The Government's administration of the Pharmaceutical Benefits Scheme (PBS)

Finance and Public Administration References Committee Inquiry

Prepared by Pfizer Australia

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Pfizer

Australia

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Disclosure

This submission has been prepared by Pfizer Australia – a wholly owned subsidiary of Pfizer Inc., based in New York. Pfizer Australia is this country's largest manufacturer of prescription medicines.

Pfizer Australia is a member of Medicines Australia – the peak industry body for the innovative medicines industry in Australia.

Pfizer is directly impacted by the decision announced 25 February 2011 to defer the listing of a number of PBAC recommended medicines on the Pharmaceutical Benefits Schedule. The Pfizer medicines already impacted are Fragmin® (dalteparin sodium), for the treatment of venous thromboembolism (VTE) in cancer patients and Synarel® Nasal Spray (nafarelin) for inclusion in the Section 100 IVF/GIFT Program. We also have a number of other medicines currently being considered by the PBAC which may be affected by this new approach to PBS cost-cutting. Our submission details the consequences Cabinet deferrals will have on the future access to medicines for Australian consumers and the impact on Pfizer as an employer and local manufacturer.

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Executive summary

The Australian healthcare system is underpinned by the National Medicines Policy[1] (NMP) and is based on "A *partnership for better health outcomes*". The NMP objectives include: *timely access to the medicines that Australians need, at a cost individuals and the community can afford* and *maintaining a responsible and viable medicines industry.*

In 2006 the Government and pharmaceutical industry negotiated a PBS Reform package to ensure the long-term sustainability of the PBS. The reform was built on the principle of achieving value for money to allow the funding of innovative medicines. Independent verification showed the original PBS Reform savings estimates of $3 billion over 10 years had grossly underestimated the actual savings of $5.8 billion.

In 2010, the industry negotiated a further savings package with the Rudd and Gillard governments. The Memorandum of Understanding signed by the two parties allowed the government to bank $1.9 billion in the forward estimates. In return for these very substantial savings, the industry was assured it would receive a predictable business environment in which it could make decisions about investment and employment:

> *"Under the MOU, the Government will provide the industry with pricing certainty over the next four years. In return for implementing new pricing arrangements that are the subject of this Bill, the Government will undertake not to introduce further new policy to generate price-related savings from the PBS over the life of the MOU. This will provide stability to the industry, helping to foster investment and availability of new and innovative drugs in Australia…*
>
> *The robust process for listing new medicines on the PBS will continue.*
>
> *Australians will benefit as consumers and taxpayers from a more sustainable PBS through lower prices for medicines and access to new medicines sooner".*[2]

The Cabinet deferral decision is directly at odds with these statements. Deferring the listing of medicines recommended by the PBAC as clinically and cost effective has removed any "predictability" and "stability" for industry. The government may argue that deferring new medicines is technically not a new "pricing policy" (as precluded by the MOU), but the decision undermines business predictability which was the founding principle of the MOU for both of the co-signatory parties and is at odds with the principles of PBS Reform.

The recent decision to defer the listing of medicines on the PBS contravenes the intent of the MOU.

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[1] http://www.health.gov.au/internet/main/publishing.nsf/Content/national-medicines-policydoc~national-medicines-policy-2

[2] 29 SEP 2010: NICOLA ROXON: National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 - Second Reading Speech

The recommendation of the Pharmaceutical Benefits Advisory Committee is clear

The rigour of the Pharmaceutical Benefits Advisory Committee in determining clinical and cost effectiveness is indisputable. The PBAC has determined that Fragmin® and Synarel® meet a clinical need for consumers and represent value for money. This should be the expected level of rigour applied consistently across the Health budget.

The "robust process" for listing has not continued. It had been interrupted by a new and uncertain process, for which there appears to be no set criteria.

There is a clear need for Fragmin and Synarel

The two Pfizer medicines currently "deferred" offer significant alternatives for patients and clinicians.

Fragmin is an anti-clotting medicine for the treatment of venous thromoembolism, a **serious and life-threatening condition**, in cancer patients. While Cabinet deferred this medicine on the grounds an alternative is PBS-listed, the Therapeutic Goods Administration has determined that **Fragmin and Clexane are not clinically interchangeable.** In addition, the non-health benefits to cancer patients if they were to receive Fragmin are: half the number of injections per day, one-third the number of prescriptions and 2 visits to the doctor in comparison to 9 with current treatment options.

The PBAC identified a need for Synarel on the PBS in a request to Pfizer. Synarel would allow women receiving IVF treatment to receive a hormone agonist. **There are no other hormone agonists PBS listed for IVF.** The proposed alternative therapies are hormone antagonists, which have a different mechanism of action. Effectively this decision has removed the choice for consumers and clinicians for the IVF Program. Synarel is a nasal spray instead of a daily subcutaneous injection required with the proposed alternative therapies. This is a significant advance for some women.

There is a negative impact on the health of Australians

Put simply, consumers are being denied the immediate health and non-health benefits associated with essential medicines as identified by the PBAC. It is essential to recognise while doctors are prescribing for the full patient population, individual patients will respond differently to specific medicines; Prescribers and their patients will always need, and want, alternative medicines.

In the long-term the unpredictability caused by measures such as Cabinet deferrals will have a much greater impact with fewer innovative medicines reaching the Australian consumer. If there is unpredictability and limited opportunity to PBS list medicines it becomes difficult to justify the investment required. It is widely reported to bring a medicine from development to the consumer can cost $1.2 billion.

There are consequences for manufacturers

The investment required to list a medicine on the PBS is signficant. A minimum investment of approximately $1.3 million for the proposed Fragmin listing on the PBS has been required. This includes the costs to guarantee stock availability and fees to agencies such as the TGA and PBAC. This does not include any implications to Pfizer should the deferral remain for a significant period of time.

Competition and surety of supply is at risk

Restricting the PBS to one medicine for any medical condition will limit competition and risk supply. Competition is the basis of the PBS reform mechanism to ensure future savings. The listing of Fragmin and Synarel would ensure greater certainty of supply and competition in the off patent market in the years to come. Generic competition generally relies on an innovative pharmaceutical company having already provided its data as part of a comprehensive and expensive PBS listing process. We have effectively been denied an opportunity to compete even though the importance of a range of medicines was recognised with a request from the PBAC to submit for Synarel.

What criteria and advice were used in deciding to defer these PBS listings?

There are no criteria against which this decision was made.[3] As of 11 July 2011 the PBS website still states: *The decision to subsidise an item is considered by Cabinet if the net cost to the PBS is greater than $10 million per year, and then determined by the Minister for Health and Ageing. The Government also exercises a number of controls to manage the overall cost of the scheme.* [4]

From the public record a number of decision criteria have been discussed; against which we reiterate the decision to defer the PBS listing of Synarel and Fragmin.

What is the cost to the Commonwealth?

We can only comment on the costs of listing Fragmin and Synarel on the PBS from the respective applications to the PBAC. From these costs it is incorrect to estimate the Commonwealth costs on the assumption every new medicine will see an increase in the number of patients and therefore has an automatic multiplier effect on health services.

The PBS cost to include Fragmin for the treatment of VTE in cancer patients is around $1 million for 2011 and under $3 million in 2016. The total PBS cost is under $6 million to treat approximately 24,000 cancer patients with VTE; not including the associated reduction in number of doctor visits and Medicare approvals for Authority prescriptions.

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[3] 31 May 2011, Senate Estimates, Community Affairs, Secretary, Department of Health and Ageing, Jane Halton. http://www.aph.gov.au/hansard/senate/commttee/s-news.htm
[4] http://www.pbs.gov.au/info/industry/listing/listing-steps

Synarel will cost the PBS between $200,000 and $1 million per year after 5 years of listing.

These two medicines would add less than $10 million to the PBS over five years – about 0.025% of the PBS or 0.003% of the Commonwealth Health spend in that period – and would treat around 25,000 patients.

