PBS
COST RECOVERY:
ADMINISTRATIVE GUIDELINES

INFORMATION FOR APPLICANTS

Version 1.0: 12 July 2010
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Version 1.0: 12 July 2010
In this document, unless otherwise specified, a reference to the Act is a reference to the *National Health Act 1953* and a reference to the Regulations is a reference to the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009.*

Questions or comments regarding PBS Cost Recovery fees should be directed to the Cost Recovery team, Pharmaceutical Evaluations Branch, Pharmaceutical Benefits Division, Department of Health and Ageing:

[PBSCostRecovery@health.gov.au](mailto:PBSCostRecovery@health.gov.au)

1.1 Background
In December 2002 the then Australian Government adopted 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, July 2005*, along with Finance Circular 2005/09. Finance Circular 2008/08 further clarifies the governmental oversight of the cost recovery policy. 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 services will be provided to an identified group and where charging is consistent with Australian Government policy objectives.

The cost recovery policy applies to:
- all agencies subject to the *Financial Management and Accountability Act 1997* (FMA Act); and
- to relevant bodies subject to the *Commonwealth Authorities and Companies Act 1997* (CAC Act), that have been notified, under sections 28 or 43 of the CAC Act, that they are to apply the cost recovery policy.

These entities are collectively referred to as ‘agencies’ for the purposes of the *Australian Government Cost Recovery Guidelines*. In accordance with the policy, individual portfolio ministers are ultimately responsible for ensuring agencies’ implementation and compliance with the cost recovery guidelines.

1.2 Cost Recovery in the context of the Pharmaceutical Benefits Scheme
Pharmaceutical Benefits Scheme (PBS) cost recovery is a Budget and efficiency measure that has been approved by Parliament.

Cost recovery of the process to gain PBS listing is considered to be an efficient and cost-effective mechanism for funding the listing process, because:
- it is considered possible to establish a fee that links the cost of activities and services provided to sponsors; and
- it is considered administratively efficient to recover fees from sponsors seeking to list drugs on the PBS or vaccines on the National Immunisation Program (NIP).

2. Pre-Submission Meetings

2.1 Overview
If a potential applicant wishes to list a drug on the PBS, preliminary discussion should occur with the PBAC Secretariat at a pre-submission meeting.

The Secretariat will provide preliminary advice to the potential applicant on:
- the application process;
• the submission category for the prospective application, and the fee that may be payable for that submission category (see Section 3);
• whether or not the type of submission is exempt from the fee process (see Section 5.1); and
• the circumstances under which a submission fee waiver may be granted (see Section 5.2).

During pre-submission discussions between the applicant and the Department, the Department can provide advice about the fee waiver process and whether an application appears to fit within the fee waiver category. However, the PBAC Secretariat cannot give any assurance that a fee waiver will be approved if sought.

There is no separate fee payable for requesting a pre-submission meeting.

Pre-submission meetings to discuss a submission, including a possible fee waiver, can take place at most times before lodgment of the actual submission for PBAC consideration. However, pre-submission meetings are not available in the week prior to the deadline for submitting a major submission.

2.2 Who can apply for a PBS listing?
An application may be submitted by industry, medical bodies, health professionals, private individuals or their representatives. In practice, however, the applicant is usually a pharmaceutical company, as represented by a suitably authorised employee. This applicant is known in the PBAC process as the ‘responsible person’ or ‘sponsor’ in respect of that application.

2.3 Contact details for the PBAC Secretariat

Phone
+61 2 6289 7099

Fax
+61 2 6289 4175

Mail
PBAC Secretariat
MDP 952
Pharmaceutical Evaluation Branch
Department of Health and Ageing
GPO Box 9848
CANBERRA ACT 2601

Email
PBAC@health.gov.au

3. Fees for PBS Cost Recovery

3.1 Process
There are two key payment points – lodgment and pricing. There is also a fee payable should an independent review of a PBAC decision not to recommend an initial listing be requested.
The interaction between fee payments, the PBS listing process and relationships is outlined in the following flow diagram:

### 3.2 What are the types of fees?

The PBS cost recovery fee categories are defined in the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009*.


