Australian Senate

Community Affairs Committee

Inquiry into
National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008

Department of Health and Ageing Submission

Contents

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PART ONE – Relevant Background Information

History of the National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008.

The policy of applying cost recovery to the administration of the Pharmaceutical Benefits Advisory Committee (PBAC) was announced by the previous government in a 2005-06 Budget measure – *Pharmaceutical Benefits Advisory Committee – cost recovery arrangements* (Budget Paper No.2). The effect of that policy was to propose a fee for the process of evaluating submissions for listing prescription medicines on the Pharmaceutical Benefits Scheme (PBS). Applicants proposing listings are usually pharmaceutical companies and are known as 'sponsors'.

The 2005-06 measure was to commence on 1 July 2007. However, this was deferred until 1 January 2008 to allow for consultations with industry over the more broadly based issues to be considered in the Pharmaceutical Benefits Scheme Reform. Legislation was not introduced at that time and the measure therefore lapsed.

The current proposal, announced by the Government as part of the 2008-09 Budget process, was scheduled to take effect on 1 July 2008.

Purpose of the Bill

The Bill amends the *National Health Act 1953* (the Act) to authorise regulations that will allow cost recovery of certain services provided by the Commonwealth. The relevant services are associated with submissions for new, or changes to existing, listings on the PBS and the 'designation' of vaccines for the National Immunisation Program (NIP). The Bill also provides that unpaid fees are a debt due to the Commonwealth.

The Bill is not a taxing Bill and provides that fees may not amount to taxation.

The desired scope of the regulation-making power for cost recovery is broad to allow for the flexible, efficient and transparent administration of the cost recovery arrangements. The regulations will be subject to Parliamentary scrutiny following their preparation.

The Bill also stipulates that the regulations may include fees payable for other services provided by the Commonwealth, such as the making of declarations, determinations, agreements and arrangements.

The regulations will set out the specific fees that are payable for the relevant services provided by the Commonwealth and specify the time and manner of payment, as well as consequences for failure to pay the fee. The Bill empowers the Minister to refuse to exercise powers under section 9B or Part VII of the Act until a fee is paid.

The regulations will allow for exemptions from fees. For example, it is expected that Therapeutic Goods Administration (TGA) designated orphan drugs and drugs approved for temporary supply will be automatically exempted from fees. Waiver of fees in exceptional circumstances is also anticipated, where the submission involves a public interest component and the payment of the cost recovery fee would mean the submissions would not be financially viable.

The regulations will also provide for the review of administrative decisions made in relation to cost recovery. The Department is committed to ensuring that there is a due process in relation to fees and charges being levied in a fair and equitable way. Such reviews would be separate to the existing review process applying to PBAC decisions (see note 4 on page 18).

In the first instance, if the matter cannot be resolved through discussion, the Department will ask a more senior Departmental officer who has not been party to the original decision to reassess the original material. If this does not satisfy the sponsor, the sponsor will have recourse to the Administrative Appeals Tribunal.

There will be no additional fee charged for the process of reviewing fees charged under cost recovery arrangements.

Overview of the Pharmaceutical Benefits Scheme

The PBS has been in operation for over 60 years and along with Medicare, is a key component of Australia's healthcare system.

The overarching aim of the PBS is to provide timely, reliable and affordable access for all Australians to necessary medicines through government subsidy of products listed on its schedule. Medicines and vaccines that meet specific criteria set out in the Act, Section 101 in particular, as assessed by PBAC are subsidised through uncapped appropriations that assist people with the cost of treatment for most medical conditions. Patients are required to make a co-payment, which in 2008 is $5.00 for concession card holders and up to $31.30 for general patients.

One of the continuing challenges facing the PBS and other developed countries is managing the growing demand for medicines, within the context of community expectations that access to pharmaceuticals includes every available medicine, particularly those of high cost.