Lack of consultation and transparency

Pfizer was informed at the same time as the public with the 25 February 2011 media release from the Minister of Health and Ageing, Nicola Roxon MP. We have not had any further correspondence regarding the reasons why Fragmin and Synarel were deferred from listing on the PBS. At no point during the PBAC process was there any indication that the standard process no longer applied. On 13 January 2011 we agreed our obligation to ensure guarantee of supply from 1 April 2011, as per the NHA 1953.

The government's consultative process effectively excluded the companies which developed, tested and manufactured these medicines. The truncated timeframe and non-transparent process for the deferral of listings on the PBS means companies have had limited capacity to challenge the decision or seek clarification. Procedural fairness cannot be selectively applied. The advice provided to date is inadequate.

In conclusion, the decision to defer certain medicines was taken without consultation with stakeholders and insufficient notice was given. The negative impact of this decision to patient outcomes or safety cannot be ignored. This is simply a bad policy decision made without full consideration of the unintended consequences to manufacturers, consumers and prescribers and ultimately the Government. The pharmaceutical industry has already delivered significant savings, and there are continued and increasing savings, from the MOU signed with Medicines Australia.

Recommendations

1. **That the Commonwealth Government reverses the Cabinet deferrals decision in recognition of the value for money these medicines represent; to provide necessary treatment options for patients and clinicians and because this decision is a breach of the intent of the recent MOU which will deliver the $1.9 billion necessary to create headroom for new medicines such as these.**
2. **That the Commonwealth Government recognises the PBAC's role as the peak expert body for assessing clinical and cost effectiveness**
3. **In regard to the current medicines deferred from listing on the PBS the Government should provide:**
    a. **details of the impacts to patient health**
    b. **the financial estimates and clinical assessment upon which the decisions to defer were made**
    c. **details of the process of achieiving cost offsets across the health portfolio**
    d. **The time when the affected medicines will be PBS listed**
4. **That there is a consistent approach to transparency and consultation for the consideration of all PBS medicines.**
5. **That any proposed Government policies do not undermine the principles of PBS reform, and therefore the MOU**

Terms of Reference

On 23 June 2011, the Senate successfully moved that the Finance and Public Administration Committee conduct an inquiry into the Government's administration of the Pharmaceutical Benefits Scheme (PBS)[5].

The terms of reference (TOR) for this inquiry are as follows.

The Government's administration of the Pharmaceutical Benefits Scheme (PBS), with particular reference to:

a) the deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee;
b) any consequences for patients of such deferrals;
c) any consequences for the pharmaceutical sector of such deferrals;
d) any impacts on the future availability of medicines in the Australian market due to such deferrals;
e) the criteria and advice used to determine medicines to be deferred;
f) the financial impact on the Commonwealth Budget of deferring the listing of medicines;
g) the consultation process prior to a deferral;
h) compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010; and
i) any other related matter.

The information in this submission will be presented as per the TORs, from our perspective as a member of the pharmaceutical industry, and will highlight the negative impact in the short and long term the Cabinet deferrals decision will have on the access to medicines in Australia. Our submission will utilise the examples of Fragmin and Synarel to highlight the impacts of the Government's decision to disregard the PBAC recommendations and defer the listing of key medicines on the PBS.

The desirable outcome from this inquiry is to see this deferral of PBS listings reversed and recommendations for amendments, where appropriate, to ensure all parties respect the role of the PBAC and the principles of PBS reform.

[5] http://www.aph.gov.au/SENATE/committee/fapa_ctte/pharma_benefits_scheme/index.htm

Impact of Cabinet deferrals on access to medicines in Australia

The National Medicines Policy (NMP)[6], which is designed to bring about better health outcomes for all Australians, focusing especially on people's access to, and wise use of, medicines, forms the foundation of the healthcare system in Australia.

The National Medicines Policy focuses first on people's needs and brings individual partners' skills, experience and knowledge to bear on these central objectives. The Cabinet deferral decision is in direct conflict with the central objectives of the NMP:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

The sustainability of the Pharmaceutical Benefits Scheme

The Pharmaceutical Benefits Scheme (PBS) was introduced in 1948 with *the primary objective … to improve health. The range of drugs and forms available under the PBS provides a formulary of drugs to meet the health needs of the majority of the Australian community.*[7] The PBS provides Australians with affordable and equitable access to the medicines they need. Approximately 80% of prescriptions dispensed in Australia are subsidised by the Commonwealth through the PBS.

The need for reform of the PBS to ensure sustainability and to allow the funding of innovative medicines was recognised by Government and industry. In response, the pharmaceutical industry collaborated with the Government in 2006 to develop PBS Reform (see Appendix A).

In 2009 the impact of PBS reform was independently verified to show the previous Government's original estimate of $3 billion dollars of savings over 10 years grossly underestimated the actual savings of $5.8 billion over the same period. These savings have been achieved largely through savings provided by the pharmaceutical industry (as shown in Figure 1). Further details on the savings provided by PBS reform are provided in Appendix B.

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[6] http://www.health.gov.au/internet/main/publishing.nsf/content/National+Medicines+Policy-1

[7] *PBAC Guidelines, Section 1.3 Assessing suitability for listing*

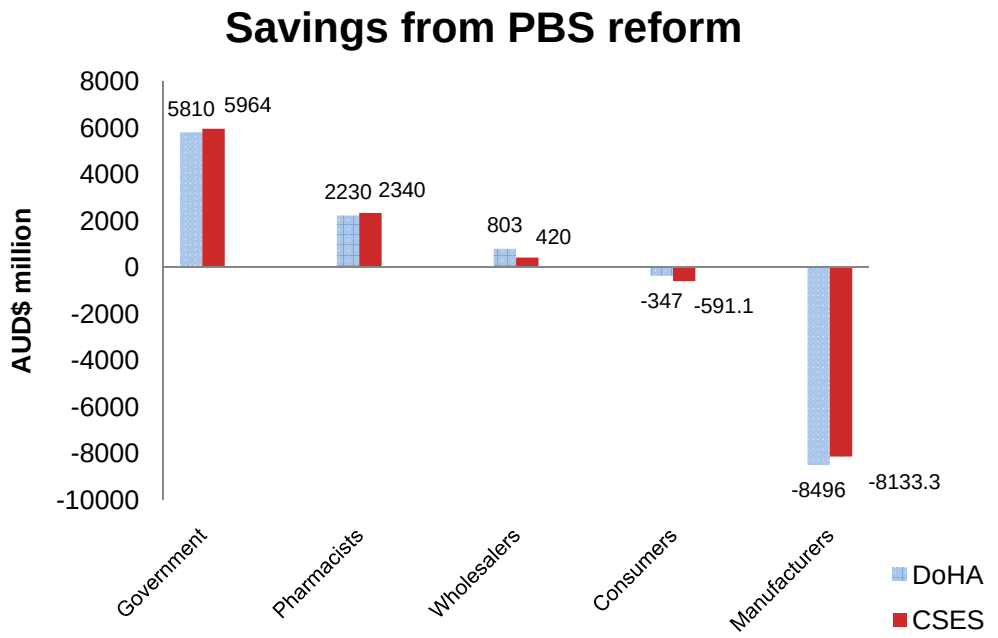

Figure 1: CSES and PwC (DoHA) modelled savings of PBS reform

NOTE: Estimates based on greatest generic competition assumptions. Detail provided in Appendix B.

As has been previously argued long-term fiscal policy, as exemplified by PBS Reform in 2006 and in 2010, is the key to achieving the best value for the money spent. Benefits from the reform include ongoing access to essential medicines, direct savings to Government and consumers plus “head-room” to allow the continued funding of innovative medicines on the PBS.

The effectiveness of PBS reform packages has not been fully accounted for as the growth figures quoted are based on original assumptions around the minimum savings from the MOU and do not include the totality of savings delivered by pervious reforms.

