PBS/NIP listing cost recovery administrative guidelines: information for applicants

Version 6.0 July 2023

Australian Government

Department of Health and Aged Care

Title: PBS/NIP listing cost recovery administrative guidelines: information for applicants

Contents

1 Australian Government Charging Framework

In December 2002, the Australian Government adopted a cost recovery policy to improve the consistency, transparency and accountability of its cost recovery arrangements and promote the efficient allocation of resources.

Cost recovery involves government entities charging individuals or non-government organisations some or all of the efficient costs of a specific government activity. This may include goods, services or regulation, or a combination of these. In 2015, the Australian Government implemented revised Australian Government Cost Recovery Guidelines which set out the framework under which government entities design, implement and review cost-recovered activities.

The Australian Government Charging Framework applies to non-corporate and corporate Commonwealth entities as defined in the *Public Governance, Performance and Accountability Act 2013 (PGPA Act).* The Department of Health and Aged Care (the Department) is a non-corporate Commonwealth entity.

The Australian Government's cost recovery policy is that, where appropriate, non-government recipients of specific government activities should be charged some or all of the cost of those activities.

1.1 Associated legislation and documentation

In this document, unless otherwise stated, the:

- Act refers to the *National Health Act 1953.*
- Regulations refers to the National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022.
- CRIS refers to the Cost Recovery Implementation Statement.
- Procedure Guidance refers to the Procedure Guidance for listing medicines on the Pharmaceutical Benefits Scheme (including consideration of vaccines for the National Immunisation Program).
- PBS calendar refers to the PBAC cycle timeframe for each calendar year and outline of PBS related activities surrounding the PBAC meeting cycles.
- Submission due day is the date by which the Department needs to have received applications for a specified evaluation category for the PBAC meeting that is to consider that application. The submission due day for applications in one evaluation category could be different from that for applications in another evaluation category.

For completeness, this document should be read in conjunction with the Regulations, the Procedure Guidance, and the CRIS.

2 PBS/NIP cost recovery

Effective 1 January 2021, the cost-recoverable services for Pharmaceutical Benefits Scheme (PBS)/National Immunisation Program (NIP) listing and management are:

- Australian Technical Advisory Group on Immunisation (ATAGI) pre-submission advice;
- PBAC pre-submission meetings;
- Submission services (submissions and resubmission pathways) and Notice of Intent (previously Intent to Apply) for submission services);
- Pricing services (pricing pathways) and Notice of Intent for pricing;
- PBS list management services; and
- Independent reviews.

The PBS cost recovery fee categories are defined in the Regulations.

The Cost Recovery Implementation Statement (CRIS) provides information on how the Department is implementing the revised cost recovery arrangements announced by the Australian Government in October 2020 and applied from 1 January 2021.

Questions or comments regarding management of cost recovery fees and administrative processes for PBS/NIP listing should be directed to the Cost Recovery Unit (refer to contact details in Section 12).

2.1 Notification (including invoicing of fees)

After receiving a submission or application for a cost-recoverable service, the Department will issue a notice (i.e., a letter and invoice) to the primary contact outlined in the submission or application (referred to as the 'applicant' for the purposes of this document). Further information on the timing for issue of a notification is outlined within Sections 3 to 8 below.

The notification (or 'notice') will include:

- confirmation of receipt of the application or submission
- category of the application or submission as proposed by the applicant
- if requested, the outcome of any fee exemption/waiver application (refer to Section 9)
- invoice for fees payable or refundable
- due date of invoice
- manner for payment of fees
- the applicant's review rights under Part 6 of the Regulations.

All invoices will be accompanied by a notice as described above. The letter will include a Unique Identifying Number that should be quoted in all correspondence with the Cost Recovery Unit pertaining to that application. The cover letter will also provide advice on preferred payment methods.

Fees are due in full by the due date as specified in the invoice. The Department may accept payments by instalments, if agreed to in writing by the Secretary or a delegate.

2.2 Payment terms

All fees payable for cost-recoverable services are payable in Australian dollars.

All days or weeks in this document are business days, unless otherwise noted.

Payment terms are 28 calendar days from the date of notification of fees to the applicant.

Applicants are responsible for payment of all invoices issued. All invoices must be paid before an item is listed on the PBS or NIP.