The definitions in the Regulations are explained in the *Explanatory Statement (Minute No. 42 of 2009)*.


The Regulations and the Explanatory Statement do not introduce any changes to the way the PBAC, the Pharmaceutical Benefits Pricing Authority (PBPA) or the PBS Independent Review Convener evaluate submissions.

#### 3.2.1 Evaluation fee

The evaluation fee relates to the evaluation work of the (PBAC) and all its supporting administrative functions. The PBAC evaluation fee includes the evaluation work, if any, of the Drug Utilisation Sub-Committee (DUSC) and the Economics Sub-Committee (ESC).
There are three lodgment fee categories: Major, Minor and PBAC Secretariat listing. The categorisation reflects the amount of work required to complete the assessment tasks within each application category type.

<table>
<thead>
<tr>
<th>Evaluation Fee Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBAC Evaluation – Major</td>
<td>In general, a major application seeks to list new drugs or medicinal preparations for PBS subsidy, or to make substantial changes to current listings. An application for a variation to an existing listing may also be major if it requires the PBAC to apply a health advantage test (as defined in Regulation 2.4). Major evaluations are complex evaluations of drugs for which PBS-listing will have significant financial implications.</td>
</tr>
<tr>
<td>PBAC Evaluation – Minor</td>
<td>In general, minor applications include those for new forms of an already listed drug or medicinal preparation, or changes to the conditions of the prescription or supply of an already listed drug or preparation. These applications involve changes to existing items that do not have significant cost implications but that do require consideration by PBAC for clinical effectiveness and/or potential impact on the PBS.</td>
</tr>
<tr>
<td>PBAC Secretariat Listing</td>
<td>These are a subset of minor applications that are straightforward and not considered as a separate agenda item at a meeting of the Committee. The Committee would still decide the merit of each application. They may be considered in or out of session by the PBAC.</td>
</tr>
</tbody>
</table>

Applicants will be forwarded an evaluation fee invoice following lodgment of a submission.

### 3.2.2 Pricing fee

The pricing fee relates to the pricing work of the PBPA and supporting functions. Applicants are required to pay the pricing fee after the decision of the PBPA and following successful pricing negotiations. The pricing fee category will not necessarily mirror the evaluation fee category, but will reflect the extent of the work required of the PBPA.

There are three categories of pricing fees: Complex, Simple and Pricing Authority Secretariat.
### Pricing Fee Category

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complex</td>
<td>‘Complex’ pricing assessments usually require negotiation and one or more of the following:</td>
</tr>
<tr>
<td></td>
<td>- Involve an increase in the cost to Government;</td>
</tr>
<tr>
<td></td>
<td>- The PBAC did not accept all of the applicant’s claims, usually in relation to the comparator;</td>
</tr>
<tr>
<td></td>
<td>- There is a conditional recommendation from the PBAC (that is Deed(s) of Agreement apply).</td>
</tr>
<tr>
<td>Simple</td>
<td>‘Simple’ pricing assessments in general are those that do not involve an increased cost to the government as a result of listing the medicine or vaccine.</td>
</tr>
<tr>
<td>Pricing Authority</td>
<td>An application is in the Pricing Secretariat pricing category if it is neither complex nor simple.</td>
</tr>
</tbody>
</table>

Applicants will be forwarded a pricing fee invoice following completion of pricing negotiations.

#### 3.2.3 Generic listing fee

This fee applies to a request for the listing of a new brand (generic) of an existing listed pharmaceutical item on the PBS. The fee reflects the administrative work required. A generic listing request may be applicable where there is bioequivalent or biosimilar certification from the Therapeutic Goods Administration.

An application in respect of a new brand listing for somatropin or a glucose indicator requires PBAC evaluation, and may have implications in regards to the pricing fee required to be paid (Regulations 2.9 and 2.13; Schedule 1, Part 3; Schedule 2).