There have been examples of price reductions of 13.3% to 71.2% as a result of price disclosure. This has occurred prior to the largest volume PBS-listed medicines, such as simvastatin and atorvastatin, being subject to price disclosure. Further price reductions of these magnitudes are possible as early as April 2012, as per the MOU.

a) the deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee

The role of the PBAC

The legislated role of the Pharmaceutical Benefits Advisory Committee (PBAC) is to assess the clinical and cost effectiveness (value for money) a medicine represents for Australian consumers.[8]

1. The PBAC considers the clinical need for each medicine

The first section of a PBAC submission requires the agreement with the manufacturer as to how the medicine will be used in clinical practice (to inform the economic analysis).

2. The PBAC considers non-health outcomes, such as, convenience or productivity gains

PBAC may also consider nonhealth outcomes….for example, greater convenience or production gains to society…. the valuation of nonhealth outcomes is not straightforward and those outcomes might not be as influential in decision making as health outcomes.[9]

Increases in productivity, reduced carer burden and reductions in State and Territory health service use are not directly captured therefore the benefit to the population is often undervalued.

3. Clinical equivalence does not mean medicines are substitutable at a patient level

A submission to the PBAC will be a: cost-effectiveness analysis where the new medicine is clinically superior to the current medicine, or a cost-minimisation analysis where the medicines are equi-effective or non-inferior. A cost minimisation analysis does not mean:

- every patient on the current medicine is appropriately treated and could not benefit from the new medicine
- every patient with the condition is treated with or can tolerate the current medicine
- the two medicines in question are substitutable for every patient.

Clinical equivalence is not a clinical treatment tool but a health technology assessment tool with very specific statistical and evidentiary parameters based on population level evidence; the results of which are not applicable to every patient. Having one medicine on the PBS does not provide all consumers with a clinically appropriate treatment.

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[8] NHA (1953), Section 101*(3A) ..the Committee shall give consideration to the effectiveness and cost of therapy involving the use of the drug, preparation or class, including by comparing the effectiveness and cost of that therapy with that of alternative therapies, whether or not involving the use of other drugs or preparations.*

[9] PBAC Guidelines, Section 1.3 Assessing suitability for listing. http://www.pbs.gov.au/info/industry/listing/elements/pbac-guidelines/a-part-1/section-1

PBAC advice on Fragmin

The PBAC[10] recommended Fragmin be listed on the PBS for the treatment of venous thromboembolism (VTE) in cancer patients:

The PBAC accepted the submission's claim that dalteparin was non-inferior to enoxaparin in terms of both effectiveness and safety …. The PBAC noted that both the survey of oncologists and the American College of Chest Physicians Guidelines recommend extended treatment of VTE with enoxaparin and other low molecular weight heparins in cancer patients. ***The PBAC noted that enoxaparin was not specifically TGA registered for this indication. However, prescribers may prescribe enoxaparin for this indication as the current PBS listing is as an unrestricted benefit.***

PBAC advice on Synarel

On the 23 December 2009, the PBAC, having recommended the PBS listing of ganirelix[11] at its November 2009 meeting, contacted Pfizer in recognition of the fact *there is a clinical need for gonadotropin releasing hormone (GnRH) analogues on the IVF/GIFT Program, and considered that listing of nafarelin on the same basis as that recommended for ganirelix may be appropriate and indicated a willingness to consider a submission to this effect*.

At the November 2010 meeting: *The PBAC recommended the listing of nafarelin … as a Section 100 benefit for use in IVF/GIFT, under the same circumstances as ganirelix.*

The clinical need for Synarel and the greater certainty in supply and competition on the PBS was re-emphasised at Senate estimates, 31 May 2011:*… the PBAC considers that there is a clinical need for these products on the program. If one was listed there is always the intention to write to other suppliers to also get some benefit from competition from other suppliers.*[12]

The PBAC has clearly indicated there is a clinical need for Fragmin and Synarel, two medicines with demonstrated clinical and cost effectiveness, for Australian consumers.

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[10] Fragmin, Public summary document,. November 2010 PBAC meeting.
[11] Ganirelix (Orgalutran) was listed on the PBS in 2010 for the IVF/GIFT Program.
[12] 31 May 2011, Senate Estimates, Community Affairs, Assistant Secretary, Pharmaceutical Evaluation Branch, Pharmaceutical Benefits Division, Adriana Platona.
http://www.aph.gov.au/hansard/senate/commttee/s-news.htm

b) the consequences for patients of such deferrals

The immediate impact to consumers of the Cabinet deferral decision is clear: for the majority of patients treatment cost is a barrier to access. Even if the patient is able to self fund there is no guarantee a medicine will be available privately as the manufacturer may not be able to support the medicine without PBS subsidisation. Furthermore, if a medicine is not listed on the PBS this may affect availability in hospitals. The Cabinet deferral decision is in breach of QUM principles: right person, right medicine, right time.

Considerable variation in the response of individuals to the same medicine is accepted. Accordingly, clinicians must have access to a variety of therapeutic options, especially in such difficult to treat areas such as cancer where inadequate response or treatment failure can be fatal. Prescribers and their patients will always need, and want, alternative medicines.

In addition, it is not clear what other potential flow-on effects this policy may have, is the deferral seen to overturn the PBAC recommendation, as a clinical decision that the deferred medicines do not have a role in therapy or do not provide value for money and therefore should not be prescribed, irrespective of the health and non-health benefits.

The Commonwealth must ensure equity of access to medicines which are clinically needed and cost-effective.

Consequences for patients of deferring the listing of Fragmin on the PBS

The PBS listing for Fragmin[13] that was deferred by Cabinet is as a *Restricted Benefit*[14] *listing for the treatment of symptomatic venous thromboembolism (VTE) in cancer patients with active solid tumour; and secondary prevention of VTE in cancer patients with solid tumours and previous VTE.* The deferred application included new strengths of Fragmin specifically for VTE treatment in cancer patients and are not PBS listed.[15]

The serious and life-threatening nature of the VTE in cancer patients is irrefutable.

Patients with cancer are 6-7 times more likely than non-cancer patients to develop venous thromboembolism (VTE).[16] [17] Reports of 1-year survival in cancer patients without VTE of 36% versus 12% in cancer patients with VTE.[18] Treatment of VTE in cancer patients is challenging.[19]

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[13] Fragmin is currently PBS listed on the General Schedule and as a Restricted Benefit for haemodialysis.
[14] *Restricted benefits* - can only be prescribed for specific therapeutic uses (noted as Restricted benefit.
[15] On 1 September 2011, PBS-listing of 2,500 iu and 5,000 iu will be max quantity 20, repeats 0; plus 12,500 iu will be listed for higher weight patients.
[16] Patients with cancer have an increased risk of developing symptomatic VTE partly as a result of cancer being a hyper-coagulable state. Erythropoiesis-stimulating agents and white blood cell growth factors have been introduced as important medicines for the treatment of cancer patients with anaemia and neutropenia as a consequence of chemotherapy.
[17] Blom et al., 2005; Buller et al., 2007.
[18] Sorensen et al., 2000; Chew et al., 2006.
19 Prandoni et al., 2002.

Fragmin and Clexane are not clinically interchangeable

Fragmin and Clexane belong to the class of lower molecular weight heparins. The medicines in this class are not clinically interchangeable:

TGA Product Information

Clexane: *LOW MOLECULAR WEIGHT HEPARIN PRODUCTS ARE NOT CLINICALLY INTERCHANGEABLE* (P9)

Fragmin: *As low molecular molecular heparins are unique and separate entities with regard to potency, kinetics and possibly modes of action, these products are not interchangeable clinically.* (P5).