If the applicant's payment exceeds the fee, the Department will refund the difference within 20 business days of whichever is later of:

- the day of the payment by the person of the fee amount; or
- the day of the notice to the applicant of the amount payable.

2.3 Applicant withdrawals and refunds

Applicants may withdraw an application or submission at any time, by written notice to the Department. The applicant must notify the relevant area within the Department of their withdrawal. Contact details for all relevant areas can be found in the Procedure Guidance under *Appendix A – Information sources and contacts*.

If an application is withdrawn more than 10 business days after the notification of fees is provided, the applicant will remain liable for those fees.

2.4 Requests for review

Applicants may request a review of decisions associated with some cost recoverable services, see Sections 10 and 11.

2.5 Delays in paying fees

If a fee is not paid within the payment term specified in the notice, the Department may do either, or both, of the following until the fee is paid or no longer payable:

- refuse to consider any application sent (or to be sent) by the applicant under the Regulations; and
- refuse to provide any services relating to such an application.

The Department could, instead of or in addition to refusing to do these things, seek to recover the unpaid fee as a debt (see subsection 99YBA(5) of the Act).

Applicants should note that the Department may halt processing of a submission if 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.

3 Australian Technical Advisory Group on Immunisation (ATAGI) pre-submission advice

ATAGI pre-submission advice (evaluations) is provided as part of the NIP listing process. ATAGI evaluations assess the suitability of a vaccine for the NIP. These evaluations involve the analysis and review of complex clinical, vaccinology and epidemiological data.

Details of the application process and timelines for requesting ATAGI advice are available on the Department's website.

3.1 Fees for ATAGI evaluations

The fees for ATAGI evaluations are specified in the Regulations and are outlined on the PBS cost recovery webpage. Fees are charged based on the following categories:

1. NIP - Complex Category applications; and
2. NIP - Simple Category applications.

The complex category fee will be invoiced unless an applicant receives the Secretary or a delegate's agreement in writing that the application meets the criteria for simple category. Requests for simple category ATAGI application must be sought in writing. The Department recommends that applicants wishing to request a simple category ATAGI application should seek a meeting with the ATAGI Secretariat in advance of lodging their Notice of Intent to discuss whether their proposal meets the criteria in the Regulations for simple categorisation.

A fee waiver or fee exemption may apply for eligible applications – refer to Part 7 of the Regulations. Fee waiver requests for ATAGI advice must be requested as part of the Notice of Intent for ATAGI services or in an ATAGI application if the Notice of Intent is not required. Where a fee waiver or fee exemption is granted for ATAGI advice, any fees paid will be refunded. An invoice will only be raised if the fee exemption or waiver is not granted.

The ATAGI procedures document is available on the Department's website which outlines the criteria for complex and simple applications.

Administrative deposit amount

A non-refundable administrative deposit is included in the total fee amount for both ATAGI application categories.

Applicants remain liable for the administrative deposit fee whether or not a fee had been paid prior to withdrawal of a Notice of Intent or ATAGI application.

This also applies if the Department refuses to accept an application. The fee (if any) that is paid for providing services in response to the application will be refunded, except the administrative deposit fee.

3.2 Notice of Intent for ATAGI advice

The Notice of Intent process is a mandatory first step in the submission process for all applications requesting ATAGI advice. Applicants are required to provide a Notice of Intent to the Department in relation to an ATAGI submission at least 10 business days before the ATAGI application due date.

ATAGI will not provide advice in response to the ATAGI application if a Notice of Intent in relation t**o** the ATAGI application was not given, unless a Notice of Intent was not required because of an urgent public health need.

Notice of Intent exception if an urgent public health need

Where the Notice of Intent form would otherwise apply to an application to ATAGI, but has not been submitted, the Secretary or delegate may decide that providing ATAGI application services without prior notice is necessary to address an urgent public health need. An applicant must provide justification for this exception when lodging their application to ATAGI.

The Department will notify the applicant in writing whether or not the Notice of Intent exception is granted.

The notice will include an invoice for the fees payable for application for the applicant's nominated category. Where the Department does not agree to grant a Notice of Intent exception, the applicant will be required to re-submit their application following the Notice of Intent process and timelines for the next ATAGI application date. The Department's decision regarding an urgent public health need is a reviewable decision under Part 8 of the Regulations.

