Report to Parliament on the 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.

February 2012
LIST OF ACRONYMS

API          Australian Pharmaceutical Industries
CHF          Consumers Health Forum of Australia
CSO          Community Service Obligation
DIISR        Department of Innovation, Industry, Science and Research
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 between the
             Commonwealth of Australia and Medicines Australia.
PBAC         Pharmaceutical Benefits Advisory Committee
PBPA         Pharmaceutical Benefits Pricing Authority
PBS          Pharmaceutical Benefits Scheme
PDWG         Price Disclosure Working Group
PIDG         Pharmaceutical Industry Discussion Group

SCOPE OF THE REPORT

The purpose of this report is to inform the Parliament of the outcomes of the first meeting of the Pharmaceutical Industry Discussion Group (PIDG), which took place on 28 July 2011. The PIDG was convened to identify and examine any potential unintended consequences of, or relevant issues relating to, the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010, which gave effect to the 2010-11 Budget Measure ‘Further Pharmaceutical Benefits Scheme (PBS) Pricing Reform’ from 1 December 2010.

From 1 December 2010, the following reforms came into effect:

- Several one-off price reductions as of 1 February 2011:
  - A price reduction of two or five per cent for all drugs on Formulary 2 (F2) at 11 October 2010.
  - An increase to 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.
- The introduction of data collection for drugs with prices below the general patient copayment (previously only collected for prescriptions attracting Government subsidy) to address gaps in the current PBS prescription data.
- Expanded and Accelerated Price Disclosure (EAPD), which extended price disclosure arrangements to apply to all non-exempt drugs on F2. This means that the Government will be better able to share in the benefits of existing competition between pharmaceutical companies.

Through a Memorandum of Understanding (MoU) with the Commonwealth Government in September 2010, Medicines Australia (MA) guaranteed that the average price reduction (weighted by volume) for those drugs included in the first main cycle of EAPD (reduction day 1 April 2012) will be a minimum of 23 per cent. The price disclosure cycles were also reduced from 24 months to 18 months (including a 12 month data collection period) and the reporting requirements of manufacturers disclosing data were reduced from four times a year to twice annually.

EXECUTIVE SUMMARY

The PIDG met on 28 July 2011 and discussed the potential impacts on patients and the pharmaceutical industry of Further PBS Pricing Reform. These included new or increased statutory price reductions and EAPD, to apply to all non-exempt drugs listed on F2 (mostly off-patent drugs subject to competition).

No unintended consequences of reforms implemented so far were reported to the PIDG; however the members noted that there had been concerns around the possible impact of the largest of the measures, EAPD, which will trigger its first round of price reductions on 1 April 2012. The PIDG noted the mechanisms already in place to ensure patient access is not interrupted and that sectors of the
pharmaceutical industry are supported to ensure smooth transition through the changes.

The PIDG recommended that the Department for Health and Ageing (the Department) work with peak bodies to continue to manage the potential impacts of EAPD, and monitor the sector in the months after the price reductions come into effect.

BACKGROUND

The Pharmaceutical Benefits Scheme (PBS)
The PBS is a world class system that aims to provide Australians with timely, reliable and affordable access to necessary drugs. Through the PBS, the Government subsidises the cost of drugs so that the maximum cost to the patient for a PBS item at a pharmacy (as of 1 January 2012) is $35.40 for General patients and $5.80 for Concessional patients (the ‘copayment’), plus any applicable special patient contribution, brand premium or therapeutic group premium.

Current provisions governing the operations of the PBS are embodied in Part VII of the National Health Act 1953 (the Act) together with the National Health (Pharmaceutical Benefits) Regulations 1960 (the Regulations).

PBS Pricing Reform
The 2010 amendments to the Act set out changes to the PBS pricing mechanisms with the aim of achieving a more economically sustainable PBS, by reforming pricing arrangements for multi-brand drugs subject to market competition.