> *In the context of the ongoing development and release of new medicines which are often relatively expensive, it can be difficult to meet the community's expectations regarding subsidised access to all available medicines. Both the effectiveness and*

> *cost-effectiveness of the treatments need to be considered in making decisions about subsidisation.*[1]

A number of strategies are therefore used to ensure that medicines listed on the PBS combine utility or efficacy with best value for money. Broadly, the government subsidises medicines that contribute to the cost-effective maintenance of the health of the community. This is achieved by carefully assessing the therapeutic benefits and costs of medicines, including comparisons with other treatments, where appropriate. If a medicine is found to be cost effective, then PBAC recommendation for approval is followed by negotiation with industry over the price.

The Minister for Health and Ageing considers PBAC recommendations and medicines can only be listed on the PBS with the Minister's approval. The Minister cannot approve a medicine for listing on the PBS unless it has been recommended by the PBAC. If the cost to the government is high (currently greater than a net cost of $10 million per annum in any of the first four years of listing) the proposed medicine is considered by Cabinet before the Minister may act to list that medicine on the PBS.

In addition to the medicines available through the PBS, there is also the Life Saving Drugs Program (LSDP), which provides access to expensive and lifesavings medicines. These medicines are accepted by PBAC as clinically effective, but are not routinely available under the PBS because of their failure to meet cost effectiveness criteria. Unlike the PBS however, the LSDP operates under a fixed appropriation, with specific eligibility criteria and certain conditions agreed by the Ministers for Health and Ageing, and Finance and Deregulation.

The National Immunisation Program

The National Immunisation Program (NIP) is a joint program of Commonwealth and State/Territory governments. The program provides fully funded vaccines for major preventable diseases and is administered through grants from the Commonwealth to the States and Territories. The States and Territories in turn provide vaccines free of charge to health providers for them to administer to the community. Submissions for vaccines to be funded through NIP are also considered by PBAC.

The Pharmaceutical Benefits Scheme Listing Process

The PBS listing process encompasses the many procedures associated with a medicine or vaccine being approved for government subsidy. The process commences with the lodgement of a submission to PBAC and is managed by the Department of Health and Ageing (the Department), on advice or recommendations from the relevant expert bodies. Medicines, their uses, prices and other terms and conditions (such as dispensing quantities and number of repeats per prescription) are set out in the Schedule of

[1] *National Medicines Policy 2000.*

Pharmaceutical Benefits. The schedule is updated monthly and is available to the general public, prescribers and dispensers. In brief, the listing process for sponsors comprises the following steps:

- Therapeutic Goods Administration (TGA) registration
- Submission to and recommendation by PBAC
- Recommendation by the Pharmaceutical Benefits Pricing Authority (PBPA)
- Approval by the Minister.

A submission for PBS listing can be made for any medicine for any use, for which it is registered (or in the process of being registered) by TGA. There are no restrictions on who can propose or sponsor medicines and vaccines for listing. However, in practice this is mostly pharmaceutical companies, as they hold the detailed technical information required to complete a submission and have a commercial interest in achieving this outcome. Nonetheless, sometimes a sponsor will be a community organisation that is acting on behalf of its members, for example, a disease based non-government organisation.

A medicine can only be listed on the PBS following a positive recommendation by PBAC.

Pharmaceutical Benefits Advisory Committee

PBAC is an independent statutory body which makes recommendations and provides advice to the Minister for Health and Ageing about which medicines should be subsidised under the PBS. It assesses the clinical benefit and cost effectiveness compared with other treatments or products for the same condition or use. PBAC makes similar assessments, when preparing its recommendations about the vaccines to be included in NIP.

PBAC has two statutory sub-committees that provide advice and comments on medicines: the Economics Sub-Committee (ESC); and the Drug Utilisation Sub-Committee (DUSC). PBAC may refer submissions to one or both of these committees. There are a number of other committees, non-statutory, that assist in finalising a listing. The most significant of these is the Restrictions Working Group. Its role is to settle the restrictions that may be placed on the use of a medicine to ensure its use is consistent with the cost effectiveness assessment of PBAC. PBAC is also assisted by the PBAC secretariat and expert drug evaluators.