<table>
<thead>
<tr>
<th>Fee Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>New brand of existing pharmaceutical item</td>
<td>Where a new product is listed on the PBS because it is bioequivalent or biosimilar and the price is already determined by an existing item.</td>
</tr>
<tr>
<td></td>
<td>However, if the application is in respect of a product listed in Schedule 2 of the Regulations, it is deemed to be an exception under Regulations 2.9 or 2.13, and is reclassified as PBAC Evaluation – Minor or PBAC Secretariat Listing eg somatropin or glucose testing strips.</td>
</tr>
</tbody>
</table>

#### 3.2.4 Independent review fee

The Independent Review (PBS) was established as part of Australia’s agreed commitments to the Australia-United States Free Trade Agreement. Independent Review (PBS) provides an opportunity for review to occur when an application to the PBAC after 1 January 2005 does not result in a PBAC recommendation for inclusion of a product in the Schedule of
Pharmaceutical Benefits. This fee relates to the work undertaken by the Independent Review (PBS) in completing a full review of an unsuccessful application. Applicants are required to pay the independent review fee at the time a submission is made to the independent review convener.

<table>
<thead>
<tr>
<th>Fee Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent Review</td>
<td>Independent review is available for applicants where:</td>
</tr>
<tr>
<td></td>
<td>- the PBAC has declined to recommend the listing of a drug on the Pharmaceutical Benefits Scheme; or</td>
</tr>
<tr>
<td></td>
<td>- in certain circumstances, where the PBAC has not recommended a change in circumstances in which a prescription may be written for the supply of the existing pharmaceutical benefit.</td>
</tr>
<tr>
<td></td>
<td>Refer to the website <a href="http://www.independentreviewpbs.gov.au">http://www.independentreviewpbs.gov.au</a> for additional information.</td>
</tr>
</tbody>
</table>

### 3.3 What are the fees that are payable?

#### Evaluation Fee Category

<table>
<thead>
<tr>
<th>Evaluation Fee Category</th>
<th>Fee Payable</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBAC Evaluation – Major</td>
<td>$A119,500</td>
</tr>
<tr>
<td>PBAC Evaluation – Minor</td>
<td>$A12,500</td>
</tr>
<tr>
<td>PBAC Secretariat Listing</td>
<td>$A1,000</td>
</tr>
</tbody>
</table>

#### Fee Category

<table>
<thead>
<tr>
<th>Fee category</th>
<th>Fee Payable</th>
</tr>
</thead>
<tbody>
<tr>
<td>New brand of existing pharmaceutical item (generic)</td>
<td>$A500</td>
</tr>
</tbody>
</table>

#### Pricing Fee Category

<table>
<thead>
<tr>
<th>Pricing Fee Category</th>
<th>Fee Payable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complex</td>
<td>$A25,000</td>
</tr>
<tr>
<td>Simple</td>
<td>$A6,000</td>
</tr>
<tr>
<td>Pricing Secretariat</td>
<td>$A1,000</td>
</tr>
</tbody>
</table>

#### Fee Category

<table>
<thead>
<tr>
<th>Fee Category</th>
<th>Fee Payable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent Review</td>
<td>$A119,500</td>
</tr>
</tbody>
</table>

All fees are deemed to be exempt from GST under Division 81-5 Treasurer’s Determination of the *A New Tax System (Goods and Services Tax) Act 1999*. 
4. Lodgment of Submissions to the PBAC

4.1 What processes specific to cost recovery must be undertaken at the time of submission to the PBAC?

Applicants must download a copy of the PBS SERVICE FEE APPLICATION FORM: TO ACCOMPANY PBAC SUBMISSION (the Application Form) from the PBS website. A completed form must be lodged with every submission except submissions for new brand (generic) listings (see Section 6). The form provides essential information for the fee for service administration.

The applicant is to self-assess the submission fee category for the own application in the first instance. The Application Form includes a section for the applicant to indicate the evaluation fee category self-assessment.