The TGA states that Fragmin demonstrates the benefit of treatment for VTE for up to 6 months for patients with CAT. With Clexane, the TGA indicated the average duration of treatment for VTE (not CAT specific) in the clinical trials was 10 days but no data are available on the safety of long term treatment in patients with VTE. [20],[21]

There is a difference in the non-health benefits to patients if Fragmin is PBS listed, the example below is based on a 75kg patient. There are substantial non-health benefits, such as the reductions in the number of injections, fewer clinician visits and the costs with fewer prescriptions, to cancer patients with VTE if Fragmin were listed on the PBS.

	Clexane	Fragmin
Daily dose	112.5mg	15,000 IU initially then 11,250IU
Treatment regimen	1 X 100mg injection One prescription provides medicine for 10 days; as 1 plus 1 repeat (total period 20 days) PLUS 1 X 20mg injection One prescription provides medicine for 20 days: as 1 plus 0 repeats (total period 20 days)	1 X 15,000 units injection Treatment phase: One 15.000 prescription provides medicine for 30 days; as 1 plus 0 repeats (total period 30 days) THEN 1 x 11,250IU injection Prophylaxis phase: One 12,500IU prescription provides drug for 30 days: as 1 plus 4 repeats (total period 5 months)
Number of injections per day	2	1
Number of GP visits required	**9**	**2**
Duration of treatment	6 months	6 months
Total number of prescriptions dispensed	**18**	**6**

[20] *The PBAC noted that enoxaparin was not specifically TGA registered for this indication. However, prescribers may prescribe enoxaparin for this indication as the current PBS listing is as an unrestricted benefit.* *http://agencysearch.australia.gov.au/search/search.cgi?collection=agencies&client=445556fb&cool0=41&cool1=15&cool2=5&cool3=0&stem=2&scope_disable=off&num_ranks=20&profile=health&query=fragmin+psd*

21 Clexane approved Product Information.

Consequences for patients of deferring the listing of Synarel on the PBS

There are two main treatment protocols for IVF treatment:

Agonist protocol: involves the prolonged use of a GnRH agonist, such as Synarel.

The other agonist treatment (Lucrin®)[22] available on the PBS, a once daily injection, is only TGA registered and PBS listed for use in the treatment of prostate cancer.

Antagonist protocol: consists of a regimen of fertility medicines including the use of GnRH antagonists (such as ganirelix and cetrorelix).

Certain doctors or clinics may deem the agonist protocol to be the most suitable protocol to adopt for specific patients.

The IVF/GIFT Program on the PBS includes two GnRH antagonists but no GNRH agonist. In addition, both GnRH antagonists are injections whereas Synarel is a nasal spray which may be more suitable or efficacious for certain patients.

The unavailability of Synarel on the PBS would limit funded treatment options for certain patients and for doctors who deem the agonist protocol as the most appropriate clinical option for particular patients. **There are no alternative treatments to Synarel on the PBS: where clinicians choose to adopt the agonist protocol for their patients, these patients are required to self-fund the GnRH agonist (in contrast to the GnRH antagonists that are funded).**

[22] Lucrin is indicated in the palliative treatment of metastatic or locally extensive prostatic cancer (Stage C and D). https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=pi&q=lucrin. PBS listing Authority Required (STREAMLINED) treatment of Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate cancer. http://www.pbs.gov.au/medicine/item/8877F-8876E-8875D

c) any consequences for the pharmaceutical industry of such deferrals?

The immediate impacts to manufacturers with affected medicines are shown below. The implications are both direct in terms of costs and also in terms of the level of support that can be provided.

Investment costs for Fragmin for VTE in cancer patients

Impact to the Pfizer business	Cost to Pfizer
TGA dossier preparation costs: Consultancy fees plus the cost of full-time Regulatory officer for six months	Minimum $120,000
TGA registration fees for the CAT TGA indication	$150,000
PBAC dossier preparation costs: Prescriber survey data plus the cost of full-time health economics specialist for six months and specialist statistical support	Minimum $150,000
PBAC submission cost recovery fee for major submission	$120,000
Redundant stock on hand: Collectively >$300,000 (minimum order) of high strength Fragmin syringes (12,500IU; 15,000IU; and 18,000 IU) with a two years shelf expiry were purchased end of 2010 specific for CAT PBS and will expire in 18 months. These are highly unlikely to be used without PBS listing, and cannot be used in other overseas markets due their Australian specific label	$300,000
Pre-PBS-launch planning costs: Development and production of educational materials including detail aids and doctor notification materials with a CAT specific dosage card. Development of an accredited CAT specific healthcare professional CPD program and two pre-PBS launch CAT Advisory Board meetings.	Minimum $150,000
Personnel costs: Recruitment & training of 5FTE field force staff including training costs, field force start-up costs (computers, phones, cars, stationary, etc). HR costs associated with redeployment. One Marketing and one Medical Officer working a minimum of six months full time on the brand launch prior the Cabinet deferral decision	Minimum $350,000
Total investment costs to the date of Cabinet deferral decision	**Minimum $1,340,000**

Pfizer estimates a minmum of approximately $1.3 million in investment costs to bring Fragmin to the point of PBS listing. The scale of investment will vary depending on the size of the patient population and the increases in stock and speciliased support required. The financial implications to Pfizer of the Synarel decision are lower as the same strength and presentation of Synarel as is currently listed on the PBS was proposed for inclusion whereas the proposed Fragmin PBS listing required new strengths and presentations.

This is a significant investment and will certainly be a central consideration for both local affiliates and global headquarters in future investment decisions.The indirect consequence of this policy will be the reluctance of global companies to invest in the required infrastructre and personnel to support the supply of medicines in Australia. Particularly when there is ongoing rationalisation of investment and the revenue reductions due to patent expiration facing the pharmaceutical industry.

d) any impacts on the future availability of medicines in the Australia market due to such deferrals?

The implications to the pharmaceutical industry are inextricably linked with the implications to patients. If there is limited opportunity to PBS list medicines, this means both limited affordable access to patients and difficulty in justifying investment in bringing medicines to the Australian market.

It is widely reported that it costs approximately $1.2 billion to bring a medicine from development to the consumer.

The impacts of ongoing deferrals will flow-on to clinical trials and access to medicines in hospitals. It is the risk to the future investment in innovative medicines which should be of greatest concern to Australian consumers and manufacturers.

It is essential for any industry to have a degree of certainty around the environment in which it operates, through measures such as patent protection and PBS reform. The indirect consequence of this policy will be the reluctance of global companies to supply medicines and the associated support that is required for a medicine that will not be able to be commercialised and accessed by the consumer. Particularly if the level of scrutiny across other areas of health spending is not commensurate.

e) the criteria and advice used to determine medicines to be deferred

In contrast with the PBAC process[23]: for Cabinet deferral decisions [24]. ….*are there formal criteria, no; is there an explanation for the ones that were chosen, yes, but in terms of a formal criteria, no.*[25]

When was the decision for Cabinet to review all potential PBS listings with the view to deferral proposed?

It is reasonable for the sponsor company to be informed as to what information was considered by the Cabinet in making these decisions.

At the simplest level there has been a lack of due process and consultation with the stakeholders who would be negatively affected by these decisions.

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[23] 25 February 2011, Minister of Health and Ageing, Patients Benefit from New Medicines Listed on the PBS and NIP http://www.health.gov.au/internet/ministers/publishing.nsf/Content/mr-yr11-nr-nr029.htm?OpenDocument&yr=2011&mth=02; 21 June 2011. Erbitux and other medicines listed on the PBS. http://www.health.gov.au/internet/ministers/publishing.nsf/Content/mr-yr11-nr-nr123.htm?OpenDocument&yr=2011&mth=06

[24] As of 11 July 2011 the PBS website still states: *The decision to subsidise an item is considered by Cabinet if the net cost to the PBS is greater than $10 million per year, and then determined by the Minister for Health and Ageing. The Government also exercises a number of controls to manage the overall cost of the scheme* http://www.pbs.gov.au/info/industry/listing/listing-steps

[25] 31 May 2011, Senate Estimates, Community Affairs, Secretary, Department of Health and Ageing, Jane Halton. http://www.aph.gov.au/hansard/senate/commttee/s-news.htm

Based on the limited information available in the public domain it is apparent that Fragmin and Synarel should be listed on the PBS.