PBAC also provides advice to the Pharmaceutical Benefits Pricing Authority about comparable medicines and the relative cost effectiveness of medicines for which a listing is being sought.

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Pharmaceutical Benefits Pricing Authority

When a drug is recommended for listing by PBAC, the sponsor makes a pricing application to the Pharmaceutical Benefits Pricing Authority (PBPA).

The PBPA then provides advice to inform negotiations on the initial price of the medicine, taking into account PBAC's recommendations about the cost-effectiveness of the medicine. The recommendations of PBAC and PBPA are then considered by the Department which negotiates the initial price with the sponsor of the medicine. As mentioned earlier, if the cost to the government is high (currently greater than a net cost of $10 million per annum in any of the first four years of listing) the proposed medicine is considered by Cabinet before the Minister may act to list that medicine on the PBS.

Independent Review

From 1 January 2005, independent review has been available to any sponsor whose submission to PBAC has not resulted in a recommendation to list on the PBS. Independent review has also been available since July 2006 for instances where PBAC has declined to recommend an extension of the listing of an already listed pharmaceutical or medicine.

Independent Review is managed by the Convenor, who is responsible for overseeing and ensuring the efficient conduct of reviews, including the selection of a reviewer with appropriate skills and expertise. If sponsors seeking an independent review of a PBAC decision submit the application for review by close of business of the seventh week following the last PBAC meeting, the findings will be considered at the following meeting. Sponsors may only submit information already submitted (that is, no new evidence) in the review process.

If sponsors wish to provide new information for PBAC's consideration then the option of resubmission is available to them. This will not change under cost recovery arrangements, although independent review like all other applications will attract a fee – see table on pages 17 and18 for details.

Details of Pharmaceutical Benefits Scheme Expenditure

As of 1 July 2008 there were 641 medicines with 2,995 branded products available under normal PBS arrangements through community pharmacies. Another 71 drugs with 222 branded products are available through alternate arrangements such as the Highly Specialised Drugs Program and Human Growth Hormone Program. These figures change throughout the year, as new medicines and brands are added to, or removed from, the programs.

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In 2006-07 Commonwealth government expenditure under the PBS totalled over $6.4 billion[2]. It is expected that PBS outlays for 2007-08 will be around $7 billion.[3] A further $280 million was provided by the Commonwealth to the States and Territories for the fully funded supply of vaccines under NIP within their respective jurisdictions. The cost of the Life Saving Drug Program in 2006-07 was approximately $28.8 million.

The government subsidises approximately 85% of the total cost of PBS prescriptions, with the remaining 15%, (approximately $1.15 billion in 2006-07), paid for by patient contributions.

Cost Recovery Policy: The Broader Australian Government Context

In December 2002 the then Australian Government adopted a formal cost recovery policy to improve the consistency, transparency and accountability of its cost recovery arrangements and promote the efficient allocation of resources. Cost recovery policy is administered by the Department of Finance and Deregulation and outlined in the *Australian Government Cost Recovery Guidelines* while the Review Schedule is outlined in Finance Circular 2005/09. The underlying principle of the policy is that agencies should set charges to recover all the costs of products or services where it is efficient and effective to do so, where the beneficiaries are a narrow and identifiable group and where charging is consistent with Australian Government policy objectives.

The policy applies to all *Financial Management and Accountability Act 1997* (FMA Act) agencies and to relevant *Commonwealth Authorities and Companies Act 1997* (CAC Act) bodies that have been notified, under sections 28 or 43 of the CAC Act, to apply the cost recovery policy. These entities are collectively referred to as 'agencies' for the purposes of the guidelines. In accordance with the policy, individual portfolio ministers are ultimately responsible for ensuring agencies' implementation and compliance with the cost recovery guidelines.