The Application Form, once completed, must be signed by an authorised person within the company. It must be forwarded, with the submission, by the relevant deadline for the PBAC submission category.

The address for PBAC submissions is:

**Mailing address:**
PBAC Secretariat
MDP 952
Pharmaceutical Evaluation Branch
Department of Health and Ageing
GPO Box 9848
CANBERRA ACT 2601

**Physical address:**
PBAC Secretariat
Level 9
Sirius Building
23 Furzer Street
WODEN ACT

Once received by the Department, the Application Form will be separated from the actual submission. Neither the Application Form nor any record of the fee payment amount will be forwarded to the PBAC.

An evaluation category assessment will be undertaken by a departmental officer and authorised by a delegated officer having regard to the Guidelines for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee, and noting the evaluation category self-assessment indicated by the applicant. An invoice will be generated based on the departmental officer’s determination. The applicant will be notified in writing of the evaluation category once authorised by the departmental delegate. Applicants should not forward payment before receiving an invoice.

The invoice will be accompanied by a Request for Payment letter. The letter will include a Unique Identifying Number that should be quoted in all correspondence with the PBS Cost Recovery team pertaining to that submission. The Request for Payment letter will also provide advice on preferred payment methods.

The invoice will specify a payment period of 28 days. During this 28 day period, departmental processing of the submission will continue. If the invoice remains unpaid at the end of this period, the Department may discontinue processing of the submission until payment has been received and it may also commence debt recovery action.
An applicant who disagrees with the delegate’s evaluation category assessment may request a review of that assessment (see Section 12).

Following receipt by the department of a request for review of the evaluation category assessment, the Department may discontinue processing of the submission until completion of the review.

Requests for fee exemptions or waivers may be sought at the time of lodgment. Full supporting documentation must be included. For additional information regarding the circumstances under which a fee exemption or a waiver may be approved, see Section 5.

4.2 Does the PBAC consider all applications that are submitted?

While any person may submit an application, the PBAC will only consider submissions compiled in accordance with the current version of the Guidelines for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee.

The Guidelines are periodically updated. The current Guidelines can be viewed at www.pbs.gov.au/html/industry/static/how_to_list_on_the_pbs/elements_of_the_listing_process/pbac_guidelines

Applications received that are not in accordance with the Guidelines will not be forwarded to the PBAC by the PBAC Secretariat. The PBAC Secretariat will however contact the applicant and provide advice on application requirements under the Guidelines and highlight the types of additional information that may be required to complete the current application.
4.3 Cost Recovery and PBAC Submission Pathway

Applicant downloads and completes PBS SERVICE FEE APPLICATION FORM: TO ACCOMPANY PBAC SUBMISSION, including nomination of evaluation fee category.

Applicant prepares PBAC submission and forwards to PBAC Secretariat

PBAC Secretariat assesses submission and determines evaluation category – noting applicant’s self-assessment.

APPLICATION FORM and evaluation category assessment forwarded to PBS cost recovery.

Submission forwarded to the PBAC

Written notice to applicant outlining:
- Evaluation category;
- Fee payment amount;
- Payment method; and
- Rights of review.

No payment made by due date

Fee paid

Applicant requests review of evaluation category

Department may hold submission pending review

Department may hold submission pending payment

PBAC assessment of submission.
5. Evaluation Fee Exemptions and Waivers

5.1 Evaluation Fee Exemptions

There are limited occasions where a submission for listing on the PBS will be exempt from the payment of fees. Exemptions may apply in respect of Orphan Drugs, Temporary Supply of Drugs or Changes to an Existing PBS Listing. Instances where an exemption may apply are prescribed in the Regulations at Regulation 5.1: www.comlaw.gov.au/ComLaw/Legislation/LegislativeInstrument1.nsf/asmade/bytitle/DFFE E1C9B03CE5F0CA2576580018C003?OpenDocument

If applicable, an applicant is to indicate on the relevant section of the PBS SERVICE FEE APPLICATION FORM: TO ACCOMPANY PBAC SUBMISSION (the Application Form) that an exemption is being sought. Supporting documentary evidence that the drug falls within one of these groups must be provided at the time of the application.