Decision criteria?	Fragmin	Synarel
Does an alternate medicine/s for this condition exist?	No Clexane and warfarin are PBS listed but these medicines are not interchangeable with Fragmin	No Synarel is a GnRH agonist; the PBS currently only includes GnRH antagonists such as ganirelix
Does the proposed medicine/s have a net cost to the Government?	Yes A total net cost of less than $6million over 5 years to treat approximately 24,000 patients	Yes The estimated cost to the PBS is in the range of approximately $200,000 to less than $1million per year This does not include cost savings from a reduction in ganirelix use
Was the currently listed medicine for this condition included on the PBS in the 3 years?	No	There is no clinically equivalent medicine on the PBS. Ganirelix (GnRH antagonist) was listed in 2010
Is the medicine for the treatment of a serious or life saving condition?	Yes Fragmin is proposed for the prevention of VTE in cancer patients	Patient dependent
What is the relative cost impact to the Commonwealth Budget of the listing of medicines on the PBS in comparison with other health spending priorities?	This information is not available to sponsor companies.	This information is not available to sponsor companies.

The following questions remain unanswered:

When was a decision to defer the listing of medicines on the PBS developed and by whom?

and

Who provided the advice to defer these medicines from listing on the PBS?

f) the financial impact on the Commonwealth Budget of deferring the listing of medicines

The costs of listing Fragmin and Synarel on the PBS from the respective applications to the PBAC are provided below. If the financial estimates below vary from the estimates considered by Cabinet we are not able to comment on the difference without seeing the calculations. From the PBAC costs it would be incorrect to estimate the Commonwealth costs on the assumption every new medicine will see an increase in the number of patients and therefore have an automatic multiplier effect on health services.

Fragmin cost to the Commonwealth

The financial implication to the PBS for extending the listing of Fragmin to include the treatment of VTE in cancer patients was estimated at approximately $1 million for 2011. In the fifth proposed year of listing the annual cost to the PBS was less than $3 million. In total it would cost the PBS less than $6 million to treat approximately 24,000 cancer patients with VTE.

This estimate accounts for the contribution the patient pays towards their medicine. It is also includes the savings from the reduced usage of Clexane on the PBS. The financial implications to the PBS were agreed with the PBAC.

This does not include the reduction in the number of doctor visits, due to the cancer treatment specific dose forms, with Fragmin allowing patients to receive Fragmin simultaneously with other treatment.

It was estimated there would be an increase in the number of prescriptions with the availability of Fragmin as there are currently patients who are not receiving treatment or treatment of the same duration as is approved for Fragmin. However, there will also be a decrease in the number of Authority required prescriptions that are currently required with Clexane, due to the fact clinicians have to request an authority from Medicare to increase maximum quantity to treat appropriately.

Synarel cost to the Commonwealth

The estimates provided to the PBAC showed that the cost of Synarel to the PBS is likely to range from approximately $200,000 to less than $1 million per year after 5 years of listing (accounting for the contribution the patient pays towards their medicine).

The proposed cost of the comparator to Synarel, ganirelix, to the PBS was estimated to be <$10 million in Year 5.[26] It is assumed there will be some cost savings to the PBS from a reduction in the use of ganirelix if Synarel were available. The cost savings to the PBS from a reduction in the use of ganirelix has not been included here.

[26] Ganirelix PSD, November 2010. http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-psd-Ganirelix-nov09

g) the consultation process prior to a deferral

Pfizer was informed at the same time as the public with the 25 February 2011 media release from the Minister of Health and Ageing, Nicola Roxon MP.

Correspondence between Pfizer and DoHA regarding PBS listing requests for Synarel and Fragmin is listed below. The anticipated dates of PBS listing are based on the standard reference timelines.[27] These timelines informed our planning processes.

Summary of correspondence for Fragmin and Synarel

Date	Fragmin	Synarel
23 December 2009	N/A	Request for Pfizer to make an application from PBAC for the listing on Section 100 IVF/GIFT Program
19 August 2010	N/A	Minor submission made to PBAC
7 July 2010	Major submission made to PBAC	N/A
19 August 2010	N/A	Request for cost recovery fee waiver made by Pfizer
10 September 2010	N/A	Request for justification of fee waiver request i.e. patient and financial estimates
25 September 2010	N/A	Request for cost recovery fee waiver denied by PBD.
10 November 2010	Verbal recommendation received from PBAC	Verbal recommendation received from PBAC
26 November 2010	PBAC minutes confirm recommendation to list on PBS	PBAC minutes confirm recommendation to list on PBS
16 December 2010	Agreement and completion of pricing with PBPA	Pricing not accepted by PBPA. Secretariat instructed to negotiate acceptable price
13 January 2011	N/A	Agreement on pricing
13 January 2011	Guarantee of supply signed; required paperwork for 1 April 2011 PBS listing forwarded to the PBS Listings section of the DoHA	Required paperwork for 1 April 2011 expanded PBS listing forwarded to the PBS Listings section of the DoHA
25 February 2011	Announcement of deferral by Minister of Health and Ageing	Announcement of deferral by Minister of Health and Ageing
1 April 2011	Anticipated listing on PBS based on correspondence from 13 January 2011	Anticipated listing on PBS based on correspondence from 13 January 2011
21 June 2011	Announcement by Minister of Health and Ageing: Fragmin for VTE remains deferred. However, the addition of new presentations of Fragmin for the currently PBS indication is announced. Pfizer is informed verbally 1 hour before public release of information.	Announcement of additional listings and deferrals by Minister of Health and Ageing: Synarel remains deferred
Unknown	PBS listing	PBS listing

ABBREVIATIONS: PBD, Pharmaceutical Benefits Division; PBPA, Pharmaceutical Benefits Pricing Authority.

[27] http://www.pbs.gov.au/info/industry/useful-resources/pbs-calendar

From the correspondence preceding the announcement on the 25 February 2011 we were completely unaware there was likely to be an issue with listing Fragmin and Synarel on the PBS as of 1 April 2011.

The key points in terms of the consultation process are:

- At no point during the application process was there any indication standard process no longer applied
- We fulfilled our obligation to ensure guarantee of supply from 1 April 2011 as per the terms of the Notification of Responsible Person under *National Health Act 1953.*

  > The Notification of Responsible Person under *National Health Act 1953 form requires that a sponsor company identify the Responsible Person … determined by the Minister to be the supplier of a particular brand of a PBS item. Under the National Health Act 1953 the Responsible Person has obligations in relation to: Division 3C (guarantee of supply).*

- We have not had any further correspondence or information regarding:
  - The reasons why Fragmin and Synarel were deferred from listing on the PBS
  - The financial estimates considered by Cabinet
  - When we could expect PBS listing for these medicines
- We remain unable to plan appropriately for the provision of these medicines to Australian consumers; as we have reported there are many logistical and financial considerations essential to bringing medicines to market.

The government's consultative process effectively excluded the companies which developed, tested and manufactured these medicines. In short, the truncated timeframe and non-transparent process for the deferral of listings on the PBS companies have had limited capacity to challenge the decision or seek clarification. Our exclusion from the process has compromised our right to challenge decisions. Procedural fairness cannot be selectively applied. The advice provided to date is inadequate.

The justification for the PBS deferrals has not been provided to industry, nor has industry had a real opportunity to understand or challenge this advice – this is in stark contrast to the onus on industry to comprehensively prove safety and efficacy claims for the listing of new medicines on the PBS.

There must be a consistent approach to transparency and consultation for all PBS medicines.

