SENATE FINANCE and PUBLIC ADMINISTRATION REFERENCES COMMITTEE

INQUIRY INTO: THE GOVERNMENT'S ADMINISTRATION OF THE PHARMACEUTICAL BENEFITS SCHEME

SUBMISSION OF THE AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING

15 JULY 2011

Contents

Terms of reference

On 23 June 2011, the Senate referred the following matter to the Finance and Public Administration References Committee for inquiry and report by 18 August 2011.

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.

1. Introduction

The Pharmaceutical Benefits Scheme (PBS) provides the Australian community with reliable, timely and affordable access to over 770 drugs available in more than 1,960 forms, and marketed as over 3,900 brands. In 2009-10, around 184 million PBS-subsidised prescriptions were dispensed at a cost to the Australian Government of over $8.3 billion[1]. The expenditure in 2010-11 is estimated to be around $9 billion.

The legislative authority for the PBS is contained in Part VII of the *National Health Act 1953* as amended. The PBS is funded as a special appropriation, that is, it is uncapped and responds to demand. Increased expenditure is driven by factors such as increases in total population, demographic changes - in particular the ageing of the population, increases in prescription numbers per head of population and the cost of new medicines, that are added to the *Schedule of Pharmaceutical Benefits*.

As reported in the Portfolio Budget Statements 2011-12[2], in 2008-09 PBS growth was 9.2 per cent, and in 2009-10 PBS growth was 9.0 per cent. For 2010-11 and 2011-12, PBS growth is estimated to be 7.7 per cent and 6.5 per cent respectively. This growth takes into account the impact of PBS Reform measures implemented in 2007 and 2010.

The Government has added over 500 new medicines or brands of medicines to the PBS, the Life Saving Drug Program (LSDP) and the National Immunisation Program (NIP) over the last four years, at a cost of around $4 billion.

From 1 January 2011 to 31 July 2011, 124 medicines have been listed on the PBS and LSDP with a value of $561 million over five years with a further 33 PBS and NIP listings having been approved by the Government for implementation later in 2011[3]. Their value is an additional $287.6 million over five years.

[1] 2009-10 PBPA Annual Report

[2] Portfolio Budget Statements 2011-12. Budget Related Paper No. 110. Health and Ageing Portfolio, page 121

[3] Listings on the National Immunisation Program are subject to conclusion of tender processes, so exact date of affect cannot be provided at this time.

2. The Government's Policy

All positive recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC) and the Pharmaceutical Benefits Pricing Authority (PBPA) which have a financial impact for the Commonwealth Budget, are currently being considered by the Cabinet.

The current fiscal circumstances require that the PBS, LSDP and NIP listings will be subject to the same Government scrutiny as other spending measures across the rest of the Health portfolio and Government generally.

It has always been the case that the final decisions on the listing of medicines and vaccines have been taken by the Government, based on the expert advice of the PBAC and the PBPA.

As indicated by the Minister for Health and Ageing, the processes followed by both the PBAC and PBPA remain unchanged and the Government will continue to receive and consider the independent, expert advice of both the PBAC and the PBPA as has always been the case.

The Government announced the deferral of seven medicines, one vaccine and eight price increases on 25 February 2011. One medicine and one vaccine have subsequently been listed on the PBS and NIP, respectively.

Furthermore the listing of medicines on the PBS and LSDP and vaccines on the NIP has not stopped. On 21 June 2011, the Minister for Health and Ageing announced the Government approval of 13 new medicines on the PBS at a cost of over $250 million over five years. The new listings include ERBITUX® (cetuximab) for late stage bowel cancer, GILENYA® (fingolimod) for relapsing-remitting multiple sclerosis and TOBI® (tobramycin) to treat lung infections in patients with cystic fibrosis.

From 1 January 2011 to 31 July 2011, 124 medicines have been listed on the PBS and LSDP with a value of $561 million over five years with a further 33 PBS and NIP listings having been approved by the Government for implementation later in 2011[4]. Their value is an additional $287.6 million over five years. This brings the overall total value of expenditure across the three programs to $848.6 million over five years (PBS - $675 million, LSDP - $135.9 million, NIP - $37.6 million).

More details about the PBS only listings, by type, are provided below.

[4] Listings on the National Immunisation Program are subject to conclusion of tender processes, so exact date of affect cannot be provided at this time.