The Productivity Commission has commented that by ensuring that those who use regulated services bear the costs, cost recovery can promote economic efficiency and equity by instilling cost consciousness among agencies and users. Using Productivity Commission criteria, the reasons the PBS is considered suitable for cost recovery include:

- There is an identifiable group of parties which can be charged for the services provided to them
- The parties derive a clear benefit from the listing of their products
- The financial contribution made by the Government to the PBS lowers the cost of products to the end consumer and facilitates the widespread marketing and sale of the prescribed medicines and vaccines.

[2] Department of Health and Ageing Annual Report 2006-07.

[3] Department of Health and Ageing Annual Report 2006-07.

Anticipated Revenue

Revenue from PBS cost recovery will depend on the number and type of submissions brought to PBAC for consideration. It had been expected that if the measure had been implemented from 1 July 2008 that it would generate around $9.4 million in revenue in 2008-09, rising to around $14 million per annum in 2009-10 and the following years. Cost recovery will not be applied retrospectively.

It should be noted that the Budget Measure described in the 2008-09 Budget papers included several financial components (not all of which constituted the cost recovery arrangements). [4]

The cost recovery component, subject to the passage of legislation, is estimated to generate around $51.6 million in revenue from fees over four years. The expected revenue in the first year (2008-09) as detailed in the Budget papers reflects a commencement date of 1 July 2008 and therefore does not include submissions to the July 2008 PBAC meeting, which were submitted in March 2008. Cost recovery is expected to cover all costs of the PBAC listing process from 2009-10 onward, its first anticipated year of year full operation. More generally, as cost recovery is linked to the lodgement of submissions for PBAC meetings, revenue will therefore not be spread evenly over a financial year, or necessarily be received in consistent amounts.

Over the course of four years, the Budget measure will restore $44.6 million in Departmental revenue used to fund the PBS listing process. These funds were previously removed from the Department as the expectation under the 2005-06 measure was that revenue from cost recovery would directly fund the PBS listing process. The restoration of this $44.6 million in direct funding ensures that the continuing work of the PBAC will not be dependent on revenue from cost recovery.

The Budget measure also provides around $9.2 million over four years of new funding for PBAC and the PBS listing process to ensure that PBAC can respond to an increasing workload and complexity of submissions from sponsors seeking to list medicines on the PBS or vaccines on the NIP. In particular it provides additional funding:

- for the remuneration of PBAC members in line with Remuneration Tribunal decisions
- to cover the costs of additional evaluations by independent expert evaluators and
- to provide for a more up to date and responsive web based listing process.

All of the activities funded by the additional $9.2 million will be subject to the cost recovery arrangements. Details of proposed fees and charges appear in Part 2 (d) at page 18.

[4] Portfolio Budget Statements 2008-09, Budget Related Paper No. 1.10, Health and Ageing Portfolio, p28.

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PART TWO – Matters Identified by the Committee

a i) Patients' Timely and Affordable Access to Medicines and Vaccines

Medicines supplied under the PBS are provided directly to the Australian community by approved pharmacists, medical practitioners, or in public and private hospitals.

As mentioned previously, patients are required to make co-payments, of either $5.00 for concession card holders, or up to $31.30 for general patients. The amount of these co-payments will not be affected by the cost recovery arrangements, which will be administered separately to the PBS.

The NIP is a joint Commonwealth and State/Territory government program providing fully funded vaccines for major preventable diseases. When vaccines are designated under section 9B of the Act, they become available through NIP. Funding for the NIP is provided through grants from the Commonwealth to the States and Territories. Cost recovery will not affect these arrangements, where States and Territories provide the vaccines without charge to health providers for them to administer to patients in the community.