Our expectations on transparency and consultation are based on the precedents set by consultation on PBS reform; the process for the consideration of a medicine by the PBAC; the communication of the recommendations made by the PBAC and the requirements of the United States Australia Free Trade Agreement (See Appendices C and D).

h) compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010

The clear intent of the MOU is to ensure sustainability and predictability of access to medicines in Australia

The principal objective of PBS Reform, as formalised in the Memorandum of Understanding signed by the Minister of Health & Ageing and Medicines Australia in 2010, was to provide business confidence in a predictable and stable pricing market, which in turn provides world class access to medicines for Australian patients.

> *Both parties intend that the MOU will promote efficiency and sustainability of the PBS and support by the provision of a stable pricing policy environment, a viable and responsible medicine industry in Australia, consistent with the objectives of the National Medicines Policy. Clause 3.*

The intent of the MOU is not legally binding. However, the price savings from PBS are bound in legislature in the NHA. The Government is guaranteed a minimum saving of $1.9 billion over 5 years. The intent of the Minister of Health & Ageing when signing the MOU was: *Under the MOU, the Government will provide the industry with pricing certainty over the next four years. In return for implementing new pricing arrangements that are the subject of this Bill, the Government will undertake not to introduce further new policy to generate price-related savings from the PBS over the life of the MOU. This will provide stability to the industry, helping to foster investment and availability of new and innovative drugs in Australia".*[28]

The decision not to list Synarel and Fragmin on the PBS clearly creates an unpredictable environment, rejects the valuation of innovation and reduces competition: all of which contravene the intent of PBS reform and the MOU.

[28] 29 SEP 2010: NICOLA ROXON: National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 - Second Reading Speech

The MOU was intended to build on and formalise the systematic review of the PBS as agreed in 2006.[29] This intent to maintain the principles of PBS Reform is clear: *The Commonwealth confirms its commitment to the principles and architecture of PBS Reform and, in particular, to maintain ….:*

- *the separation of drugs between the F1 and F2 formularies and combination drug list; and*
- *the different price setting and maintenance mechanisms which underpin the formularies. Clause 5.*

Restricting the PBS to one medicine for any medical condition will limit competition. Competition is the basis of the PBS reform mechanism to ensure future savings. The listing of Fragmin and Synarel would ensure competition in the off patent market in the years to come. Generic competition generally relies on an innovative pharmaceutical company having already provided its data as part of a comprehensive and expensive PBS listing process. We have effectively been denied an opportunity to compete even though the importance of a range of medicines was recognised with a request from the PBAC to submit for Synarel.

The foundation of PBS reform is value for innovation and competition.

The value of the PBS is not the same as the cost of the PBS

As demonstrated in this submission, and acknowledged by the PBAC, the value for money these medicines provide is irrefutable. In recognition of the need to monitor the growth in expenditure of the PBS the MOU[30] requires a joint working group of industry and Government representatives to monitor the drivers of growth of the PBS. This group is currently finalising the reporting system.

The decision by Cabinet to defer the subsidisation of these medicines clearly contravenes the intent of the MOU, particularly as the current responsible measures that have been put in place to manage the PBS are being undermined by ad hoc and ill advised policy changes to achieve relative minor savings.

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[29] The overarching system design agreed in 2006 was for two separate formularies, F1 and F2, designed to allow the appropriate valuation of innovative medicines whilst delivering savings to the Government through competitive commodity market forces for off-patent medicines, allowing ongoing access to medicines for the Australian population at an affordable cost, as stated in the following:

1. F1 is a market for single brand medicines where efficient price setting and control is achieved through rigorous cost-effectiveness evaluation and initial prices are set by reference to other molecules.
2. F2 is a market for multiple brand medicines where competition at the molecule level determines price – each molecule is encouraged to find its own competitive market price to extract maximum savings for the Government and there is little or no reference pricing between molecules.

[30] *Clause 7: Both parties undertake to jointly monitor trends in, and drivers of, PBS expenditure through the Access to Medicines Working Group (AMWG), which will also develop a framework for this purpose. This will commence not later than 1 January 2011. The Commonwealth agrees to share with Medicines Australia, without cost, the information and analyses required to achieve this.*

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Fragmin approved Product Information. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=pi&q=fragmin

Clexane approved Product Information. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=pi&q=clexane

Appendix A: PBS and PBS reform

PBS Reform was designed to allow the appropriate valuation of innovative medicines whilst delivering savings to the Government through competitive market forces for off-patent medicines, allowing ongoing access to medicines for the Australian population at an affordable cost.

The majority of the savings for the Government will be through price disclosure, a mechanism based on market competition amongst off-patent products; price disclosure essentially redistributes the savings previously delivered to pharmacists and wholesalers.

A key objective of PBS Reform was to provide business confidence in a predictable and stable pricing market, a premise undermined by legislative provisions that permit the Minister for Health and Ageing, at any point in time and without consultation with affected parties, to form TGs between different medicines. This is particularly important in the Australian context as the majority of innovator pharmaceutical companies are local subsidiaries of international companies.

The reforms comprise a range of inter-connected measures on the following 5 key themes:

Changes to the pricing of PBS listed medicines

- PBS medicines to be listed on two separate formularies:
- Formulary 1 (F1) will comprise single brand (essentially patented) medicines.
- Formulary 2 (F2) will comprise multiple brand medicines and any single brand medicines interchangeable with multiple brand medicines at the patient level.
- No ongoing price links across medicines listed on F1 and those listed on F2.
- Reference pricing will continue to apply:
    - between medicines linked within reference pricing groups on F1
    - within Therapeutic Group Premium (TGP) groups and across different brands of the same medicine listed on F2.

F1 is a market for single brand medicines where efficient price setting and control is achieved through rigorous cost-effectiveness evaluation and initial prices are set by reference to other molecules. F2 is a market for multiple brand medicines where competition at the molecule level determines price – each molecule is encouraged to find its own competitive market price to extract maximum savings for the Government. PBS reform (primarily through price disclosure) capitalises on the fact that the competitive drivers in single brand medicines are the relative effectiveness of different molecules while those for multiple brand medicines are commodity-like competition between brands of the same molecule.

Price cuts for medicines on F2

- Price reductions for all F2A medicines of 2% per year for three years from 1 August 2008.
- One-off 25% mandatory price reduction for F2T medicines will apply on 1 August 2008
- Price disclosure - Suppliers listing a new brand on or after:
- 1 August 2007 on F2A disclose actual market price as a condition of listing.
- 1 January 2011 on F2T disclose actual market price as a condition of listing.

F1 medicines entering F2 after 1 August 2007 will as a general rule join F2A

The 12.5% price reduction policy will continue to apply, where relevant.

Price disclosure

For medicines subject to disclosure the responsible person must supply the total sales volume and revenue for their medicine. DoHA calculates the difference between the disclosed price (the ex-manufacturer price as calculated directly from the PBS list price) and the price the manufacturer sells at (the "true" ex-manufacturer price) and adjusts the medicine price should there be more than a 10% difference, effectively capturing the savings previously delivered to the pharmacists and the wholesalers.

Pharmacy and pharmaceutical wholesaler compensation arrangements;

Pharmacists were provided the following assistance to adjust to the new arrangements;

- $1.50 (indexed) incentive to dispense a substitutable, premium-free PBS medicine.
- An incentive of 40c for each prescription processed using PBS Online; and
- Increases in pharmacy mark ups and dispensing fees.
- An additional $69 million over three years will be added to the Community Services Obligation (CSO) Funding Pool to compensate wholesalers for the new pricing arrangements.

Streamlined authority approvals for some medicines

Establishment of an access to medicines working group

Generic medicines awareness campaign

Appendix B: Impact of PBS reform

Dr Lesley Russell, Menzies Centre for Health Policy, 2009.