The Act provides that listed drugs may be assigned to formularies identified as F1 and F2. F1 is intended for drugs where there is only one brand on the PBS (usually because the drug is still on patent) and F2 for drugs that have multiple brands, or are in a therapeutic group with other drugs with multiple brands. Before drugs are listed and allocated to formularies, there are detailed consultations about the drug with the manufacturer or responsible person, and a recommendation is received from the Pharmaceutical Benefits Advisory Committee
Any PBAC recommendation is made following receipt of submissions by affected pharmaceutical companies.

There is strong evidence that Australia continues to pay more for F2 drugs than other countries. The high prices at which some multi-brand drugs are reimbursed on the PBS has allowed a market to develop in which many suppliers provide their brand of drug to pharmacies at heavily discounted rates, while Government and consumers continue to pay the PBS-listed price.

Further PBS Pricing Reform, announced in the 2010-11 Budget, builds upon existing policies of statutory price reductions and price disclosure in F2 that were introduced in the 2007 PBS Reform package and preserves the distinction between F1 and F2. Further PBS Pricing Reform was designed to address the particular characteristics of the competitive market for F2 drugs, namely the discounting to pharmacies, where both generic and innovator manufacturers have products. Further PBS Pricing Reform is designed to allow taxpayers to benefit from this discounting by delivering an estimated $1.9 billion in savings over five years as well as direct price reductions to consumers.

The National Health (Pharmaceutical Benefits Scheme) Bill 2010

On 2 June 2010, the proposed amendment to the Act was first introduced into the House of Representatives as the National Health (Pharmaceutical Benefits Scheme) Bill 2010 (the Bill). On 16 June 2010, the Senate, on the recommendation of the Selection of Bills Committee, referred the provisions of the Bill to the Community Affairs Legislation Committee (the Committee) for inquiry and report. On 26 August 2010, the Committee resolved not to continue its inquiry due to the proroguing of the 42nd Parliament and the dissolution of the House of Representatives. The Bill subsequently lapsed on 19 July 2010.

The Bill was re-introduced in the first week of the 43rd Parliament with minor amendments. On 30 September 2010, the Senate again referred the provisions of the Bill to the Committee for inquiry and report by

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16 November 2010. The Committee held a public hearing in Canberra on 9 November 2010.

In its report into the Bill, the Committee acknowledged the effectiveness of price disclosure as a mechanism for achieving better value from drugs and stated that it did not believe that the 2007 PBS Reforms went far enough. The Committee stated that the proposed measures in the Bill would improve the sustainability of the PBS and provide direct savings to patients and taxpayers. For these reasons, the Committee recommended that the Bill be passed.

The Bill was passed by both houses of Parliament on 22 November 2010 and received royal assent on 23 November 2010.

Establishment of the Pharmaceutical Industry Discussion Group (PIDG)

As part of the passage of the Bill, the Government also committed to:

Convene a discussion group every six months until 1 July 2014, with the Pharmacy Guild of Australia, the National Pharmaceutical Services Association, the Generic Medicines Industry Association and Medicines Australia on the impact of the reforms in this Bill and any unintended consequences or relevant issues and to table a report on this discussion every six months.²

The Terms of Reference for the PIDG were approved by the then Minister for Health and Ageing, the Hon Nicola Roxon MP. Under the Terms of Reference, the scope and purpose of the PIDG are as follows:

1. The PIDG is a consultative group which will discuss the impacts of the reforms in the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 and any consequences of this or related issues.
2. The purpose of the PIDG is to identify issues related to the National Health Amendment (Pharmaceutical

Benefits Scheme) Bill 2010 and to provide advice on potential solutions to issues raised.

3. Following each PIDG meeting a report will be tabled with Parliament covering the outcomes of each PIDG meeting.

4. Pharmaceutical Benefits Division will be responsible for providing the report to the Minister for tabling.

Membership of the PIDG
As per the Terms of Reference, 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;
- MA, representing the discovery-driven or ‘innovator’ pharmaceutical industry;
- National Pharmaceutical Services Association (NPSA), representing Australian wholesalers; and
- The Pharmacy Guild of Australia (the Guild), representing community pharmacy.

The Department also provides Secretariat support for the PIDG.