The Department has no evidence to suggest the introduction of cost recovery arrangements will result in a reduction in access to effective new medicines under the PBS. Fees charged under a full year of cost recovery are expected to total approximately 14 million, which as a proportion of Commonwealth outlays on pharmaceuticals (using $6.7 billion as the denominator) represents around 0.2%.

The trigger for fees under the cost recovery proposal will be the lodgement of a submission which, in the case of pharmaceutical companies, is a commercial decision. Pharmaceutical companies are free to market their products in Australia independently of the PBS or NIP subsidies. However, financial returns from the PBS and NIP, especially in relation to high sale 'prescription only' items, are significantly increased by PBS listing.

As mentioned previously, there will be exemptions from fees under the regulations, for TGA designated 'orphan' drugs and the capacity to waive fees where the submission involves a separate public interest component and the payment of the cost recovery fee would mean the submission would not be financially viable. Orphan drugs are intended to treat, prevent or diagnose a rare disease or must not be commercially viable to supply to treat, prevent or diagnose another disease or condition.

This will ensure that medicines to treat rare diseases or those that are not commercially viable will continue to be considered by PBAC and therefore availability of new medicines to patients is expected to remain unchanged.

a ii) The Australian Pharmaceutical Industry

The pharmaceutical industry is already familiar with cost recovery, following its introduction for the pre-market evaluation of products by the TGA in 1991. Multi-national pharmaceutical companies would also be familiar with cost recovery arrangements as they operate in other countries for comparable assessments made for TGA equivalent registration.

Achieving a product listing on the PBS provides a high level of commercial certainty to a company in relation to that product's sales.

As mentioned in Part One of this submission, the cost of providing subsidised medicines and fully funded vaccines to the Australian community is a significant financial outlay to the Commonwealth and tax payers, costing nearly $6.7 billion in 2006-07. Turnover in the Australian pharmaceutical industry in 2006-07 was estimated to be around $18 billion[5].

The Department anticipates revenue from cost recovery will be around $14 million over a continuous financial year, once the measure is fully operational. The financial benefits that flow to pharmaceutical companies, through government subsidy of their medicines or vaccines under the PBS and NIP, are significant. In this context, it is reasonable that pharmaceutical companies contribute to the administrative cost of operating a scheme, which provides a high level of certainty to companies in relation to income from subsidised medicines and vaccines.

a iii) New products and innovation

The Department does not anticipate that the introduction of cost recovery arrangements will limit or inhibit innovation, the listing of new medicines on the PBS and/or designating vaccines on the NIP.

Cost recovery arrangements have been in effect for TGA processes for over 15 years and new and innovative medicines continue to be listed on the Australian Register of Therapeutic Goods. Based on this experience, there is no reason to assume the introduction of cost recovery arrangements for the PBS listing process will have an adverse impact on the number of submissions being lodged with the PBAC Secretariat.

As discussed above, the high level of commercial certainty provided to a pharmaceutical company through product subsidy will ensure that the benefits of listing a product, in most cases, outweighs the short-term costs of the fee for having that product listed. Niche products, with a small market and those developed by smaller companies will be given consideration under the cost recovery arrangements, which would allow for discretionary waiver of fees on these grounds. In the cases of orphan products fees will

[5] Department of Innovation, Industry Science and Research *Pharmaceuticals Industry FactSheet*

not be charged. There will also be a capacity to waive fees where the submission involves a public interest component and the payment of the cost recovery fee would mean the submission would not be financially viable.

a iv) The Independence of PBAC

The PBAC is the independent expert body, established by section 100A of the *National Health Act 1953* to assess applications for listing of medicines under the PBS. PBAC members are selected from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and other specialists. The composition of PBAC will remain unchanged and there is no plan to alter its composition in the future, as a result of any cost recovery arrangements introduced.

The functions of PBAC include making recommendations to the Minister as to medicines and vaccines which it considers should be made available for government subsided supply to the Australian community under the PBS or NIP. This also remains unchanged.