Simple Category application requests

If simple categorisation of an ATAGI application is requested, the reasons for the request must be lodged with the Notice of Intent form. Where a Notice of Intent form is not required, and simple categorisation has been requested, the request and the reasons for the request must be lodged with the ATAGI application – refer to Section 3.4 below and/or Section 8 of the Regulations.

Fee waiver or fee exemption requests

If a fee waiver or fee exemption is requested, the supporting evidence must be lodged with the Notice of Intent form. Where a Notice of Intent form is not required, and a fee waiver or fee exemption has been requested, the supporting evidence must be lodged with the application requesting ATAGI advice – refer to Section 3.4 below and/or Part 7 of the Regulations.

3.3 Notification timing

The Department will issue a notice within 15 business days after lodgement of a Notice of Intent to request ATAGI advice.

In instances where an applicant seeks to make an ATAGI application to which Notice of Intent is not required, the Department will issue a notice within 15 business days of receiving the ATAGI application.

Simple categorisation requests

If the Notice of Intent or, the ATAGI application where Notice of Intent is not required due to an urgent public health need, requests simple categorisation, the Department will issue a notice within 15 business days of receiving the ATAGI application. This notification will notify applicants of the simple categorisation request decision and an invoice will be provided for payment. This notification will also give the applicant information on their review rights under Part 8 of the Regulations.

Fee waiver or fee exemption requests

If the Notice of Intent includes a request for a fee waiver or fee exemption, the notice issued by the Department will also notify applicants of the fee waiver or fee exemption decision, and where a

waiver or exemption is not granted, an invoice will be provided for payment. This notification will also give the applicant information on their review rights under Part 8 of the Regulations. If a Notice of Intent also includes a request for simple categorisation, in addition to a fee waiver or fee exemption request, the invoice for payment will be provided 15 days after the ATAGI application is received.

If a Notice of Intent is not required due to an urgent public health need, and a fee waiver or fee exemption request is made with the ATAGI application, the Department will issue a notice 15 business days after receiving the ATAGI application. This notification will notify applicants of the fee waiver or fee exemption decision, and where a waiver or exemption is not granted, an invoice will be provided for payment. This notification will also give the applicant information on their review rights under Part 8 of the Regulations.

3.4 Withdrawal

Applicants may withdraw a Notice of Intent or an application requesting ATAGI advice at any time by written notice to the relevant area of the Department (refer to Appendix A of the Procedure Guidance).

If the Notice of Intent or application requesting ATAGI advice is withdrawn within 10 business days from the date the notification is given, the Department will process a refund for any fee paid except the amount of the administrative deposit included in the fee amount. If no fee amount was paid before the withdrawal, a fee for the provision of administrative services by the Department in relation to the Notice of Intent or the ATAGI application will be payable.

4 Pre-submission meetings

Pre-submission meetings are available at the request of the applicant. The aim is to provide the potential applicant with preliminary advice to assist in the preparation of uncertain or complex submissions.

Applicants must request a pre-submission meeting by lodging a Pre-submission Meeting Request Form in the Health Products Portal (HPP). After considering the meeting application, the Department may agree or not agree to hold the pre-submission meeting.

4.1 Fees for holding pre-submission meetings

The fees for pre-submission meetings are specified in the Regulations and are outlined on the PBS cost recovery webpage. Fees are charged based on the following categories:

1. PBAC – First meeting; and
2. PBAC – Second or subsequent meeting.

The Regulations provide that an applicant may remake a pre-submission meeting request in the same or an amended form. A remade application is treated as a new application under the Regulations. A new fee would also be charged by the Department in response to a remade application.

The fee for a second or subsequent meeting will only apply if a first meeting had been previously convened and invoiced in relation to the submission.

Fee waivers or fee exemptions do not apply for pre-submission services.

4.2 Notification Timing

The Department will issue a notice within 10 business days after lodgement of a pre-submission meeting application.

If a decision is made to hold a pre-submission meeting more than 30 business days before the intended meeting date, the Department will issue a notice not more than 20 business days before the scheduled meeting date.

4.3 Withdrawal

Applicants may withdraw a pre-submission meeting application at any time prior to the last business day before the scheduled meeting date by written notice to the relevant area of the Department (refer to Appendix A of the Procedure Guidance).