The PIDG members representing manufacturers and wholesalers were also members of the Price Disclosure Working Group (PDWG), formed in June 2010 to provide an opportunity for key stakeholders to provide input into the implementation of the EAPD program and, once the Bill was passed, to allow members to discuss issues relating to the program, including data collection, quality assurance, dispute resolution and calculation processes. The PDWG met on four occasions, most recently in February 2011.
Scope of the meetings
The first meeting of the PIDG was held on 28 July 2011.

At the time of the meeting, all Further PBS Pricing Reform components had been implemented with the exception of EAPD, which commenced on 1 December 2010 and will trigger its first price reductions on 1 April 2012.

All members were invited to propose agenda items that were in scope of the Terms of Reference. The agenda items for the first meeting related broadly to the possible impacts of Further PBS Pricing Reform on patients and industry, based on examining reform components that had been implemented to date, and identifying potential impacts of EAPD reductions yet to occur.
OUTCOMES OF PIDG

The purpose of this report is to identify and examine any potential unintended consequences of, or issues relating to, the 2010-11 Further PBS Pricing Reform Budget Measure, as reported at the first meeting of the PIDG.

The following potential impacts were discussed by the PIDG:

Part 1. Impacts of reforms to date.
Part 2. Potential impacts of EAPD reductions on 1 April 2012:
  2A. Impacts on patients:
    • Drug stock levels
    • PBS listings into the future
  2B. Impacts on industry
    • Manufacturers
    • Wholesalers
    • Administrative requirements

PART 1: IMPACT OF REFORMS TO DATE

The PIDG first focused its discussion on the components of Further PBS Pricing Reform that had come into effect prior to the meeting date of 28 July 2011. These were:

• Two and five per cent price reductions on 1 February 2011 for drugs in F2.3
• Increasing the price reduction applied to single-brand PBS drugs on the listing of the first competitor brand (marking the transition from F1 to F2) from 12.5 per cent to 16 per cent.

3 From 1 August 2007, PBS drugs were listed on separate formularies. Over time, drugs listed on F2 were intended to move into price disclosure. A transitional pricing arrangement applied to F2 with two sub-formularies: F2A, comprising drugs where there is limited price competition, and F2T, comprising drugs where there is significant price competition. On 1 February 2011, drugs in the original F2A sub-formulary took a one-off two per cent price reduction and drugs in the original F2T sub-formulary took a one-off five per cent price reduction.
Impacts on patients

CHF advised the PIDG that no interruptions to patient access to PBS drugs had been reported at the time of, prior to, or after the price changes came into effect. The consensus of the PIDG was that these price reductions had been implemented very well, in part due to early notification of the reductions.

The PIDG noted that industry was advised (as part of the 2010-11 Budget announcement) of statutory price reductions well in advance of the reduction day, providing them significant lead time in which to prepare for the reductions. The PIDG also acknowledged the collaborative work of the organisations represented – manufacturers, wholesalers, pharmacies and government - that contributed to the smooth implementation of this aspect of the reforms.

The PIDG noted that patients benefit directly from Further PBS Pricing Reform where it results in drug prices falling below the maximum copayment threshold or drugs already below copayment becoming cheaper. For example, the price disclosure reduction that was applied on 1 August 2011 to escitalopram, a drug used to treat depression and anxiety, reduced the price paid by General patients for brands of the drug by more than $7.00. In a report commissioned by the Department, it was estimated that the Further PBS Pricing Reform measure will lead to patient savings on PBS listed drugs of an estimated $0.6 billion over ten years, or around $3.00 per general ordinary script, contributing to combined savings of $0.9 billion over ten years as a result of both the 2007 and 2010-11 Reforms.4

Patients also benefit from price reductions on brands of drugs with patient contributions such as brand price premiums, as the amount paid by the patient is also reduced commensurate with the overall price reduction. For example, the premium on two brands of escitalopram was reduced by more than $2.00, savings that are passed on to any patient choosing to use those brands.