Table 1: Summary of New or changes to existing listing on the PBS: 1 January to 1 September 2011.

Category of Listing	Number Listed	Number Approved not yet listed
Listings with an estimated net cost of more than $10 million in any of the first four years of listing	6	2
Listings with an estimated financial impact of less than $10 million in any of the first four years of listing	6	9
Listings with no financial impact	111	18

Importantly, high cost innovative medicines that treat serious or life threatening conditions continue to be listed.

Table 2: Listings with an estimated net cost of more than $10 million in any of the first four years of listing in 2011

Medicine	Expenditure ($ million over five years)	Indication	Listing Date
Eculizumab	135.9	Paroxysmal Nocturnal Haemoglubinuria	1 January 2011[5]
Azacitidine	124.2	Leukaemia	1 February 2011
Dutasteride	77.1	Enlarged Prostate	1 February 2011
Nicotine Patches (extension)	54.5	Smoking Cessation	1 February 2011
Varenicline (extension)	48.9	Smoking Cessation	1 February 2011
Romiplostim	73.0	Rare Blood Disorder	1 April 2011
Levodopa with carbidopa	49.2	Parkinson Disease	1 May 2011
Fingolimod	To be published in MYEFO [6]	Multiple Sclerosis	1 September 2011*
Cetuximab (extension)	To be published in MYEFO [7]	Colorectal Cancer	1 September 2011*
Prevenar 13 Catch-up	40.7	Pneumococcal vaccination	TBA[8]

*Subject to listing conditions being met.

The Government's policy reflects its focus on listing medicines that treat serious or life threatening conditions where there are no alternative treatments on the PBS.

[5] Listing on Life Saving Drugs Program
[6] Included in the $200 million in new PBS listings announced by The Minister for Health and Ageing on 21 June 2011.
[7] As above.
[8] Listings on the National Immunisation Program are subject to conclusion of tender processes, so exact date of affect cannot be provided at this time

3. Response to the Terms of Reference

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

The sustainability of the PBS as a key to keeping medicines affordable and accessible, and delivering better health services for all Australians, has been a matter which had concerned successive governments.

The cost of the PBS has continued to grow over the past ten years, averaging growth of about nine percent a year and it is estimated it will cost about $9 billion this financial year (2010-11). This growth rate is higher than the six percent annual increase for general hospital and medical services, and much higher than the Consumer Price Index.

Given current fiscal circumstances, the Government is concentrating on listing medicines that treat serious or life threatening conditions where there are no alternative treatments.

On 25 February 2011, the Minister announced that the Government had approved the listing of seven new medicines and vaccines on the PBS and the NIP. At that time, it was announced that the Government had decided to defer the listing of seven other medicines, one vaccine and eight price increases including medicines for conditions where existing treatments are already available on the PBS and to defer price increase for some already PBS listed medicines.

On 21 June the Minister for Health and Ageing announced the listing of a further 13 medicines on the PBS at a cost of over $250 million over five years. Also announced on this date was the deferral of the NIP listing of Priorix-Tetra, vaccine combining two existing vaccines already on the NIP for measles, mumps and rubella, and varicella.

Over the same period that seven medicines, two vaccines and eight price increases have been deferred (1 January to 1 September 2011), 124 medicines have been listed on the PBS and LSDP with a value of $561 million over five years with a further 33 PBS and NIP listings having been approved by the Government for implementation later in 2011[9]. Their value is an additional $287.6 million over five years. This brings the overall total value of expenditure across the three programs to $848.6 million over five years (PBS - $675 million, LSDP - $135.9 million, NIP - $37.6 million).

Information is provided in the following table about the PBS and NIP listings and price increases deferred by Government, as announced by the Minister for Health and Ageing on 25 February and 21 June 2011.

[9] Listings on the National Immunisation Program are subject to conclusion of tender processes, so exact date of affect cannot be provided at this time.