There have been concerns expressed about how cost recovery may impact upon the independence of the PBAC. However, the continued independence of the PBAC will not be compromised by the introduction of cost recovery arrangements. The Department will continue to fund directly, all activities of PBAC and its subcommittees, while revenue raised from cost recovery fees will be paid to the Department of Finance and Deregulation.

There will be a clear separation of the proposed fee administration process and PBAC's deliberations. PBAC will have no role in setting fees and it will not receive any revenue from industry. It will not be involved in revenue collection, nor any decision about revenue. All monies collected from cost recovery will be paid directly into consolidated revenue.

b) Cost Recovery Mechanisms in Other Countries

Cost recovery mechanisms for TGA equivalent processes (that is, approval to market a pharmaceutical product) exist in other OECD countries. Submissions considered as part of the PBS listing process is a parallel process to TGA deliberations over whether or not to register a pharmaceutical. Cost recovery already applies to the TGA registration process.

A number of other countries approach reimbursement by operating, like Australia, a 'positive list', which involves a second separate decision after registration about whether or not to subsidise pharmaceuticals. Systems that utilise only one assessment, which combines registration and subsidy considerations, operate a 'negative' list, which details those medicines that are excluded or have been removed.

The difficulty with making comparisons between Australia's approach and those of other countries is that most systems have unique features that qualify any conclusions that may be drawn as a result of the comparison. For example, the National Institute for Health and Clinical Excellence (NICE) approves pharmaceuticals for distribution in England and Wales and does not charge fees. However, once entered the market has other features, in this case capped physician controlled budgets, which are not mirrored in Australia. This highlights the unique structure of the PBS in providing subsidised access to pharmaceuticals with universal coverage and modest patient co-payments.

Despite the different approaches employed by national governments, the combined expense of TGA and possibly PBS cost recovery fees would be less costly than some registration fees alone, namely in the European Union (EU) and the United States (US).

The table that follows provides further information on fees and any other relevant information. It is important to note that it includes countries with comparatively low fees for registration of pharmaceuticals. This can be explained in terms of the European countries imposing a nominal charge, following EU assessment, which attracts a substantial fee. For the remaining countries with comparatively small charges, they are more likely to be an administrative fee for registering pharmaceuticals that have already been assessed for safety and efficacy by countries with greater infrastructure and capacity, including Australia.

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Costs associated with registration processes in other countries

Country	*Amount*	*Other explanatory information*
United States	**1,197,519 AUD** 1,178,000 USD **598,759 AUD** 589,000 USD	(applications requiring clinical data) (applications not requiring clinical data)
European Union	**376,299 AUD** 242,600 EURO	full fee
Bulgaria	**1,142 AUD**	(registration quoted in 2002 values - latest found)
Canada	**114,796 AUD**	(application with clinical data)
Denmark	**8,545 AUD**	(registration quoted in 2002 values latest found)
Hong Kong	**1,392 AUD**	(initial registration quoted in 2002 values – latest found)
India	**1,016 AUD**	(initial registration quoted in 2002 values - latest found)
Ireland	**8,518 AUD**	(registration quoted in 2002 values - latest found)
Japan	**67,780 AUD**	(initial registration quoted in latest value found – 2002)
Netherlands	**15,248 AUD**	(registration quoted in 2002 values - latest found)
New Zealand	**114,795 AUD**	(application for new medicine)
Portugal	**508 AUD**	(registration quoted in 2002 values - latest found)
Sweden	**35,997 AUD**	(registration quoted in 2002 values - latest found)
Australia - TGA	**176,300 AUD**	This is the uppermost fee applicable and relates to registration of a new medicine.

The Australian dollar values have been determined using exchange rates as advertised on the Commonwealth Bank's website, current as of 2 July 2008.

c) Timeliness and effectiveness of the PBS listing of new medicines

The PBAC processes for assessing pharmaceuticals and vaccines are well known in other countries for rigour and integrity. It is often used as a point of reference or source of information for countries seeking to improve their approach to pharmaceutical regulation. The continued independence and professional operation of PBAC will not be altered by the introduction of cost recovery arrangements.