Impacts on industry
PIDG members representing manufacturers reported that the statutory price reductions that occurred on 1 February 2011 went smoothly, although the PIDG noted that long-term impacts on industry cannot be determined at this stage and will require further monitoring. For example, GMiA expressed concern that increasing the F1-F2 transition reduction from 12.5 per cent to 16 per cent could potentially be a deterrent to generic companies seeking PBS listing for new brands of existing drugs into the future. The PIDG noted however that there is no evidence yet of any disincentive effect for new generic entrants as a result of the increase of the statutory price reduction from 12.5 per cent to 16 per cent, as listing of generic brands remains steady. The PIDG noted that further analysis should be done over time to examine the effects of the increase.

PIDG members representing wholesalers reported that wholesalers believe that the Further PBS Pricing Reforms have exacerbated existing commercial pressures. For drugs with an ex-manufacturer price of up to $930.06, the wholesale mark-up is a proportion of the price (7.52 per cent), which means the dollar value of the mark-up is reduced if the price of the drug is reduced (for higher priced drugs, the mark-up is a fixed payment of $69.94). NPSA advised the PIDG that, because of low margins, high fixed costs and no change in the volume of stock being distributed, it is difficult for wholesalers to absorb price changes.

API, a pharmaceutical wholesaler, advised the PIDG that API had recently closed distribution centres and changed terms with pharmacies. It was noted, however, that these changes were in response to several other existing and emerging commercial pressures and could not be solely attributed to Further PBS Pricing Reform. It was also noted that wholesalers continue to be compensated by the Government in the form of the Community Service Obligation (CSO) in addition to the wholesaler markups built into PBS drug prices (see ‘Part 2B. Industry impacts of Further PBS Pricing Reform’ for further discussion).

Outcomes
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.
PART 2: EXPANDED AND ACCELERATED PRICE DISCLOSURE (EAPD)

The remainder of the meeting focused on the potential future impacts of the first round of price reductions from EAPD, scheduled for 1 April 2012. EAPD calculations will be made for all non-exempt F2 drugs that became subject to price disclosure on or prior to, 1 December 2010.

At the time of the meeting, it was unknown how many drugs would be subject to a price reduction, as data collection was not scheduled to be completed until November 2011. PIDG members expected that a significant number of the 200-plus drugs currently subject to EAPD will trigger a price reduction, as a high level of discounting is known to occur in F2.

The PIDG did note however, that the following products will not be subject to EAPD price reductions on 1 April 2012:

- Drugs listed on F1;
- Exempt drugs;
- Drugs not included in the first main cycle or transitional cycles one and two of EAPD;
- Drugs where there is less than 10 per cent difference between the ex-manufacturer price and the weighted average disclosed price.

EAPD calculations and price reductions

The rationale behind price disclosure is that competitive pricing already exists for off-patent drugs, and that Australian taxpayers should be benefiting from that competition. It also ensures that prices follow the market, rather than imposing flat reductions that do not take into account variations between drugs.

Under EAPD, all manufacturers of brands containing F2 drugs submit sales information to the Price Disclosure Data Administrator (an independent service provider selected by the Department following an
open tender process) and, based on this information, the price the Commonwealth pays is adjusted to reflect more closely the price at which the drugs are supplied.

For the purposes of EAPD, drugs are grouped by ‘manner of administration’. For example, tablets and capsules are calculated together but injections are considered separately. This is to ensure that drugs that work in similar ways are priced similarly, while drugs that are used differently are priced separately. In this report, ‘drug’ will be used to refer to a drug with a particular manner of administration.

As some manufacturers offer higher discounts than other manufacturers, a ‘disclosed price’ is calculated for each brand, which is the approved ex-manufacturer price minus any discounts or incentives being applied. A weighted average disclosed price is then calculated for each drug based on the differences between the current agreed price and the disclosed price of each brand, and then weighted by volume. The weighted average percentage is the percentage by which the price of each brand of the drug will be reduced. This weighting occurs so that one company with very small sales, but with big discounts, does not artificially skew the result.

*For example, Company A sells 1,000 packs of a drug for $100,000 and company B sells 100 packs of the drug for $10. A simple average price would then be $55 ($100 plus $10 divided by two) or a percentage difference of 45 per cent. If however you ‘weight’ the prices based on market share, the weighted average price at which the drug is being sold is $91.80, or a percentage difference of 8.2 per cent.*

If the weighted average percentage is equal to or greater than 10 per cent, then that drug incurs a price reduction. The current (approved) ex-manufacturer price of the drug is reduced by the weighted average percentage.