The Department will refund any fee paid if the meeting request is withdrawn on or before the last business day prior to the scheduled meeting date.

5 Submission services (including Notice of Intent)

No medicine can be listed (or have its listing amended) on the PBS or the NIP, unless the PBAC makes a positive recommendation. The PBAC has two sub-committees: the Drug Utilisation Sub Committee (DUSC) and the Economics Sub Committee (ESC) to assist with analysis and advice.

Submission services are provided by the Department in response to an applicant's submission (or resubmission) to the PBAC or application for a Generic Listing of a new brand of an existing pharmaceutical item.

Applicants must request submission services via lodgement of an Notice of Intent form and submission (application) through the HPP. Refer to the Procedure Guidance for information on the application process and details on lodging a submission or a resubmission to the PBAC.

5.1 Fees for submissions and resubmission pathways

Fees for submission services are specified in the Regulations and are outlined on the PBS cost recovery webpage. Fees are charged based on the following evaluation categories and resubmission pathways:

Submission Categories

- Category 1;
- Category 2;
- Category 3;
- Category 4;
- Committee secretariat; and
- Generic Listing of a new brand of existing pharmaceutical item – refer to Section 5.3 below for information on the notification timing and withdrawal.

Resubmission Pathways

Following a 'not recommended' PBAC outcome, the following pathways for PBAC reconsideration apply:

- Standard Re-entry Pathway;
- Early Re-entry Pathway;
- Early Resolution Pathway; and
- Facilitated Resolution Pathway.

Refer to Part 3 of the Regulations or the Procedure Guidance for information on submission categories and resubmission pathways.

Fee amounts

Applicants are required to nominate their proposed submission evaluation category and provide reasons for this category nomination or accept (or not) a PBAC nominated Resubmission Pathway via the Notice of Intent form – see Section 5.2 below. Applicants will be invoiced based on their nominated submission evaluation category or resubmission pathway.

An application for submission services may include more than one request, but only if each of the requests relates to the same drug, medicinal preparation, or vaccine; and to the same disease or disorder that is the subject of the proposed therapy. If the application is for more than one request, the evaluation category of the application is determined by the earliest of the Regulations set out in Division 2, unless the submission is resubmitted. The evaluation category of a resubmission may depend on matters not resolved by the previous submission.

A fee waiver or fee exemption may apply for eligible submissions – refer to Section 9 below and/or Part 7 of the Regulations. For submission services, fee waiver or fee exemption requests must be made through the Notice of Intent form – see Section 5.2 below.

Administrative deposit amount

A non-refundable administrative deposit is included in the total fee amount for all evaluation categories except applications for a Generic Listing of a new brand or new oral form of an existing pharmaceutical item.

The Regulations provide for the following administrative deposit amounts:

1. For all submissions to the PBAC – the administrative deposit fee; and
2. For Facilitated Resolution Pathway – the administrative deposit fee and workshop fee.

Applicants remain liable for the administrative deposit fee whether or not a fee had been paid prior to withdrawal of an Notice of Intent or submission.

This also applies if the Department refuses to accept a submission. The fee (if any) that is paid for providing services in response to the submission will be refunded, except the administrative deposit fee.

5.2 Notice of Intent

The Notice of Intent process, is a mandatory first step in the submission process for all applications for consideration by the PBAC. Notice of Intent lodgement timeframes vary – refer to the Procedure Guidance.

There are two instances where an Notice of Intent form is not required:

1. if the application is in the 'Generic Listing of a new brand or oral form of existing pharmaceutical item' evaluation category – refer Section 9; or
2. Where an urgent public health need exists.

Notice of Intent exception if an urgent public health need

Where the Notice of Intent form would otherwise apply to a submission (or resubmission) to the PBAC, but has not been submitted, the Secretary or delegate may decide that providing submission services without prior notice is necessary to address an urgent public health need. An applicant must provide justification for this exception when lodging their submission (or resubmission) to the PBAC via the HPP.

The Department will notify the applicant in writing whether or not the Notice of Intent exception is granted.