Notwithstanding a request for exemption, an applicant is required to indicate on the Application Form the evaluation category that would apply in the absence of an exemption.

If the departmental delegate does not agree that grounds for exemption have been demonstrated, the applicant will be advised of the delegate’s decision within 14 days of receipt by the department of the application and supporting documentation.

5.1.1 Orphan Drugs

An orphan drug is one that is designated by the Secretary to be an orphan drug under Regulation 16J of the Therapeutic Goods Regulations 1990.

For a drug to be declared an orphan drug, it:

- must be intended to treat, prevent or diagnose a rare disease (where "rare disease" means a disease, or condition, likely to affect not more than 2,000 individuals in Australia at any time); or
- must not be commercially viable to supply to treat, prevent or diagnose another disease or condition.¹

5.1.2 Temporary Supply

Temporary supply relates to approval by the Secretary under Section 19A of the Therapeutic Goods Act 1989 for importation into Australia, or the supply in Australia, of specified therapeutic goods that are unavailable or are in short supply.

5.1.3 National Emergency

An exemption will apply if the Secretary considers that the supply of a drug or vaccine is necessary for the management of:

- a public health event of national significance²; or
- a public health emergency under section 2B or 12A of the Quarantine Act 1908.

5.1.4 Changes to existing PBS Listings

There are a number of PBS listing changes that do not attract a fee. These include:

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¹ Therapeutic Goods Regulations 1990, Regulation 16H
² A public health event of national significance is defined in section 3 of the National Health Security Act 2007.
• offering a price reduction;
• changing the manufacturer name;
• removing a product;
• changing pack size with no price implications; and
• Government mandated changes.

5.2 Evaluation Fee Waivers

A request for waiver of an otherwise applicable evaluation fee may be approved if:
• the submission involves a public interest component; and
• payment of the fee would make proceeding with the submission financially unviable.

The criteria under which a waiver may be granted are prescribed in the Regulations:
E1C9B03CE5F0CA2576580018C003?OpenDocument

and further defined in the Explanatory Statement to the Regulations:
E1C9B03CE5F0CA2576580018C003?OpenDocument&VIEWCAT=attachment&COUNT=999&START=1

5.2.1 Waiver requests before lodgment of a submission

A fee waiver cannot be approved before lodgment of a PBAC submission. However, the
Department can provide an early indication about whether a submission meets the criteria for
fee waiver approval if discussed at a PBAC pre-submission meeting.

Discussions on fee waiver at a pre-submission meeting should be supported by a short
document containing information on what the medicine, vaccine or other product seeks to do,
its benefit, the target population including estimated utilisation and a brief outline of the
anticipated financial viability of the application.

If an applicant has been invited to seek the listing of a medicine, vaccine or other product by
either PBAC or one of the Department’s health working groups, that information should also
be included with the waiver request.

At the pre-submission meeting, senior PBAC Secretariat staff will be able to provide an
initial, non-binding assessment against the waiver criteria. The provisional assessment will
permit the company to make a reasonably informed business decision whether or not to
proceed with developing the submission.

A company may seek further meetings before lodging the application to ensure the
submission still meets the provisional fee waiver criteria as the business case and data
particular to the submission develop over time.

5.2.3 Waiver requests at the time of, or following, lodgment of a
submission

At the time of submission an applicant may formally seek a waiver of fees. This must be
done by letter, attached to the PBS SERVICE FEE APPLICATION FORM: TO
ACCOMPANY PBAC SUBMISSION (the Application Form). Notwithstanding a fee
waiver request, the Application Form is to be completed according to the evaluation category
that would apply in the absence of a fee waiver.
Alternatively, an applicant may seek a fee waiver after submission; for example, following the PBAC evaluation and recommendation. Again, the request for waiver must be by letter, however an additional Application Form is not required.