*For example, if the ex-manufacturer price is currently $100 and the weighted average percentage is 20 per cent a price reduction occurs equal to the weighted average percentage, so the new ex-manufacturer price becomes $80.*
If the weighted average percentage for the same drug was 9.8 per cent no reduction would occur (and it would not occur in any example where the weighted average percentage is less than 10 per cent).

This calculation is performed for all drugs with the same manner of administration that are subject to the EAPD provisions.

As the new price is a weighted average across the disclosed prices, for every pharmaceutical item that takes an EAPD reduction, there will be some high discounting brands that are already being purchased at less than the new price, and some brands being purchased at or less than the current agreed price, but more than the new price. In this way, EAPD ensures that prices follow the market, balancing commercial viability with ensuring the sustainability of the PBS.

The Guaranteed Adjustment Proportion (GAP) calculation
The EAPD measure is the major component of the $1.9 billion in savings over five years that are delivered under Further PBS Pricing Reform as outlined in the MoU with MA.

Whilst the statutory price reductions are fixed, price reductions under price disclosure are variable. To ensure that the expected savings from EAPD are realised, as part of the MOU, MA agreed that the minimum weighted average price reduction under the first main cycle of price disclosure would be 23 per cent of the total value of the F2 formulary. In the event that these levels of savings are not achieved, the MoU made provision for a Guaranteed Adjustment Proportion (GAP) calculation to be used to increase the average to 23 per cent.

Consistent with the MoU, the GAP calculation is included in the Act for use in the first main cycle of price disclosure only, and only where the expected level of savings achieved from EAPD are not realised. If the overall weighted average price reduction (including those where the reduction was zero) resulting from the first main cycle is less than 23 per cent, the GAP calculation has been designed to incrementally increase price reductions, and until the 23 per cent average is achieved.
If the GAP calculation is run, only drugs with a weighted average percentage difference of more than 10 per cent would have their reductions increased in the GAP calculation and no brand would have its price reduced beyond that of the lowest disclosed price for that item. Given these restrictions, the GAP calculation may need to be performed more than once to achieve the guaranteed savings expected from this program.

It is important to note that the price of a drug would not be reduced beyond that of the lowest disclosed price. If a drug reaches its lowest disclosed price it would be reduced to that price, and removed from any further iterations of the GAP calculation. This is designed to ensure that no drug incurs a reduction greater than the highest level of discounting in the market for a brand of that drug, so that the drug remains commercially viable.

The final outcome would be an adjusted ex-manufacturer price for each drug required to take a price reduction, which is based on the current price minus the calculated reduction, and with any required GAP adjustments applied.
2A. POTENTIAL IMPACTS ON PATIENT ACCESS TO DRUGS

Drug stock levels
Ensuring timely and affordable access to medicines is the primary objective of the PBS. All PIDG members noted the importance of ensuring that there is no disruption to patient access to PBS drugs during the period of transition to the lower prices resulting from the application of EAPD on 1 April 2012.

The PIDG noted that there is some confusion across the industry around the magnitude and scope of the upcoming reductions. In particular, there is a misconception that all F2 drugs, even non-discounting ones, will be affected by price reductions and as a result, stock of any brands purchased prior to the reduction day will drop in value. The PIDG noted that there is a potential risk that this misconception could lead to unwarranted anxiety and consequently, reactive reductions of stock levels beyond what can be managed through the supply chain.

In fact, pharmacies will continue to be able to purchase brands at discounted prices equal to or lower than the advised new price, and these brands will not lose value. This is because the new price of each brand affected will be an average of the disclosed prices currently available, weighted by sales volume.