If the PBS plus RPBS had grown at the same rate post 2004-05 as the average rate up until that time, then it would now cost $9.33 billion a year. So on that basis alone, without savings from generics, the government has saved $5.4 billion, considerably more than the $1.9 billion the previous Treasures Peter Costello predicted in 2002-03 Budget papers"[31]

Examining the future of the PBS, Access Economics, 1 October 2009[32]

PBS is no longer a strong driver in health care spending

Moderation of PBS growth has been achieved largely due to PBS reform and increasing patient co-payments (2008-9 patient co-payments totalled $2.8 billion).

Generic pressures will create new pressures on the pharmaceutical industry to reduce the cost of medications in the future (p.42). Over 100 drugs will experience patent expiry over the next 10 years.

Access Economics poses:

The question is not merely "how much will the PBS cost?', but more equally "what will the PBS achieve for the cost?"

In terms of the broader government finances picture, the results in this report underscore the need for more careful modelling of future spending pressure and the danger of treating temporary surges in commodities and associated government revenue as permanent.

The Impact of PBS Reforms on PBS Expenditure and Savings. The Centre for Strategic Economic Studies (CSES), October 2009. [33]

The CSES report, commissioned by Medicines Australia, projects the Government will achieve savings between $8.25 billion and $9.88 billion in the period 2008-09 to 2017-18 depending on the competitiveness of the PBS. The majority of savings are delivered through PBS Reform initiatives ($4.76 to $6.38 billion to 2017-18).

The magnitude of the savings from PBS reform was verified in the report from the Department of Health & Ageing (DoHA) (Impact of the PBS Reform) as illustrated in Figure B1.

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[31] http://www.pharmainfocus.com.au/news.asp?newsid=2996
[32] http://www.accesseconomics.com.au/publicationsreports/showreport.php?id=218
[33] http://www.medicinesaustralia.com.au/pages/page61.asp

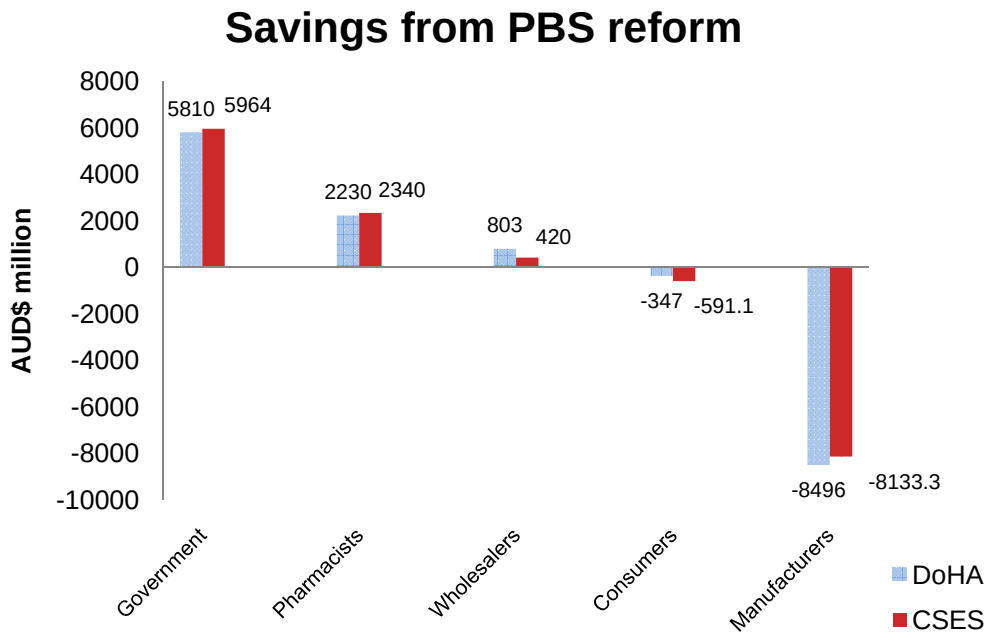

Figure B1: CSES and PwC modelled savings of PBS reform

NOTE: Estimates based on highest generic competition assumptions from both reports

A breakdown of the savings by stakeholder clearly shows the greatest gains are achieved by consumers, both directly at the point of payment, as tax payers and also with the continued availability of new medicines.

A criticism of the estimated savings is a lack of guarantee of price cuts from price disclosure or generic competition. There have already been significant savings to the Commonwealth from price disclosure (see Table B1). In addition, an arrangement (details of which are in the public domain) for a generic atorvastatin to be available in Australia at the time of Lipitor® patent expiry shows that the largest medicine on the PBS will be subject to immediate generic competition.

Table B1: Weighed average price disclosure price reductions

Molecule	Price disclosure Price cut 01 Dec 2009	Price disclosure Price cut 01 April 2010	Price disclosure Price cut 01 Aug 2010
Carvedilol		25.8%	
Cefalotin			41.1%
Doxorubicin	62.8%		34.62%
Fluconazole		54.3%	
Meloxicam			18.0%
Mitozantrone	33.1%		13.33%
Ondansetron	13.6%		17.61%
Vancomycin		71.2%	

The 2010 intergenerational report, Australia to 2050: future challenges January 2010. Treasury, Australian Government.[34]

Ageing and health pressures are projected to result in an increase in total government spending from 22.4% of GDP in 2015–16 to 27.1% of GDP by 2049–50. The current GDP fiscal gap (spending greater than revenue) is 2.75%, which is an improvement on the 3.25% of GDP fiscal gap projected in the previous IGR. The IGR2010 states:

By acting early, the Government's fiscal strategy will reduce the size of the adjustment costs required in the long run.

Australian government spending on health

Pharmaceutical spending remains a significant share of the health budget, $410 per capita in 2009-10 to $500 in 2019-20. However, the PBS as per cent of GDP is unchanged at 0.7% from 2009-10 to 2019-20 (See Figure B2). This is consistent with the estimates of from CSES which reported PBS spending of 0.67% of GDP in 2009-10 and 0.69% in 2011-12.[35] This is in comparison to the IGR2 (2007)[36] which reported the PBS would cost 0.8% of GDP in 2011-12 increasing to 1.0% in 2016-17 and 1.5% in 2026-27.

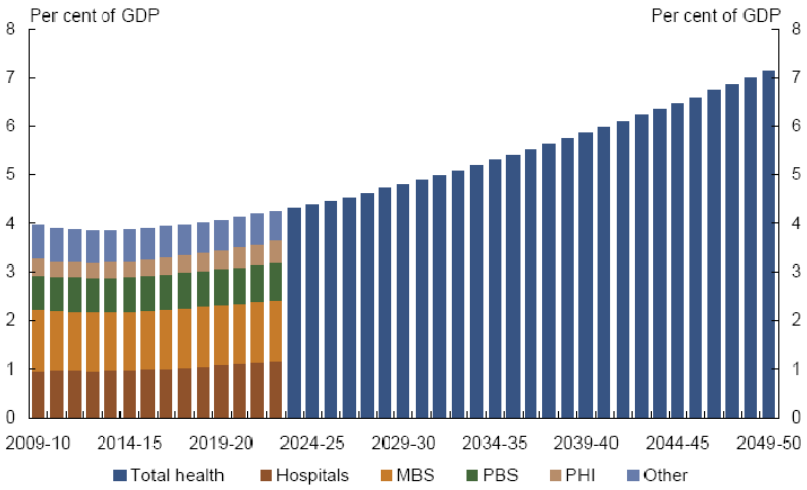

Figure B2: Projected Australian government health spending

Higher productivity is the key

Australia's productivity performance has slowed in the recent past, averaging only 1.4% in the past decade compared with 2.1% in the 1990s. The IGR2010 has assumed that the current 30-year historical average of 1.6% will continue. If productivity growth were increased to 2% per annum, the economy would be over 15% larger in 2049–50.