PBAC currently operates on a timely 17 week assessment cycle, which will not be interrupted by any cost recovery arrangements. Rather, cost recovery arrangements have been shaped around PBAC's established processes. Other PBS listing functions undertaken by the Department, which take place around PBAC's assessments will also be unaffected by cost recovery arrangements. It is possible a cost recovery fee may also serve to focus the way sponsors approach the application process, but there is little information available to confirm this suggestion. In addition, sponsors are often affected by a complex interplay of local and international factors that would make any change to the way they engage with PBAC difficult to gauge with any certainty.

It is also anticipated that cost-recovery will not effect any change to the current willingness of sponsors to seek PBS listing for potentially less commercial, but nonetheless clinically important medicines. This is because exemptions and waivers from fees will be available in these circumstances.

Aside from the cost recovery proposal, the Department is working cooperatively with Medicines Australia in the Access to Medicines Working Group (AMWG) exploring the capacity to further streamline and coordinate processes to reduce the time it takes to list a medicine on the PBS.

It should be noted that while every effort will be made to streamline the registration and listing process, all parties involved stress that this work will be conducted with absolute regard to maintaining high standards in relation to the assessment of efficacy, safety and cost-effectiveness in the processes of the registration and PBS listing of new medicines.

d) Modelling and Consultation Underpinning the Decision

<u>Background to the Department's Costing Processes</u>

The Department uses an activity based costing methodology for the assignment and allocation of all direct, indirect and overhead costs to its various activities and services.

The methodology was developed internally and enables costs to be allocated to activities and services at each stage they are undertaken.

The model uses a two stage process to allocate:

1. costs to each business unit, and
2. costs to specific activities and services.

The full costs associated with the operation of the business units that undertake the full range of activities comprising the listing process, and all other resources utilised in fulfilling that function are detailed below.

Information Specific to Cost Recovery of PBAC activities

Staff Costs - $4.1 million

Staff costs include the base salary, superannuation and other direct employee costs of staff who are directly involved in the listing process, based on the Department's collective agreement and the estimated on costs for superannuation and other employee expenses.

Direct Costs - $7.3 million

Direct costs incurred in connection with the PBS listing process include:

- Committee costs:
  - Pharmaceutical Benefits Advisory Committee (PBAC);
  - Pharmaceutical Benefits Pricing Authority (PBPA);
  - Economic Sub-Committee (ESC);
  - Drug Utilisation Sub-Committee (DUSC); and
  - Restrictions Working Group (RWG);
- Other relevant committees and working groups;
- External evaluations;
- Legal fees associated with the development of pricing agreements;
- IT systems supporting the PBS listing process; and
- Direct administration costs.

Overheads - $2.6 million

Overhead costs have been imputed into the cost of the listing process. These include departmental overheads associated with the business units performing the listing process and also include corporate overheads, such as:

- IT infrastructure;
- Property operating expenses;
- Business support group (finance, Human Resources etc); and
- Executive costs.

The same costs allocated according to activity and service, estimated to be around $14 million per annum in 2008-09 values, are outlined below.

Activity	Cost ($m)
Receipt and processing of application	0.67
Expert evaluation	7.80
Committee review	3.63
Undertake price and risk sharing discussions through PBPA	1.24
Restrictions Working Group and related activities	0.48
Liaison with applicants	0.24
Total Cost of Listing Process	**14.06**

Proposed fees

The proposed schedule of fees is set out as follows.