The notice will include an invoice for the fees payable for submission services for the applicant's nominated category. Where the Department does not agree to grant an Notice of Intent exception, the applicant will be required to re-submit their application following the Notice of Intent process

and timelines for the next PBAC submission date. The Department's decision regarding an urgent public health need is a reviewable decision under Part 8 of the Regulations.

Fee waiver or fee exemption requests

If a fee waiver or fee exemption is requested, the supporting evidence must be lodged with the Notice of Intent form. Where an Notice of Intent form is not required, and a fee waiver or fee exemption has been requested, the supporting evidence must be lodged with an application (new brand); or submission (or resubmission) to the PBAC – refer to Section 9 below and/or Part 7 of the Regulations.

5.3 Notification Timing

Applicants will be notified that the Department has received the Notice of Intent at least 10 days before the submission due day.

If an urgent public health need is granted, and an Notice of Intent form is not required, the Department will issue a notice within 15 business days after lodgement of a submission (ore resubmission) to the PBAC.

Fee waiver or fee exemption requests

Where an applicant requests a fee waiver or fee exemption, the Department will issue a notice at least 5 business days before the submission due day. This notice will also notify applicants of the fee waiver or fee exemption decision, and where a waiver or exemption is not granted, an invoice will be provided for payment.

If a fee exemption is granted due to an urgent public health need, and an Notice of Intent form is not required, the Department will issue a notice within 15 business days after lodgement of an application (or resubmission) to the PBAC.

5.4 Withdrawal

Applicants may withdraw their Notice of Intent form, or submission (or resubmission) to the PBAC at any time by written notice to the relevant area of the Department (refer to Appendix A of the Procedure Guidance).

With the exception of the Facilitated Resolution Pathway, the Department will refund any fee paid, except for the administrative deposit amount, if the Notice of Intent is withdrawn:

1. on or before the submission due day; or
2. for the early re-entry pathway, the early resolution pathway or facilitated resolution pathway, within 10 business days from the date the notification is given.

If payment has not been received, the Department must notify the applicant that the administrative deposit fee is still payable for the provision of administrative services related to the Notice of Intent or submission. Where an Notice of Intent, or submission (or resubmission) to the PBAC is withdrawn after the timeframes specified above, the full fee for submission services remains payable.

Facilitated Resolution Pathway

For the Facilitated Resolution Pathway, the Department will refund any fee paid except for the administrative deposit fee and workshop fee amount related to the provision of services for the preparation of the delivery of the workshop, if the Notice of Intent is withdrawn on or before the last business day before the scheduled workshop date. However, if the Notice of Intent is withdrawn

after the business day before the scheduled workshop date, the Department has discretion to provide a refund of any fee paid except for the administrative deposit fee and workshop fee amount.

Refer to the Procedure Guidance for further information on Facilitated Resolution Pathway workshops.

5.5 Category determination process

Following receipt of submission (or resubmission) to the PBAC, and during the evaluation process, the Department may determine that the application is in a different evaluation category to that initially notified by the applicant.

This determination step occurs after the Department has reviewed the full PBAC submission and is able to assess the entirety of the submission services that need to be provided to the applicant. In instances where a different evaluation category is identified, the Department will provide the applicant with a written notice stating the following:

- fees payable for the submission services that applied when the notification for the application was given;
- the amount of fees already paid, or refunded, for the submission services;
- the fee amount that is to be refunded to, or is payable by, the applicant to reflect the difference in fees;
- manner for payment of fees; and
- the applicant's review rights under Part 8 of the Regulations.

If an adjustment to the invoice is required after the determination of the evaluation category, the adjusted invoice will have an additional 28 calendar day payment term.

Where the applicant has requested a fee exemption or fee waiver, any category redetermination that occurs will not affect the delegate's recommendation.

5.6 Incomplete applications to the PBAC

The Department may decline to accept a submission (or resubmission) to the PBAC, where the Department determines that the submission (or resubmission) to the PBAC is incomplete and does not provide the information required by the PBAC for decision-making purposes.

This determination step occurs after the Department has reviewed the full submission or resubmission to the PBAC and is able to assess the entirety of the submission. If the Department declines to accept a submission (or resubmission) to the PBAC, the Department will:

- notify the applicant in writing within 10 business days of the decision; and
- refund any fee paid for providing submission services in response to the application except for the administrative deposit included in the fee.