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[34] The 2010 intergenerational report. http://www.treasury.gov.au/igr/igr2010/
[35] The impact of PBS reforms on PBS expenditure and savings, Centre for Strategic Economic Studies, October 2009.
[36] InterGENERATIONAL report 2, 2007. http://www.treasury.gov.au/igr/

There is scope for Australia to improve its labour force participation rates, especially through policies that target improvements in education, health and attachment to the labour market. *For those wishing to continue working, key factors influencing workforce participation include: health outcomes; educational attainment; the tax-transfer system; cultural attitudes; workplace flexibility; and access to retraining and support services.*

The IGR2010 underlines the need for healthcare reform. *Simply cutting the health budget in order to achieve fiscal sustainability would not be appropriate. Rather, adjusting spending to obtain better value for money is necessary. This requires a more responsive and better coordinated health system. Health reform is required so that every health dollar will buy more and better quality health services.* [37]

The Impact of the PBS Reform - Report to the Parliament. Department of Health and Ageing, February 2010. [38]

The Impact of the PBS Reform report includes an independent assessment by PricewaterhouseCoopers (PwC). The savings from PBS reform, as discussed, are similar to those reported by CSES (See Figure 1). The Commonwealth will save almost $6 billion over 10 years with no negative effect on health outcomes delivered. In contrast the savings of $162 million over 4 years from the introduction of the four new TGs does not appear to justify the uncertainty created for consumers, clinicians and industry.

Future cost of the PBS

The greatest difference seen between the DoHA report and the CSES report is the projection of the future cost of the PBS (See Chapter 10 DoHA report). The estimates from DoHA suggest that the future PBS cost will be between $13 and 13.7 billion by 2018. This is in comparison to a projected cost of the PBS in 2018 of under $13 billion "before reform" (p.74).

CSES predicts the Government expenditure on the PBS would have been $9 billion in 2017-18 without PBS reform. With PBS reform the expected Government expenditure will between $7 and 7.5 billion in 2017-18 depending on the degree of competition in the market. The estimates for the total cost of the PBS are based on detailed information around the historical value of new medicines, savings due to PBS reform including price disclosure and price reductions with the entry of generic molecules. Given the alignment of the impact of the savings measures from the PwC and CSES reports it is concerning to see a significant disparity in the estimates of future PBS expenditure. There is limited detail in the DoHA report so it is not possible to replicate the projections that total PBS expenditure will be $13 to 13.7billion in 2017-2018.

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[37] The impact of PBS reforms on PBS expenditure and savings, Centre for Strategic Economic Studies, October 2009.
[38] The Impact of the PBS Reform. February 2010.
http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-reform-report

Appendix C: Consultation and transparency

The expectations of the industry and undoubtebly other external stakeholders is based on the premise that underpins the majority of intereactions with the PBAC. PBAC is conscious of the need to be as open as possible in its proceedings, consistent with the secrecy provisions of the Act. It therefore provides to sponsors all relevant documents and evaluations considered by the committee (P.8, PBAC Guidelines Vr. 4.3).

The Australia United States Free Trade Agreement (FTA) provides very clear direction regarding the need for both countries to "*promote timely and affordable access to innovative pharmaceuticals*" and to "*recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedure that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical*." The lack of consultation and transparency surrounding the Cabinet deferrals submisison is clearly inconsistent with these principles.

Consultation on PBS Reform

The PBS Reform package was developed with the consultation of industry prior to implementation from 1 August 2007. Medicines Australia, as the industry representative body, proposed a number of solutions in response to the DoHA consultation document: *PBS Reform – a guide to the legislation.*

Consideration of a medicine by the PBAC and transparency

The NHA 1953(101) does not mandate timelines for review however the PBAC Guidelines detail the timelines of consideration of medicines and also the transparency measures and communication responsibilities of the PBAC, generally through the PBAC Secretariat.

PBAC is conscious of the need to be as open as possible in its proceedings, consistent with the secrecy provisions of the Act. It therefore provides to sponsors all relevant documents and evaluations considered by the committee. It allows up to two sets of written pre-PBAC consultation documents from each sponsor as well as a hearing before the committee. (p.8, Section 1.4) [39]

[39] http://www.health.gov.au/internet/main/publishing.nsf/content/pbacguidelines-index

The timeframes for communication of any deliberations around a sponsor's medicine or a medicine that will impact on the use of the sponsor's medicine are clear (See Box 1.3).

Box 1.3 Timeline of PBAC procedures

Action or event	Time relative to PBAC meeting
• TGA delegate's overview/advice to ADEC and/or ADEC resolution and/or TGA registration granted	
• Cut-off date for major submissions to department	17 weeks before
• Cut-off date for minor submissions to department	11 weeks before
• Departmental papers to sponsors	6 weeks before
• Sponsor's pre-subcommittee response to department	5 weeks before
• Meeting of subcommittees	4 weeks before
• Subcommittee papers to sponsors	2 weeks before
• Sponsor's pre-PBAC response to department	1 week before
• PBAC meeting	
• Verbal advice to sponsor	half a week after
• Written advice to sponsor	3 weeks after
• Publication of PBAC outcomes on departmental website	6 weeks after
• PBAC ratified minutes to sponsor	10 weeks after
• Publication of public summary document on departmental website	16 weeks after
• Publication of public summary document (first time rejections)	18 weeks after

A number of initiatives to increase the transparency around PBAC recommendations have been introduced including Public Summary Documents, to provide detail on the decision-making criteria and evidence, which were introduced in 2004 and the PBAC meeting agenda and opportunity for consumer submissions to the PBAC which were intrdouced in 2008.

Requirements of the Australia United States Free Trade Agreement

The Australia United States FTA is clear in the recognition that the Government of each country must be transparent in decision making. See Appendix D for further details.

The process relating to the Cabinet deferrals decision has been conducted in secret by the Australian Government.

Companies have been provided with an opportunity to comment, only after the public announcement by the Minister of Health and Ageing that the PBS listings for certain PACB recommended medicines has been deferred.

Appendix D: Australia United States Free Trade Agreement

Key elements of Australia United States Free Trade Agreement for pharmaceuticals

Annex 2-C - Pharmaceuticals

1. Agreed Principles

The Parties are committed to facilitating high quality health care and continued improvements in public health for their nationals. In pursuing these objectives, the Parties are committed to the following principles:

(a) the important role played by innovative pharmaceutical products in delivering high quality health care;

(b) the importance of research and development in the pharmaceutical industry and of appropriate government support, including through intellectual property protection and other policies;

(c) the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious, and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety, and efficacy; and

(d) the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.

2. Transparency[2c-1]

To the extent that a Party's federal healthcare authorities operate or maintain procedures for listing new pharmaceuticals or indications for reimbursement purposes, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs, it shall:

(a) ensure that consideration of all formal proposals for listing are completed within a specified time;

(b) disclose procedural rules, methodologies, principles, and guidelines used to assess a proposal;

(c) afford applicants timely opportunities to provide comments at relevant points in the process;

(d) provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities;

(e) provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law; and

(f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.

3. Medicines Working Group

(a) The Parties hereby establish a Medicines Working Group.

(b) The objective of the Working Group shall be to promote discussion and mutual understanding of issues relating to this Annex (except those issues covered in paragraph 4), including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes.[2C-2]

(c) The Working Group shall comprise officials of federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.

4. Regulatory Cooperation

The Parties shall seek to advance the existing dialogue between the Australian Therapeutic Goods Administration and the U.S. Food and Drug Administration with a view to making innovative medical products more quickly available to their nationals.

5. Dissemination of Information

Each Party shall permit a pharmaceutical manufacturer to disseminate to health professionals and consumers through the manufacturer's Internet site registered in the territory of the Party, and on other Internet sites registered in the territory of the Party linked to that site, truthful and not misleading information regarding its pharmaceuticals that are approved for sale in the Party's territory as is permitted to be disseminated under the Party's laws, regulations, and procedures, provided that the information includes a balance of risks and benefits and encompasses all indications for which the Party's competent regulatory authorities have approved the marketing of the pharmaceuticals.

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