Regardless of the timing of the request, the waiver request letter should be addressed to the Assistant Secretary, Pharmaceutical Evaluation Branch, and should outline the information supporting the request. Any documentary evidence in support of the waiver request should accompany the letter.

The fee waiver request will be assessed by the delegate against strict criteria. There may be liaison between the delegate, the applicant) and any relevant departmental area (for example, PBAC Secretariat, Generics, High Cost Drugs) to assist the delegate’s decision making.

The delegate’s decision and the reasons for that decision will be provided to the applicant within 14 days of receipt by the department of the waiver request.

The applicant may apply, in writing, for a review of a decision by a delegate to refuse the grant of a waiver (see Section 12).

6. New Brand (Generic) Applications

6.1 Overview

This section applies to applications for the listing of a new brand of an existing listed pharmaceutical item, where no PBAC evaluation is required.

Completion of a PBS SERVICE FEE APPLICATION FORM: TO ACCOMPANY PBAC SUBMISSION is not required for submissions for new brand (generic) listings.

These submissions are typically sent directly to the Publishing, Industry Liaison and Listing Section (PILLS) within the Pharmaceutical Evaluation Branch. The Listing Unit Requirements outline the information that needs to be submitted for these applications. The Listing Unit Requirements can be viewed at http://www.pbs.gov.au/html/industry/static/how_to_list_on_the_pbs/elements_of_the_listing_process/listing_unit_requirements

The address for the Listing Unit is as follows:

**Mailing address:**
- Listing Unit
- MDP 952
- Pharmaceutical Evaluation Branch
- Department of Health and Ageing
- GPO Box 9848
- CANBERRA ACT 2601

**Physical address:**
- Listing Unit
- Level 9
- Sirius Building
- 23 Furzer Street
- WODEN ACT

An applicant is not required to forward fee payment with the submission. Following receipt of the application and a departmental assessment of the fee category, a request for payment letter with an accompanying invoice will be forwarded to the Responsible Person nominated by the applicant.
The invoice will specify a payment period of 28 days. During this 28 day period, departmental processing of the submission will continue. If the invoice remains unpaid at the end of the period, the Department may discontinue processing of the submission until payment has been received and it may also commence debt recovery action. Should an applicant request review of the fee category assessment, the Department may similarly discontinue processing of the submission until completion of the review.

If the applicant requests a fee waiver (see Section 5.2), processing will continue pending the delegate’s decision. If the waiver is not approved by the delegate, and payment has not yet occurred, the Department may discontinue processing the application until the fee has been paid.

7. Withdrawal of the Submission by the Applicant

7.1 Withdrawing a submission
The applicant may withdraw a submission by written notice to the department.

However, for an invoice to be cancelled or for a refund of any evaluation fee to occur, the submission must be withdrawn within 14 days of the applicant’s receiving notice of the fee required to be paid.

If the submission has been withdrawn within 14 days of receipt of the fee notice, and the invoice remains unpaid, the invoice will be cancelled.

If the submission has been withdrawn within 14 days of receipt of the invoice, and the invoice has been paid, the fee will be refunded.

If the submission is withdrawn more than 14 days after the date of receipt by the applicant of the notice of the fee required, the applicant will remain liable for those fees.

8. Request for Independent Review of a PBAC Listing Decision

8.1 Requesting an independent review
The Australia-United States Free Trade Agreement provides an opportunity for independent review of decisions by the PBAC where an application has not resulted in the Committee making a recommendation to list a drug on the PBS. Independent review may also be available in other circumstances in accordance with material on the Independent Review PBS website.

As of May 2009, Independent Review is also available in certain circumstances where the Committee, having considered new evidence or additional information in respect of an existing pharmaceutical benefit, has declined to recommend a change in circumstances in which a prescription may be written for the supply of the existing pharmaceutical benefit. Further information about independent review is available at the Independent Review (PBS) website at http://www.independentreviewpbs.gov.au
The independent review process is managed by the Convener of the Independent Review (PBS) on an arm’s-length basis from the Department, industry and other stakeholders. The Convener selects and contracts reviewers to undertake reviews and is responsible for the timely and efficient operation of the independent review process. At the completion of a review, the Convener provides a reviewer’s report to PBAC which will reconsider the applicant’s submission in light of the findings of the review. Decisions on which drugs are listed remain in the hands of the Government on advice from the PBAC.