The Department's decision to not accept an incomplete application is not a reviewable decision under Part 8 of the Regulations.

6 Pricing services (Procedures for a positive recommendation to list)

Pricing services may be sought after a positive recommendation has been made or positive advice has been given by the PBAC. Pricing services are provided by the Department in response to an applicant's pricing application. A separate pricing application is required for pricing services sought in relation each PBAC submission.

6.1 Pricing pathways and fees

Fees for pricing services are specified in the Regulations and are outlined on the PBS cost recovery webpage. The fee categories for pricing services are:

- Pricing pathway A – Facilitated
- Pricing pathway B – New Deed
- Pricing pathway C – Existing Deed
- Pricing pathway D – No Deed
- Pricing Secretariat

Refer to the Procedure Guidance or Part 4 of the Regulations for information on the pricing application process, approved forms, and timing of submission for a Pricing Offer Package following the Notice of Intent for Pricing process.

Fee amounts

Applicants are required to nominate their pricing pathway (listing arrangement) via the Notice of Intent for Pricing form – see Section 6.2 below. The Department will confirm this nomination on receipt of the pricing application.

Applicants will be invoiced based on their nominated pricing pathway and an administrative deposit fee is included in the total fee amount.

Fee waivers or fee exemptions may apply for eligible applications – refer to Section 9 below and/or Part 7 of the Regulations. For pricing services, a fee waiver or fee exemption request must be made through the Notice of Intent for Pricing form – see Section 6.2 below.

Rebate management fee

The five-year 'rebate management fee' is included in the fee charged for Pricing pathway A, B and C. This fee includes the activities undertaken by the Department to manage rebates associated with deed arrangements over the standard five-year deed term.

The Department will refund the rebate management fee paid where:

1. the pricing application is withdrawn; or
2. the Department ceases pricing services.

Administrative deposit fee amount

The Regulations provide for the following administrative deposit fee amounts:

1. For all pricing applications – the administrative deposit fee; or
2. For Pricing Pathways A, B or C – the administrative deposit fee and the pricing pathway fee – this fee only applies where:
    a. an applicant withdraws their Notice of Intent for Pricing or pricing application more than 10 business days after the date the notification is given; or
    b. the Department ceases to provide pricing services – refer Section 6.6 below; and
    c. a deed arrangement has not been entered into.

6.2 Notice of Intent for Pricing

The Notice of Intent for Pricing process, is a mandatory first step in the listing process and must be provided at least 5 business days before lodgement of a Pricing Offer Package (pricing application) – refer to the Procedure Guidance.

Pricing services will not progress unless a Notice of Intent for Pricing is provided, unless an exception is granted from Notice of Intent in line with the Regulations.

Notice of Intent exception if an urgent public health need

Where the Notice of Intent for Pricing form would otherwise apply to a pricing application but has not been submitted, the Secretary or delegate may decide that providing pricing services without prior notice is necessary to address an urgent public health need. An applicant must provide justification for this exception when lodging their pricing application with the relevant area of the Department (refer to Appendix A of the Procedure Guidance).

The Department will notify the applicant in writing whether or not the Notice of Intent exception is granted.

The notice will include an invoice for the fees payable for pricing services for the applicant's nominated pricing pathway. Where the Department does not agree to grant a Notice of Intent exception, the applicant will be required to re-submit their application following the Notice of Intent for Pricing process and timelines. The Department's decision regarding an urgent public health need is a reviewable decision under Part 8 of the Regulations.

Fee waiver or fee exemption requests

For pricing services, if a fee waiver or fee exemption is requested the supporting evidence must be lodged with the Notice of Intent for Pricing form. Where a Notice of Intent for Pricing form is not required, the fee waiver or fee exemption request supporting evidence must be lodged with a pricing application – refer to Section 9 below and/or Part 7 of the Regulations.

6.3 Notification timing

The Department will issue a notice within 10 business days after lodgement of a Notice of Intent for Pricing form.

If an urgent public health need is granted, and a Notice of Intent for Pricing form is not required, the Department will issue a notice within 15 business days after lodgement of a pricing application.