Table 3: PBS and NIP listings announced as deferred on 25 February and 21 June 2011

Medicine	Sponsor	Indication	Alternative Therapies Available	Date deferred	Current Status	Cost recovery impact
Dutasteride with tamsulosin hydro-chloride (Duodart®)	GSK	Enlarged prostate	Single agents dutasteride prasozin	25 February 2011	To be PBS listed 1 August 2011	PBAC evaluation and listing fees applicable
Paliperidone palmitate (Invega Sustenna®)	Janssen-Cilag	Schizophrenia.	Risperidone long acting injection twice monthly as opposed to once monthly and Olanzapine long acting injection once or twice monthly.	25 February 2011	Deferred	PBAC evaluation fee only
Oxycodone with naloxone (Targin®)	Mundipharma	Chronic disabling pain not responding to non-narcotic pain medicines.	Single agent long acting oxycodone plus various PBS listed laxatives (which are also available OTC at lower prices for general patients)	25 February 2011	Deferred	PBAC evaluation fee only
Budesonide with eformoterol (Symbicort®)	AstraZeneca	Chronic obstructive pulmonary disease	Fluticasone with salmeterol	25 February 2011	Deferred	PBAC evaluation fee only
Dalteparin sodium (Fragmin®)	Pfizer	Treatment of blood clots in patients with cancer	Enoxaparin	25 February 2011	Deferred	PBAC evaluation fee only
Nafarelin (Synarel®)	Pfizer	in vitro fertilisation (IVF) program	Cetrorelix Ganirelix	25 February 2011	Deferred	PBAC evaluation fee only
Vaccine: Prevenar 13® catch-up	Wyeth	Pneumococcal disease	Prevenar 7® was already on NIP	25 February 2011	Funded in 2011-12 Budget	PBAC evaluation fee only
Botulinum toxin type A (Botox®)	Allergan	Severe excessive underarm sweating	No alternate option on PBS, but drugs to treat secondary infections are available	25 February 2011	Deferred	Not applicable. PBAC application made prior to cost recovery
Vaccine: Priorix-Tetra®	GlaxoSmithKline	Measles, mumps, rubella and varicella	Vaccines for these diseases are already on the NIP	21 June 2011	Deferred	Not applicable. PBAC application made prior to cost recovery

Table 4: PBS price increases announced as deferred on 25 February 2011

Medicine	Sponsor	Indication	Alternative Options Available	Deferral Date	Current Status	Cost recovery impact
Acarbose	Bayer	Type II diabetes,	Many other oral antidiabetic agents including Pioglitazone, Sitagliptin	25 February 2011	Deferred	**No fees payable
Erthromycin ethyl succinate	Link Medical Products & Alphapharm	Antibiotic	Clarithromycin liquid Azithromycin	25 February 2011	Deferred	No fees payable
Erthromycin lactobionate	Link Medical Products	Intravenous Antibiotic	Available through public hospitals	25 February 2011	Deferred	No fees payable
Glucose Indicator	Bayer	Diabetes type II indicator,	Glucose and ketone indicator urine	25 February 2011	Deferred	No fees payable
Hexamine hippurate	i-Nova	Antibacterial	Other PBS subsidised antibiotics	25 February 2011	Deferred	No fees payable
Neomycin sulfate	Alphapharm	Bowel sterilisation prior to surgery	Available through hospitals for TGA approved indication	25 February 2011	Deferred	No fees payable
Pancreatic extract	Abbott	Enzyme replacement for cystic fibrosis	Pancrelipase	25 February 2011	Deferred	No fees payable
Sucralfate	Alphapharm and Aspen	Duodenal ulcer	Various others including Ranitidine; or Omeprazole	25 February 2011	Deferred	No fees payable

** No PBAC evaluation fee incurred, subsequent pricing fee only applies if listing occurs

Those listings which have been deferred in the prevailing fiscal environment remain eligible for future consideration when fiscal circumstances permit. Deferred listings do not need to be reconsidered by PBAC or the PBPA, unless the sponsoring company wishes to present further clinical evidence to support a price increase or propose a price reduction

As Table 3 above shows, one medicine (dutasteride with tamsulosin (Duodart®)) and one vaccine (Prevenar 13® for catch-up cohort) deferred in February 2011 have subsequently been approved for listing on the PBS and NIP, respectively.

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3 (b) Any consequences for patients of such deferrals

The Government has announced that it is concentrating on listing medicines that treat serious or life threatening conditions where there are no alternative treatments on the PBS.

Alternative medicines exist for all the deferred medicines, except for one, the use of Botox to treat severe excessive underarm sweating. Whilst no other treatments are currently listed on the PBS to treat the underlying cause of this condition, there are PBS listed medicines available to treat any secondary infections associated with the condition.

Details of the alternative PBS listed medicines are contained in Table 3, in section 3 (a) of this Submission.