The Government has regulated that the cost of this activity is recovered from the applicant on a cost reflective basis. A flat review fee has been set for the independent review process.

9. Pricing Fees Following a PBAC Recommendation for Listing

9.1 Pricing fees
Following a positive recommendation for listing by the PBAC, a fee is payable by the applicant for the pricing work of the PBPA and its supporting functions once that work is completed.

The pricing category will not necessarily mirror the evaluation category, but will reflect the extent of the work required of the PBPA. A pricing category assessment will be undertaken by a departmental officer and authorised by a delegated officer. A payment invoice will be generated based on this assessment. The applicant will be notified in writing of the pricing category once authorised by the departmental delegate. Applicants should not forward payment before receiving an invoice.

The invoice will be accompanied by a Request for Payment letter. The letter will include a Unique Identifying Number that should be quoted in all correspondence with the PBS Cost Recovery team. The Unique Identifying Number will be the same as that issued on submission of the application to the PBAC. The Request for Payment letter will also provide advice on preferred payment methods.

The invoice will specify a payment period of 28 days. During this 28 day period, departmental processing of the submission will continue according to usual practices. If the invoice remains unpaid at the end of this period, the Department may commence debt recovery action and may refuse to consider any other application submitted by the applicant.

An applicant who disagrees with the delegate’s pricing category assessment is able to request a review of that assessment (see Section 12).

Following receipt by the department of a request for review of the pricing category assessment, the department may discontinue processing of the submission until completion of the review.

10. Pricing Fee Exemptions and Waivers

10.1 Pricing Fee Exemptions
If a fee exemption has previously been approved in respect of the PBAC evaluation of the submission, it is assumed that the circumstances which permitted that approval will continue
to apply with respect to the pricing process. A separate application for a pricing fee exemption is not necessary.

10.2 Pricing Fee Waivers
An applicant may formally seek a waiver of pricing fees. This must be done by letter, addressed to the Assistant Secretary, Pharmaceutical Evaluation Branch, and outlining the supporting information behind the request.

A waiver may be approved if:
- the submission involves a public interest component; and
- payment of the fee would make proceeding with the submission financially unviable.

A fee waiver may have been approved, at lodgment, for the PBAC evaluation of the submission. However, this approval applies in respect of the PBAC evaluation process only and does not apply with respect to the pricing process. At the time of pricing, an applicant may indicate that a waiver is also sought in respect of the pricing process and may wish to rely on the same reasons and the same documentary evidence.

Alternatively, an applicant may have declined to seek a fee waiver in respect of the PBAC evaluation process, but now wishes to do so in respect of the pricing process. This may occur, for example, when a submission seeks an unrestricted listing, but the PBAC has recommended a restricted listing which the applicant claims could adversely impact on the financial viability of the product should there also be a requirement for pricing fee payment.

The pricing fee required to be paid will be determined by the complexity of the pricing negotiations. A request for pricing fee waiver can only be assessed by the departmental delegate on completion of those negotiations; that is, once the fee has been ascribed. An applicant may choose to submit a waiver request before completion of the negotiations, however the delegate will be unable to consider the request until the fee amount is determined.

The fee waiver request will be assessed by the delegate against strict criteria. There may be liaison between the delegate, the applicant and any relevant departmental area (for example, Pricing section, High Cost Drugs section) to assist the delegate’s decision making.

The delegate’s decision and the reasons for that decision will be provided to the applicant.

An applicant may apply in writing for a review of a decision by a delegate to refuse the grant of a waiver (see Section 12).

11. Listing a Product on the PBS

11.1 PBS Listing
A separate fee payment is not required for listing, except for new brand (generic) listings (see Section 6).