Fee Category	Estimated volume	Proposed Fee	Projected Revenue ($m)
Lodgement fees			
PBAC Evaluation – Major	93	$A119,500	11.11
PBAC Evaluation – Minor	76	$A12,500	0.95
Secretariat listing	39	$A1,000	0.04
Generic listing	100	$A500	0.05
Pricing fees			
Price negotiation – Tier 1	5	$A6,000	0.03
Price negotiation – Tier 2 and 3	75	$A25,000	1.88
Independent Review	-	$A119,500	-
Est Total for first full year (2008-09 pricing)			**14.06**

Notes

1 The fees will be charged on a per submission basis.
2 Actual revenue will vary as the actual number and type of submissions fluctuates.

3 Fees will be GST exempt under Division 81 of the *A New Tax System (Goods and Services Tax) Act 1999.*

4 The Department has established a process for the independent review of PBAC recommendations **not** to list medicines on the PBS. This was agreed under the 2005 Australia-United States Free Trade Agreement (AUSFTA).

5 Fees are indicative only. Final figures will be set in the Regulations, which are subject to Parliamentary scrutiny.

Alternatives models for cost recovery

Options for cost recovery models include:

- fees that charge individuals or firms directly for the cost of individual services; or
- levies on a group of individuals or firms (legally a form of taxation). Levies need to be established using a tax Act.

The cost recovery guidelines stipulate that where cost recovery is appropriate, charges should be based on fees, where they are efficient, cost effective and consistent with the policy objectives of the agency.

Cost recovery arrangements that would rely on charges for individual services (rather than the proposed global fee) are not considered to be practical for administrative purposes nor cost effective for industry.

Conversely, levies are not so closely linked to the cost of individual activities and do not have the efficiency advantage of fees. They may also place less direct pressure on the agency to improve efficiency. Where levies are used, they should be closely linked to costs and focused on recovering costs from only those groups of firms that use the services or create the need for regulation.[6]

The PBS listing process is considered to be a specific service provided to the sponsor of a drug. Given that approximately 90% of the Department's costs in administering the PBS relate to the evaluation of submissions, direct fees and charges are considered to be the appropriate basis of cost recovery, with the post listing activities (ie some scheme support activities and services to Parliament that are directly related to the listing process) imputed as an overhead.

Cost recovery by way of a levy would result in some clear disadvantages:

- although the levy would spread the cost across the full industry it would significantly reduce the link between cost and charge, potentially resulting in cross subsidisation between firms; and

[6] Australian Government Cost Recovery Guidelines July 2005

- a levy would be administratively expensive to set up and maintain. Also, given that a levy is legally a form of tax appropriate legislation would also need to be established.

The imposition of a levy is not proposed and was rejected after consultation with industry.

Consultation

From the time of the announcement of the 2005-06 Budget measure, the Department has undertaken and continues to undertake a broad, inclusive approach to stakeholder consultation with peak pharmaceutical industry peak bodies. Consultation has included other peak pharmacy, medical and consumer organisations.

The Cost Recovery Industry discussion paper, released in April 2007, presented the key questions for consideration by the pharmaceutical industry, Government, and other interested parties at that time. It was informed by the views and questions raised by peak organisations, particularly Medicines Australia, the Generic Medicines Industry Association and the Consumers' Health Forum in earlier discussions.

The paper presented the facts about cost recovery, including a description of the guidelines and principles, as well as the process and legislative requirements set down for introduction of cost recovery arrangements. The paper outlined the specific scope of recoverable costs for the PBS listing process and raised some key questions for stakeholder comment.

During consultations with stakeholders in 2006 and 2007 there was general agreement on a fees-only model with two payment points: the first for the receipt and evaluation of a submission, and the second for pricing and listing activities following a positive PBAC recommendation. A simple fee structure is proposed, in line with the existing submission categories, with which industry is already familiar.

Information Sessions for the pharmaceutical industry on implementation of the measure were held in both Sydney and Melbourne in June 2008 to provide information about fees and administrative processes that will operate once the regulations come into effect.

The Department has established a consultative mechanism with industry, specifically on cost recovery arrangements and has already had the first of those meetings with Medicines Australia and the Generic Medicines Industry Association on 3 June 2008.