Based on the evidence provided to the PBAC which is reflected in the PBAC recommendations, four of the six medicines that remain deferred to date, paliperidone (Invega Sustenna®), budesonide with eformoterol (Symbicort®), dalteparin sodium (Fragmin®) and nafarelin (Synarel®) produce similar health outcomes to existing PBS-listed therapies. They did not demonstrate superior clinical benefits to those items already on the PBS, but had an additional cost to the Commonwealth budget.

With respect to oxycodone with naloxone (Targin®), the PBAC considered that it could provide an alternative pain management therapy to opioids alone or in conjunction with prophylactic laxatives. This was reflected in the cost of this medicine which was similar to oxycodone plus an over-the-counter laxative. The potential for reduction in illicit drug use claimed in the submission to the PBAC was not based on evidence.

3 (c) Any consequences for the pharmaceutical sector of such deferrals

The six medicines still deferred represent less than 3.9 percent of all listings that Government has considered for PBS-listing this year. From 1 January 2011 to 1 September 2011, 152 medicines and brands have been approved by the Government to be either added to the PBS or have their listings extended, with a total value of $675 million over five years.

It has always been the case that the final decisions on the listing of medicines and vaccines have been taken by the Government, based on the expert advice of the PBAC and the PBPA.

As indicated by the Minister for Health and Ageing, the processes followed by both the PBAC and PBPA remain unchanged and the Government will continue to receive and consider the independent, expert advice of both the PBAC and the PBPA as has always been the case.

It has always been the case that the Department of Health and Ageing contacts companies following a positive PBAC recommendation to discuss pricing issues and documentation requirements. Similarly, the Department contacts companies to advise of approval to list and to confirm that listing that can proceed.

Decisions about whether to obtain stock, ahead of formal advice from the Department one month prior to the actual date that the listing will proceed, are commercial decisions made by individual companies. Companies are not required to pre-stock, in anticipation of a positive listing outcome. They are only required to assure the Department, that, when listing does proceed, they will be able to make stock available on the PBS. Once approval to list on the PBS is known, companies are able to proceed with their projected listing date or defer listing if they are unable to supply by that date.

It is not for the Department to speculate on each individual company's capacity to supply prior to advising of the approval to list.

In relation to the six PBS listings that remain deferred, companies can still sell stock privately and to hospitals. Further, it should be noted that of the six PBAC recommendations that remain deferred, three of the medicines are already subsidised through the PBS for other indications. These are:

- Botox® ($11.8 million in PBS expenditure in 2009-10);
- budesonide with eformoterol (Symbicort® - $66.3 million in PBS expenditure in 2009-10 for asthma) ; and
- dalteparin sodium (Fragmin® - 0.9 million in PBS expenditure in 2009-10)

A number of companies that had medicines deferred in February 2011 are also the makers of the alternative therapy already listed on the PBS. For example, Janssen-Cilag is the maker of paliperidone (Invega Sustenna®), which was deferred, as well as of the alternative therapy, risperidone long-

acting, which had a PBS expenditure in 2009-10 of $54.8 million. Similarly, Mundipharma, is the maker of oxycodone with naloxone (Targin®), and also of oxycodone, which had a PBS expenditure in 2009-10 of $74 million.

The table below summarises the PBS expenditure by company and provides further details about the alternative PBS-listed therapies.

Table 5: PBS expenditure paid to companies 2009-10, listing dates of alternatives and cost of alternative 2009-10

Medicine	*PBS expenditure received by company	Alternative Options Available	Date alternative listed on PBS	Expenditure on alternative
Paliperidone palmitate (Invega Sustenna®)	Janssen-Cilag $221.2 million	Risperidone long acting injection Janssen-Cilag or Olanzapine long acting injection Eli Lilly	1 February 2005	$54.8 million
			1 December 2009	$0.1 million
Oxycodone with naloxone (Targin®)	Mundipharma $89.6 million	Single agent long acting oxycodone Mundipharma plus various PBS listed laxatives (which are also available OTC at lower prices for general patients)	1 May 2001	$74.0 million
Budesonide with eformoterol (Symbicort®)	AstraZeneca $780.6 million	Fluticasone with salmeterol GlaxoSmithKline	1 August 2007 for COPD indication	$118.7 million
Dalteparin sodium (Fragmin®)	Pfizer $882.2 million	Enoxaparin Sanofi-Aventis	1 May 2003	$4.5 million
Nafarelin (Synarel®)		Cetrorelix Merck Serono	Cetrorelix 1 Dec 2010	12 months data not available
		Ganirelix Schering .-Plough	Ganirelix 1 August 2010	12 months data not available
Botulinum toxin type A (Botox®)	Allergan $21.5 million		Not applicable	