Expenses relating to the listing process are included in the total fee for the evaluation of a submission.
However, applicants should note that the Department may discontinue processing of a submission if PBS cost recovery fees payable in respect of that submission, or in respect of other submissions from the same applicant, remain unpaid beyond the specified invoice payment periods.

The Listing Unit Requirements can be viewed at http://www.pbs.gov.au/html/industry/static/how_to_list_on_the_pbs/elements_of_the_listing_process/listing_unit_requirements

Further information can be obtained by contacting the Listing Unit.

The address for the Listing Unit is as follows:

**Mailing address:**
Listing Unit  
MDP 952  
Pharmaceutical Evaluation Branch  
Department of Health and Ageing  
GPO Box 9848  
CANBERRA ACT 2601

**Physical address:**
Listing Unit  
Level 9  
Sirius Building  
23 Furzer Street  
WODEN ACT

## 12. Review of a Departmental Decision Regarding Fees

### 12.1 Internal Review

An applicant may apply for internal review of a decision made by the department about:
- the evaluation category of an application, and hence the evaluation fee payable;
- the pricing category of an application, and hence the pricing fee payable; or
- the waiver of a fee.

A request for internal review must be made, in writing, within 14 days of the applicant’s receiving notice of the department’s decision and must set out the grounds on which the applicant relies.

The original decision maker (or if he or she is not available, another authorised officer) must, within 14 days of receipt of the request, review the decision and give written notice to the applicant of the review decision.

The applicant may, within 14 days of receipt of notice of this decision, apply in writing to the Secretary for review of this decision.

This second review must be by an officer not involved in the first decision. That review officer must, within 14 days of receipt of the request for the second review, review the decision and give written notice to the applicant of the second review decision.

Whilst the internal review process is being undertaken, the department will “hold the clock” in terms of due date for payment of any invoice already issued about which the review applies.
The department may discontinue processing the relevant submission until the internal review process has been completed.

12.2 External review
An applicant who disagrees with the second internal review decision may apply to the Administrative Appeals Tribunal for a further review.

The department may discontinue processing the relevant submission until the external review process has been completed.
**12.3 Review process**

**A. Internal Review of Evaluation Category**
Applicant forwards PBAC submission to the PBAC Secretariat accompanied by the completed fee Application Form.

Department receives submission and assigns fee category. Invoice and request for payment letter sent to the applicant.

Applicant has:
- **28 days** from date of invoice to pay the required fee or
- **14 days** from lodgment date to withdraw application from evaluation process and not incur a fee.

**B. Internal Review of Pricing Category**
Submission progresses to Pricing following PBAC recommendation for listing.

On completion of pricing negotiations, Department assigns pricing fee category. Invoice and request for payment letter sent to applicant.

**C. Internal Review of Refusal to Approve Fee Waiver**
Applicant submits a request for waiver of a PBS cost recovery fee with their application.

Departmental delegate does not approve the grant of a waiver. Explanation is sent to applicant. Invoice and request for payment letter sent to the applicant.

Applicant may request review from the Administrative Appeals Tribunal.

**Version 1.0: 12 July 2010**
### 13. Contacts

**Physical address:**
Pharmaceutical Evaluation Branch  
Pharmaceutical Benefits Division  
Department of Health and Ageing  
Sirius Building  
23 Furzer Street  
WODEN  ACT

| PBAC Secretariat: |  
|------------------|---|
| **Phone**        | +61 2 6289 7099  
| **Fax**          | +61 2 6289 4175  

<table>
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<th><strong>Mail</strong></th>
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<tbody>
<tr>
<td>PBAC Secretariat</td>
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<td>MDP 952</td>
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| Pharmaceutical Evaluation Branch  
| Department of Health and Ageing  
| GPO Box 9848     |  
| CANBERRA  ACT 2601 |  

**Listing Unit:**

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| Department of Health and Ageing  
| GPO Box 9848         | 23 Furzer Street  
| CANBERRA  ACT 2601      | WODEN  ACT  |