Only brands of stock purchased at a higher price than the new price will lose value following the reduction day. In most cases, this will be the innovator brand, as most generic brands are more significantly discounted by manufacturers and therefore will not lose value. To ensure that innovator brands are available for patients that cannot switch or choose not to, both innovator and generic manufacturers have in the past made brands available at the lower price to wholesalers, prior to the reduction day. MA and AusBiotech reaffirmed to the PIDG their members’ continued commitment to working with wholesalers prior to the reduction day.
The Guild advised the PIDG that while it was aware of concerns from pharmacists around the price reductions, the Guild did not believe that this will lead to destocking to an extent that the supply chain would be affected. The Guild confirmed to the PIDG that all legal obligations will be met. It was noted that the regulatory structure to ensure that supply is maintained has been in effect for a long time and is well-understood by industry. Regulation 33(1) of the Regulations and the Fifth Community Pharmacy Agreement require a community pharmacy keep in stock an adequate supply of drugs to meet the expected demand for PBS dispensing.

PIDG members representing wholesalers noted that pharmacies often rely on wholesalers to ensure that they can access additional stock on short notice to meet their obligations. Wholesalers are also subject to Government required supply obligations to protect access to drugs at every stage in the supply chain. For example, for eligible wholesalers participating in the CSO there are a range of contractually enforced standards in operation:

- That at all times a wholesaler will hold stock of one originator brand and two premium-free brands of every PBS drug; and
- Wholesalers will deliver any PBS drug to any pharmacy anywhere in Australia within 24 hours when requested.

The PIDG discussed strategies to assist wholesalers and pharmacies to meet their obligations prior to the reduction day, including early notice of price reductions and collaborative arrangements between manufacturers, wholesalers and pharmacies. The PIDG noted that many of these strategies are currently in place and have worked successfully for earlier reductions.

The PIDG shared the view that communication is an important role in mitigating the risk of disruptions to access. To support these measures, the PIDG requested that the Department develop additional communication materials that can be distributed to wholesalers and pharmacies. Using these materials, PIDG organisations will work with their members to communicate the effects of EAPD, how members will be kept informed, and reiterating their legal obligations. The Department has worked in consultation with the Guild, the Agreement Consultative Committee, NPSA and API on materials including
'Frequently Asked Questions' for distribution to pharmacies and wholesalers.

The PIDG noted that the Department will continue to provide at least three and a half months notice to pharmaceutical companies and peak bodies with details of which drugs are affected by the EAPD reductions. This should allow sufficient time for stock levels and purchasing decisions to be managed prior to 1 April 2012.

The general consensus of the PIDG was that while stock levels of some brands may be pared back by pharmacies and wholesalers in the days before the reduction day, this is not expected to result in any disruption for patients, if the impacts of EAPD are communicated early, effectively and consistently.

**Outcomes**

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 their members to communicate on upcoming EAPD outcomes.
PBS listings into the future

All PIDG members agreed on the importance of ensuring PBS drugs remain commercially viable to avoid the risk of delistings. This is a primary rationale behind EAPD, which targets only drugs where brand competition exists, and ensures that price reductions follow the market price and will never be lower than the lowest price currently available in the market. Drugs where there are few or no alternatives often do not incur price reductions at all if the weighted average percentage is less than 10 per cent; most drugs incurring reductions are available as several different brands.

The PIDG noted that in some rare cases a single brand may be subject to a price reduction across that drug and manner of administration. For example, tablet and capsule forms of a drug would incur price reductions if there are high levels of discounting for the tablet form, even if there is only one brand of capsule on the PBS.

The PIDG noted that there are mechanisms in place to protect the PBS listing of such single brand drugs if an EAPD or statutory price reduction is applied. The PIDG noted that manufacturers can request a price increase after the price reduction occurs, through the Pharmaceutical Benefits Pricing Authority (PBPA). The PBPA review such requests on the basis of clinical need, taking into account factors such as increases to the cost of goods.

For this reason the existing PBPA pricing review process was considered by the PIDG to be an important safety mechanism in the event that a brand of drug is adversely affected, to avoid the delisting of products where there are no alternatives. This mechanism can also be applied in the event that prices drop below cost for manufacturers.

If it is appropriate to do so, the PBPA can recommend that the Government accept the requested price increase. Any brand of drug affected by EAPD reductions on 1 April 2012 can potentially be considered at the 1 August 2012 meeting of the PBPA.