Fee exemption and fee waiver requests

Where an applicant requests a fee exemption or fee waiver, the Department will issue a notice within 15 business days after lodgement of a Notice of Intent or pricing application. This notice will also notify applicants of the fee waiver or fee exemption decision, and where a waiver or exemption is not granted, an invoice will be issued for payment. This notification will also give the applicant information on their review rights under Part 8 of the Regulations.

6.4 Withdrawal

Applicants may withdraw their Notice of Intent for Pricing form, or pricing application at any time by written notice to the relevant area of the Department (refer to Appendix A of the Procedure Guidance).

The Department will refund any fee paid except for the administrative deposit amount, if the Notice of Intent or pricing application is withdrawn within 10 business days from the date the notification is given. If payment has not been received, the Department must notify the applicant, that the administrative fee is still payable for the payment of administrative services. An exception to this is the rebate management fee, where a Notice of Intent or pricing application is withdrawn after the timeframe specified above, the full fee for pricing services remains payable.

6.5 Pricing pathway determination process

Following receipt of a pricing application, and during the pricing process, the Department may determine that the application is in a different pricing pathway category to that initially notified by the applicant.

This determination step occurs after the Department has reviewed the full pricing application and the ratified PBAC Minutes and is able to assess the entirety of the pricing services that need to be provided to the applicant. In instances where a different evaluation category is identified, the Department will provide the applicant with a written notice stating the following:

- fees payable for the pricing service that relate to each of the pricing pathway categories;
- the amount of fees already paid, or refunded, for the pricing services;
- the fee amount that is to be refunded to, or is payable by, the applicant to reflect the difference in fees;
- manner for payment of fees; and
- the applicant's review rights under Part 8 of the Regulations.

If an adjustment to the invoice is required after the determination of the pricing pathway, the adjusted invoice will have an additional 28 calendar day payment term.

Where the applicant has requested a fee exemption or fee waiver, any category redetermination that occurs will not affect the delegate's recommendation.

6.6 Ceasing pricing services

The Department may cease to provide pricing services six months after lodgement of a pricing application if:

- an agreement or understanding has not been reached with the applicant in relation to the pricing services; and

- negotiations relevant to the pricing services are not proceeding because of the applicant's inaction.

If the Department ceases to provide pricing services, the Department will:

- notify the applicant in writing within 10 business days of the decision; and
- refund any fee paid for providing pricing services in response to the pricing application except for the administrative deposit amount (as relevant) – refer to Section 6.1 above.

The Department's decision to cease pricing services after six months is not a reviewable decision under Part 8 of the Regulations.

7 New brand (generic) or new oral form of existing pharmaceutical item category applications

This section applies to applications for the listing of a new brand or new oral form of an existing, PBS-listed pharmaceutical item, where no PBAC consideration is required, and bioequivalence advice from the TGA has been provided.

Notice of Intent processes are not required for applications for new brand (generic) or new oral form listings.

Refer to the Procedure Guidance for information regarding requirements for information on the application process, approved forms and timing for new brand or new oral form of existing pharmaceutical item submissions not requiring PBAC consideration.

New oral form of listed drug

If the drug is a new oral form of a listed drug, the same listing conditions for new brand applications apply. That is:

- if the drug contains the same active moiety in the same quantity as an already listed form; and
- there is evidence provided in the application of bioequivalence between the new form and the existing drug.

Applications seeking the listing of a new brand or new oral form of an existing pharmaceutical item are lodged via the HPP.

7.1 Fees for new brand (generic) or new oral form applications

Fees for new brand (generic) and new oral form applications are outlined on the PBS cost recovery webpage.

7.2 Notification timing

The Department will issue a notice to the applicant within 15 business days of receiving an application for a new brand (generic) or new oral form listing.

7.3 Withdrawal

Applicants may withdraw their application for a new brand or new oral form listing at any time by written notice to the relevant area of the Department (refer to Appendix A of the Procedure Guidance).

The Department will refund any fee paid (the administrative deposit fee does not apply for new brand or new oral form applications), if an application for a new brand or new oral form listing is withdrawn within 10 business days of the date the notification is given.

Where an application for a new brand or new oral form listing is withdrawn after the timeframes specified above, the full fee for submission services remains payable.

The Department may withhold PBS listing if the fee is not paid within the payment term.

8 PBS List management services

The PBS list management activities include applicant driven services to manage the PBS listing. PBS list management services are provided by the Department in response to an applicant's application.