* PBPA Annual Report 2009-10

3 (d) Any impacts on the future availability of medicines in the Australian market due to such deferrals

As at 1 July 2011, over 770 drugs available in more than 1,960 forms, and marketed as over 3,900 brands are listed on the PBS. In 2009-10, around 184 million PBS-subsidised prescriptions were dispensed at a cost to the Australian Government of over $8.3 billion[10]. The expenditure in 2010-11 is estimated to be around $9 billion.

This represents a substantial market for pharmaceuticals and is around 80 per cent of all prescriptions dispensed in Australia.

The Minister for Health and Ageing has stated[11] that the Government is committed to listing drugs on the PBS that treat serious conditions where alternate treatments are not readily available. The Minister has indicated[12] that

> '*even in difficult fiscal circumstances this Government is willing to consider proposed listings within required timeframes, and to list new drugs that come with a substantial cost'*

Further, the implementation on 1 January 2011 of both the Managed Entry Scheme and Parallel Processing of submissions to the PBAC and Therapeutic Goods Administration (TGA), as committed to under the Memorandum of Understanding (MoU) with Medicines Australia, improves the processes for PBAC consideration of company submissions.

Companies are still actively seeking listing on the PBS as evidenced by the fact there has been no change to the total number of submissions received for consideration by the PBAC over the last three meetings. The number of major submissions, those applications requesting listing of a new medicine or an additional clinical indication to a medicine already listed on the PBS, have increased during that time.

This indicates that pharmaceutical companies continue to see value and purpose in seeking listings on the PBS.

Table 6: Number of Submissions considered by PBAC at recent meetings

PBAC Meeting Date	Major Submissions	Minor Submissions	Secretariat listing requests	Total Number of Submissions
November 2010	26	29	7	62
March 2011	18	24	16	58
July 2011	31	20	11	62
November 2011	26	TBA	TBA	TBA

[10] 2009-10 PBPA Annual Report
[11] Media Release, The Hon Nicola Roxon MP, Minister for Health and Ageing, 21 June 2011.
[12] The Hon Nicola Roxon MP, Minister for Health and Ageing, Opening Address to Consumers Health Forum PBS Summit, 29 April 2011.

Of the proposed price increases that were deferred, one manufacturer, Alphapharm Pty Limited has advised the Department that it intends to remove its medicine, neomycin sulfate 500 mg (Neosulf®) from the PBS with effect from 1 September 2011. This medicine is registered by the TGA for bowel sterilisation prior to surgery. Alphapharm has advised that the medicine will remain available outside the PBS. This means it can be provided through public hospitals and via private prescription.

The commercial reasons behind pharmaceutical companies deciding whether, and at what price a medicine should be supplied or continue to be supplied on the PBS are complex and multifaceted. For example, although the Government approved on 21 June 2011 a price increase for the Alphapharm medicine, amiloride hydrochloride 5 mg tablet, Alphapharm has chosen to de-list this medicine from 1 September 2011.

The Government cannot compel a company to continue to supply a medicine through the PBS. However, when a manufacturer advises the Department that it intends to delist a drug, or a particular form or strength of a drug and there are no other brands of that drug or in that form or strength listed on the PBS, the delisting request is referred to the PBAC. Under subsection 101(4AAB) of the *National Health Act 1953,* the Minister can only remove a medicine from the PBS after receiving the written advice of the PBAC. Subsection 101(4AAC) further states that this advice must be tabled in Parliament.

The delisting of medicines from the PBS at the request of manufacturers is not uncommon as the following table demonstrates:

Table 7: Delisting requests considered by the PBAC

Year	No. of delisting requests considered by PBAC
2006-07	15
2007-08	6
2008-09	11
2009-10	9
2010-11	8

If the PBAC advises that a medicine proposed to be deleted is an essential medicine, the Department, in line with long-established practice, endeavours to find a company that may be prepared to continue to supply the medicine. For example in August 2010, AstraZeneca Pty Ltd announced that it would discontinue supplying the 10 pack of atropine sulfate injection 600micograms listed on the PBS including the listing in the "Emergency Drug (Doctor's Bag) Supplies" list, as the product was being discontinued globally by the company. The Department worked successfully with an alternative supplier, Pfizer Pty Ltd which stepped in to address the high clinical need for this product by modifying its manufacturing processes to produce the required PBS-pack of 10 injections, which was subsequently listed on the PBS on 1 May 2011.