The PIDG noted that in most cases however it would be inappropriate for a manufacturer to seek to recover the original price by requesting a
price increase through the PBPA, as the price disclosure reduction reflects the market price for the drug.

There are further safety mechanisms before a brand may be delisted. Manufacturers are required to notify the Department at an early stage if they are considering delisting a product from the PBS. This allows time for input from the Pharmaceutical Benefits Advisory Committee (PBAC), discussions about the possible impact to patients, and negotiations with manufacturers.

The PIDG identified that delistings should be monitored to determine whether the delisting can be attributed to the Further PBS Pricing Reform measure. It was noted however that it is difficult to attribute causality of the decision to delist solely to Further PBS Pricing Reform, as manufacturers decisions are affected by many factors in the national and global market and manufacturers may choose not to disclose the full reasons for their decisions.

**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.
2B. INDUSTRY IMPACTS OF FURTHER PBS PRICING REFORM

Pharmaceutical development is one of Australia’s largest industries. In 2010-11, PBS expenditure alone was around $8.9 billion, and growth is expected to continue. The PIDG affirmed the importance of maintaining a responsible and viable drugs industry, consistent with the objectives of the National Drugs Policy.

The PIDG noted there are widely held concerns that the Further PBS Pricing Reform measure could potentially have unintended consequences for industry, in particular, manufacturers and wholesalers, although this is being managed.

Manufacturers

The PIDG members representing manufacturers noted that their members were concerned about the impacts of EAPD. MA advised the PIDG that its members expected some impacts from EAPD on their business, while the GMiA maintained that price disclosure measures could particularly harm generic manufacturers, leading to factory closures or job losses, if commercial viability of affected brands is impaired.

It was noted again that as EAPD reductions bring the price of the drug down to the weighted average discounted price, the new price will never be lower than the lowest price for a drug already in the market. Furthermore, EAPD does not discourage competitiveness in the market and still leaves room for further discounting by efficient providers, allowing companies to continue to compete for market share. This is demonstrated by the fact that, of the 23 drugs which have previously incurred price disclosure price reductions, seven drugs took multiple reductions, indicating that discounting continued to occur after the first price disclosure reduction took place.

Members acknowledged that some industry impacts are to be expected. Representatives said that they would consult their members further to identify any disproportionate or undue impacts that can be brought to the PIDG for analysis.

The Department advised that the Department of Innovation, Industry, Science and Research (DIISR) will also be monitoring changes to the sector over time. The PIDG committed to monitoring the ongoing impacts and identifying potential problems. Should any major concerns emerge from feedback with members, the PIDG will discuss potential solutions.

The Department is aware of many F2 drugs that are priced significantly higher in Australia than overseas, evidence that there is capacity for manufacturers to absorb price reductions. For example, four years after patent expiry, the price for a month’s supply of the most commonly prescribed dose of simvastatin in Australia is around four times higher than the price in the United Kingdom. Although comparisons to different markets should be treated with some caution, a price reduction for this product would bring the Australian price closer to prices that remain profitable in other countries. Simvastatin is part of the first main EAPD cycle and if required, will take a reduction on 1 April 2012.

**Outcomes**

The PIDG requested the Department to provide members with reports from the DIISR monitoring 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.

**Wholesalers**

The PIDG noted that wholesalers are also concerned that the upcoming EAPD reductions have the potential to exacerbate existing commercial pressures. PIDG organisations representing wholesalers reported that there is concern that EAPD could reduce the prices of some brands

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below that which makes it viable for wholesalers. As wholesalers have obligations to supply under the CSO, many are anticipating a need to tighten their business in order to absorb the fixed costs of stocking low-profit brands. API advised the PIDG that it had estimated the costs to wholesalers of Further PBS Pricing Reform to be in the order of $250 million over five years.

