<tr>
<td>July 2010</td>
<td>18</td>
</tr>
<tr>
<td>August 2010</td>
<td>8</td>
</tr>
<tr>
<td>September 2010</td>
<td>3</td>
</tr>
<tr>
<td>October 2010</td>
<td>3</td>
</tr>
<tr>
<td>November 2010</td>
<td>2</td>
</tr>
<tr>
<td>December 2010</td>
<td>12</td>
</tr>
<tr>
<td><strong>2010 total</strong></td>
<td><strong>111</strong></td>
</tr>
<tr>
<td>January 2011</td>
<td>6</td>
</tr>
<tr>
<td>February 2011</td>
<td>5</td>
</tr>
<tr>
<td>March 2011</td>
<td>9</td>
</tr>
<tr>
<td>April 2011</td>
<td>7</td>
</tr>
<tr>
<td>May 2011</td>
<td>4</td>
</tr>
<tr>
<td>June 2011</td>
<td>1</td>
</tr>
<tr>
<td>July 2011</td>
<td>11</td>
</tr>
<tr>
<td>August 2011</td>
<td>4</td>
</tr>
<tr>
<td>September 2011</td>
<td>9</td>
</tr>
<tr>
<td>October 2011</td>
<td>6</td>
</tr>
<tr>
<td>November 2011</td>
<td>1</td>
</tr>
<tr>
<td>December 2011</td>
<td>5</td>
</tr>
<tr>
<td><strong>2011 total</strong></td>
<td><strong>68</strong></td>
</tr>
<tr>
<td>January 2012</td>
<td>1</td>
</tr>
<tr>
<td>February 2012</td>
<td>14</td>
</tr>
<tr>
<td><strong>2012 total (two months)</strong></td>
<td><strong>15</strong></td>
</tr>
<tr>
<td><strong>Total (2010 to present)</strong></td>
<td><strong>194</strong></td>
</tr>
</tbody>
</table>

⁴ Note the following:

- The nature of the data available means that this list also includes any brand name changes (for example, when a brand is acquired by a new manufacturer and given a new name).
- This list may also include brand deletions as a result of factors other than withdrawal by sponsor.
- Any analysis should also look at the number of brands of each item that remain available.
The GMiA noted that its members considered the Dispute Resolution Process an administrative burden, as all manufacturers of impacted brands of pharmaceutical items were required to re-confirm their data once a dispute is raised. However, MA noted that the process is important to ensure the accuracy of the EAPD program, and it has also minimised the burden of a full data audit. To date, MA has received no adverse feedback from their members on the Dispute Resolution Process. The Department acknowledged the cooperation shown by manufacturers in resolving the disputes.

Members acknowledged the importance of effective communication with relevant stakeholders regarding the EAPD reduction. The PIDG noted the information developed by the Department, the Guild and wholesaler representatives. The CHF suggested to the PIDG that similar information should be available for consumers prior to the 1 April reduction day. The CHF requested that the Department prepare information for consumers about the 1 April 2012 reductions, describing why the reductions are taking place and which brands will be cheaper for consumers. This was completed after the meeting and information was published at www.pbs.gov.au/info/industry/pricing/eapd/price-disclosure-info-for-consumers.

While the consensus of the PIDG was that the implementation of EAPD had progressed very well, with no unintended consequences reported to date, members did note the importance of ongoing monitoring of any impacts. All PIDG members recognised the importance of effective communication and cooperation between the Department and different industrial sectors.

The Department will continue to monitor impacts, if any, on consumers. The Department will continue to seek information from the DIISRTE around industry impacts. To date, no direct impacts from Further PBS Pricing Reform have been reported by the DIISRTE.

Overall, the total value of EAPD savings will be achieved as anticipated. As a result, the forward estimated savings for Further PBS Pricing Reform remain unchanged at $1.9 billion over five years.


3 OTHER BUSINESS

The Department is currently working with the Department of Human Services and the Guild on the under co-payment data project. The Department is required to prepare reports for the Parliament on this new data collection. The first report will be provided in September 2012 with an overview of the implementation process. A report will then be provided to the Parliament detailing the first financial year of data collected (i.e: 1 July 2012 – 30 June 2013).

Members agreed the next meeting will be held in Canberra on 18 September 2012.

There was recognition from some PIDG members that assembling, providing secretariat support for, and tabling reports on the outcomes of PIDG meetings is very resource intensive and is not funded. Therefore, following the PIDG meeting in September 2012, the Department will review the ongoing need for this consultation process.