3 (e) The criteria and advice used to determine medicines to be deferred

The PBAC[13] considers each PBS and NIP listing submission having regard to the safety, clinical effectiveness and cost-effectiveness (value-for-money) of the medicine (or vaccine) for the intended use, in comparison with other available treatments. The same evaluation requirements are applied in all cases, as required by legislation, to ensure consistency and fairness in the listing process.

No additional formal criteria exist in relation to decision making about deferring the listing of medicines on the PBS or vaccines on the NIP. The Department does not provide advice to the Cabinet about which of the PBAC recommended medicines should be funded or deferred.

The Government relies upon information provided by the PBAC in relation to the clinical need for each medicine or vaccine, including whether alternative treatment options exist and the evidence assessed by the PBAC. Additional information taken into account by the Government is whether the listing provides expenditure savings and other technical information that the PBAC considered.

The Government also relies on the expert advice from the Department of Health and Ageing and the Chief Medical Officer.

A summary of PBAC considerations and recommendations are publically available in the form of public summary documents on the Department's website[14].

[13] The PBAC's functions are defined in Section 101 of the *National Health Act 1953*.
[14] http://www.health.gov.au/internet/main/publishing.nsf/Content/public-summary-documents-by-product

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

The cost of individual measures considered by the Cabinet, including potential PBS listings are Cabinet in Confidence.

As has been previously publicly advised, the total cost of the PBS medicines deferred is over $100 million.

All drugs whose PBS listing remains deferred would have a net cost to the Government's budget if listed. The fact that a listing was associated with a net cost was known at the time the submission was considered by the PBAC. The costings for each listing include the net cost to Government, taking into account PBS, Department of Veterans' Affairs (DVA), Medicare Australia, and where appropriate, Medical Benefits Scheme (MBS), impacts.

The PBS and MBS component of costings is developed by the Department of Health and Ageing and incorporates information provided by the sponsor prior to the PBAC meeting, if any. As per usual practice for the development of New Policy Proposals from any portfolio, all costings are provided to and agreed by the Department of Finance and Deregulation.

The listing on the NIP of Prevenar 13® vaccine for catch-up pneumococcal program, deferred in February 2011, was subsequently announced in the 2011-12 Budget at a cost of $40.7 million over five years. The catch-up program will be available for one year, from 1 October 2011 to 30 September 2012.

3 (g) The consultation process prior to a deferral

All companies making applications to the PBAC are advised of the PBAC outcomes by the PBAC Secretariat. This is followed by pricing negotiations with officers in the PBPA Secretariat and Listing Section to complete other documentations which are required prior to the implementation of any PBS listing.

In addition, the Department agrees cost estimates with those companies supplying drugs which required a risk-sharing arrangement as part of the listing conditions or where the cost of the medicine is estimated to have a net cost of more than $10 million in any of the first four years of listing.

The Department is unable to discuss with companies details of Government decision making processes before these are completed, as they are Cabinet in Confidence.

In line with long-standing practice, all companies affected by a Cabinet decision about the listing of medicines on the PBS are informed by an officer of the Department prior to the Government's announcement.

3 (h) Compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010

The Memorandum of Understanding (MoU) with Medicines Australia was announced in the 2010–11 Budget. It contains key deliverables and is estimated to achieve around $1.9 billion in PBS savings over five years in exchange for new policy development in some areas and pricing stability during its operation.

Clause 3 of the MoU states that "*both parties intend that the MoU will promote the efficiency and sustainability of the PBS and support, by provision of a stable pricing policy environment, a viable and responsible medicines industry in Australia, consistent with the objectives of the National Medicines Policy*".