While the PIDG noted the anticipated pressures on wholesalers following this reduction in revenue, the PIDG also noted that the existing compensation from the Government is significant. As of June 2011, the Department had paid out $950 million in CSO payments over the last five years. Additionally, in recognition of the impact of the transition to the 2007 PBS Reforms on wholesalers, in August 2008, the CSO was increased by around $23 million a year. This is an indexed amount and continues to be paid today, well after wholesalers have adjusted to the original reforms.

Additionally, the fixed wholesaler remuneration of $69.94 (for drugs of more than $930.06 ex-manufacturer) is not affected by the price reductions under Further PBS Pricing Reform. This remuneration is significant; as of June 2011, approximately $250 million in PBS payments had been made to wholesalers over five years that are not affected by the price reductions from the PBS Reforms in 2007 or the 2010-11 Further PBS Pricing Reform measure.

The Department is also aware that generally in the pharmaceutical sector, wholesalers’ income depends on the level of discounting in the supply chain, which is a commercial arrangement between manufacturers, wholesalers and pharmacists. However, wholesalers often operate at margins of 2-3 per cent, instead of the full 7.52 per cent wholesale margin paid by agreement that is available to them to compete for market share.

While acknowledging the wholesalers’ concerns, the Department expressed confidence that this support is adequate.

It should be noted that the message from the wholesale sector is more optimistic than reported at the PIDG. For example, API stated in 2010 that “[t]he impact of PBS Reforms announced this year is significant,
however we are confident that initiatives are in place to offset or mitigate any major impact on the business”.7 Further, DHL Supply Chain (DHL), Australia’s biggest supplier of drugs to wholesalers and community pharmacies, has previously given its support to the Further PBS Pricing Reform measure and suggested that the Commonwealth actually pays too much in wholesaler remuneration ($3.24 per prescription on average in 2008-09, including both wholesale margin and CSO), recommending a significantly reduced unit rate for all PBS items of $0.70 per unit.

For these reasons, the Department considers that the Government has sufficiently compensated the wholesale sector for any potential negative impact on revenue. The Department advised the PIDG that DIISR will be monitoring the impacts on industry and these reports can be provided to the PIDG for analysis as they become available.

**Outcomes**

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 DIISR reports to the PIDG as they become available.

**Administrative Requirements**

The PIDG also discussed whether the data submission requirements of EAPD represented an undue administrative burden on manufacturers.

Price disclosure calculations are based on volume, revenue and incentives data reported to the Department by manufacturers. Prior to Further PBS Pricing Reform, data was submitted four times a year; under EAPD, this has been reduced to twice a year. Manufacturers submit year-to-date data half way through each cycle and data for the remainder of the cycle at the end of the data collection period.

GMiA reported to the PIDG that its members found this twice-annual reporting requirement to be a significant administrative burden. GMiA requested that the first submission for each cycle be made voluntary,

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with data for the entire cycle being submitted at the end of the cycle. In contrast, MA reported to the PIDG that MA members did not find the new reporting requirements to be an administrative burden and that submitting early data allowed for more quality checking.

The PIDG noted that in implementing EAPD, the Department responded to earlier concerns by reducing the reporting burden. The number of submissions was halved and the submission process itself was streamlined through online submission software. An external service provider now manages the data submission process which will assist in the quality and accuracy of submissions.

**Outcomes**

The PIDG noted that reporting requirements and timings are legislated and therefore any change recommended would require changes to the Regulations. The PIDG did not recommend the Department make any changes to the reporting requirements at this time.
CONCLUSION

The Further PBS Pricing Reform measure will provide savings to the PBS of more than $1.9 billion over five years, through the implementation of EAPD and other statutory price reductions designed to ensure that the Government pays the market price for drugs where brand competition exists. Further patient savings are also expected as a result of the measure.

In considering the impacts and unintended consequences of Further PBS Pricing Reform, the PIDG noted that while effects so far have been minimal, the real test will come after the first EAPD price reductions take place on 1 April 2012. The PIDG recommended the Department continue to work with industry and consumer representatives to ensure that the reforms are implemented smoothly and to avoid undue anxiety or pressure within each sector. The PIDG recommended that the Government continue to monitor the impacts of the Further PBS Pricing Reform measure and to provide reports to the PIDG to inform further discussion.