The Department has met the following critical deliverables under the MoU:

- Extended and accelerated price disclosure (EAPD) commenced on 1 December 2010
- Statutory price reductions of two percent and five percent came into effect on 1 February 2011 for all non-exempt medicines on the F2 formulary as at 11 October 2010
- Two new policies, the managed entry scheme (MES) and parallel processing of Therapeutic Goods Administration (TGA) and PBAC evaluations have commenced on 1 January 2011, 12 major submissions to the July PBAC meeting submitted under the parallel processing policy; and
- MoU clauses related to horizon scanning, effect of comparator prices, and the monitoring of trends in and drivers of PBS expenditure, have also commenced as of 1 January 2011

Clause 4 of the MoU states that *"the Commonwealth undertakes not to implement new policy to generate price-related savings from the PBS during the period of the agreement, that is, measures that would change the ex-manufacturer price of particular medicines, other than reflected by this MoU*". This is an undertaking[15] to provide the industry with certainty with respect to pricing.

Recommendations of the PBAC and the PBPA have always required Government approval. The referral of all PBS, NIP and LSDP listings with a financial impact for Cabinet consideration and to require that all new listings be fully offset is consistent with the commitments made under the MOU. This is not new pricing policy. It is taking a consistent approach to all listings with a financial impact by ensuring they are subject to the same processes already applied to those listings with a financial impact greater than $10 million in any financial year. The requirement for offsetting is also consistent with other new policy proposals in the health portfolio and government more broadly.

[15] The Hon Nicola Roxon MP, Minister for Health and Ageing, second reading speech, National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010, Hansard 29 September 2010, p80.

Clauses 28 and 29 of the MoU also provide for timeframes for the consideration and listing of medicines on the PBS:

- *"the Commonwealth will work with industry to examine possible methods to reduce the time taken to finalise PBS pricing negotiations after a PBAC recommendation, including for those PBS submissions that require Cabinet approval prior to the listing and this will be monitored by the Access to Medicines Working Group through a mechanism to be agreed; and*
- *for those submissions required to be approved by the Cabinet, the Commonwealth will use its best endeavours to implement a maximum time frame of six months for consideration and decision by Cabinet. The six months will commence from the date of notification by the Department of Health and Ageing to the sponsor that pricing is agreed".*

Clause 29 of the MoU applies to PBAC recommendations from its July 2010 meeting onward. At the time the MOU was signed in May 2010 and re-signed on 28 September 2010, the only new listings that required consideration by the Cabinet were those high-cost drugs with net expenditure exceeding $10 million in any of the forward estimates years.

In relation to the listing of medicines on the PBS, the Government is complying with the terms of the agreement and has brought forward PBAC recommendations for Government consideration within the agreed timeframes.

This is demonstrated through the consideration by the Cabinet of high cost[16] medicines romiplostim (Nplate®), levodopa with carbidopa (Duodopa®) and fingolimod (Gilenya®) within six months of pricing agreement between the Department and the sponsoring companies. Specific timeframes for each medicine's consideration are in the table below.

Table 8: High cost drugs considered by the Cabinet since the MoU

Medicine	Indication	Date recommended by PBAC	Date price agreed	Time to cabinet consideration	Date of PBS listing
Romiplostim (Nplate®)	Rare blood disorder	July 2010	August 2010	6 months	1 April 2011
Levodopa with carbidopa (Duodopa®)	Advanced Parkinson disease	Nov 2010	January 2011	1 month	1 May 2011
Fingolimod (Gilenya)	Multiple sclerosis	March 2011	May 2011	1 month	Expected Sep 2011

An extension to the PBS listing for cetuximab (Erbitux®) to treat metastatic colorectal cancer (bowel cancer) in patients with K-RAS wild type disease was recommended by the PBAC at its July 2010 meeting and its price was agreed on 29 September 2010. To determine whether a patient has K-RAS wild type

[16] Medicines estimated to have a net cost of more than $10 million in any of the first four years of listing

disease, a genetic test is required. This test is currently not funded through the Medicare Benefits Schedule (MBS).

The manufacturer of cetuximab only applied for the MBS listing of the genetic test after the PBAC had made its recommendation. The listing of cetuximab was complex given that it is the first time this Government has listed a medicine on the PBS while also seeking to list a co-dependent genetic test on the MBS. While the assessment of listing the genetic test on the MBS is still ongoing, the drug manufacturer has offered to pay for the genetic test in the meantime. Subject to listing conditions being met the extension to the PBS listing of cetuximab will occur on 1 September 2011.

A further two high cost drugs recommended by the PBAC await consideration by the Cabinet. Details are summarised in the following table.

Table 9: High cost drugs requiring consideration by the Cabinet

Medicine	Date Recommended by PBAC	Date price agreed	Does MoU apply	Indication
Rituximab (Mabthera®)	November 2010	May 2011	Y	for the treatment of chronic leukaemia, in combination with chemotherapy
Dabigatran etexilate (Pradaxa®)	March 2011	Apr 2011	Y	for the prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation

3 (i) any other related matter

3 (i) (a) Functions of the Pharmaceutical Benefits Advisory Committee(PBAC)

All new and extended listings of medicines on the PBS and vaccines on the NIP are recommended by the independent, expert advisory body, the Pharmaceutical Benefits Advisory Committee (PBAC). The Government cannot list a medicine on the PBS unless the PBAC makes a recommendation in favour of its listing.

As a statutory committee, the functions of the PBAC are determined by *Section 101 of the National Health Act, 1953* (the Act).

The PBAC considers each PBS listing submission having regard to the safety, clinical effectiveness and cost-effectiveness (value-for-money) of the medicine for the intended use, in comparison with other available treatments. The same evaluation requirements are applied in all cases, as required by legislation, to ensure consistency and fairness in the listing process. It is usually an industry sponsor of a product which holds the clinical and other data required for a PBS listing submission.

The Act does not provide any legislative power to the PBAC to make decisions about the listing of medicines on the PBS. These powers are, and have always been, vested in the Minister.

3 (i) (b) Functions of the Pharmaceutical Benefits Pricing Authority (PBPA)

The pricing of new medicines and extension to listings of current medicines following positive PBAC recommendations is undertaken by the Pharmaceutical Benefits Pricing Authority (PBPA).

The PBPA is the independent non-statutory body that makes recommendations to the Minister for Health and Ageing on prices for new brands of pharmaceutical items that have been recommended for listing on the PBS, and for new vaccines recommended for inclusion on the NIP, by the PBAC. In addition, the PBPA reviews prices of all brands of pharmaceutical items listed on the PBS at least once each year.

The PBPA's objective is to secure a reliable supply of pharmaceutical benefits at the most reasonable cost to Australian taxpayers and consumers, consistent with maintaining a sustainable, viable and responsible pharmaceutical industry in Australia.

3 (i) (c) Powers of Minister for Health and Ageing

The legislative power to add to or change the *Schedule of Pharmaceutical Benefits*, resides with the Minister for Health and Ageing, under Part VII of the Act[17].

3 (i) (d) Cost Recovery fees – General information

Cost Recovery for PBS processes was introduced effective for all new submissions received on or after 1 January 2010. Amendments to the Act giving effect to PBS Cost Recovery came into force on 22 July 2009.

Cost Recovery fees are levied at two points in the PBS listing process:

- when submissions are lodged for consideration by the PBAC; and
- following the outcome of pricing negotiations and confirmation that the product will be listed.

Not all applications are subject to Cost Recovery. An application may receive a full or partial fee waiver if it is considered to be in the public interest and that payment of the fee would make the application financially unviable.

Some applications are exempt from fees. These include designated orphan drugs, drugs considered necessary for a public health event of national significance, drugs required for public health emergencies under the *Quarantine Act (1908*) and other circumstances outlined in Part 5 of the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2009.*

Table 10: Current PBS Cost Recovery fees

Evaluation Fees	**Pricing/Listing fees**	**Independent Review**
Major Submission $119,500	Complex $25,000	$119,500
Minor Submission $12,500	Simple $6,000	
Secretariat Listing $1,000	Secretariat $1,000	
New Brands $500		

[17] In particular sections 85 and 100 of the *National Health Act 1953*.

3 (i) (e) Cost Recovery fees – application to deferred listings and price increases

Cost recovery fees reflect the work involved in evaluating submissions seeking to make a new listing or amend an existing listing on the PBS, LSDP or NIP. All submissions received by the due date are evaluated and considered by the PBAC at the next meeting. There is no change for this part of the process to justify a change to the operation of cost-recovery.

Sponsors submit applications to the PBAC in full knowledge that the application will be considered by the PBAC and a listing is not guaranteed.

Once the PBAC has made a positive recommendation and the application proceeds to the pricing phase, the second fee is not charged until the actual PBS listing occurs. Therefore drugs recommended by the PBAC but whose listing was deferred by the Government, only attract the initial fee in relation to PBAC evaluation.