8.1 PBS List management and fees

List management fees are outlined on the PBS Cost Recovery Fees & Charges in line with the Regulations for request of the following activities:

- Price increases/Brand premiums;
- Ministerial discretion;
- Deed renewals;
- Deed variation; and
- Ministerial determination (stockholding).

Applicants may seek to renew a deed agreement at the cessation of the existing five-year deed term; or vary the terms of an existing deed (within the current deed term). The deed renewal fee also includes the rebate management fee to account for ongoing management of the deed.

Commencement of Ministerial determination requests (stockholding requests) charging pathway

Consistent with commitments made in the 2022 Strategic Agreement with Medicines Australia, manufacturers of certain PBS listed medicines are required to hold a minimum quantity of four or six months supply within Australia. Manufacturers may submit applications seeking a determination from the Minister to alter these stockholding arrangements to remain compliant with their supply obligations.

To ensure consistency with existing cost recovery arrangements and the Australian Government Charging Framework, Ministerial determination requests are subject to cost recovery from 1 July 2023.

Fee amounts

Price increase requests, Ministerial discretion requests and Ministerial determination requests are invoiced and charged per brand of legal pharmaceutical item, which is made up of the drug, form, and manner of administration. Under the Regulations, a separate fee applies to each list management application, including in instances where multiple applications are made in a single request relating to the same drug and for the same therapy (e.g. two different strengths). For example:

- A price increase request for brand yellow, for the drug banana, 20 mg tablets, oral. There may be three PBS item codes for this pharmaceutical item, but only one cost recovery fee will be charged.
- A price increase request for the brand yellow20 for the drug banana, 20 mg tablets, oral and for the brand yellow40 for the drug banana, 40 mg tablets, oral. In this case two cost recovery fees will be charged because the applications are assessed per pharmaceutical item.

8.2 Notification timing

PBS list management applications are lodged with the Department via the HPP for:

- Price increases;
- Brand premiums;
- Ministerial discretion requests;
- New item recognised as a new preparation request; and
- Ministerial determination (stockholding)

Deed renewal requests and deed variation requests must be made by completing the List Management Application Form (refer to Appendix A of the Procedure Guidance).

The Department will issue a notice within 15 business days after lodgement of a PBS list management application.

Fee waiver or fee exemption requests

Where an applicant requests a fee waiver or fee exemption, this notice will also notify applicants of the fee waiver or fee exemption decision, and where a waiver is not granted, an invoice will be provided for payment. This will also give the applicant information on their review rights under Part 8 of the Regulations.

8.3 Withdrawal

Applicants may withdraw their PBS list management application at any time by written notice to the relevant area of the Department (refer to Appendix A of the Procedure Guidance).

The Department will refund any fee paid if the PBS list management application is withdrawn within 10 business days of the date the notification is given.

With the exception of the rebate management fee for deed renewals, where a PBS list management application is withdrawn after the timeframe specified above, the full fee for PBS list management services remains payable. The Department will refund the rebate management fee paid when the applicant withdraws their application, and a new deed arrangement has not been entered into.

9 Fee exemptions and waivers

The Regulations specify certain circumstances where an exemption or waiver of fees may apply for PBS/NIP cost-recoverable services. Some submissions will be automatically exempt from fees, while others will require the applicant to make a case to the Department to waive the fee in instances where the application is considered to be in the public interest and payment of the fee would make proceeding with the application financially unviable.

Where an exemption or fee waiver is approved for submission services, this only applies in respect of the PBAC evaluation process and does not apply with respect to a subsequent pricing services and/or list management services. While an applicant may not have sought an exemption or fee waiver in respect of the PBAC evaluation process, they may wish to do so in respect of pricing services and/or list management services. This may occur, for example, when a submission seeks an unrestricted listing and the PBAC has recommended a restricted listing that the applicant then claims could adversely impact on the financial viability of the product.

Please refer to Part 7 of the Regulations for further details.

9.1 Fee exemptions

An application for ATAGI advice, submission services, a pricing pathway or list management application will be exempt from cost recovery fees if it meets the criteria for exemption as outlined in Section 67 of the Regulations. Table 1 below provides a summary of the exemption categories in the Regulations.

All fee exemption requests must include in the application reasons why that subsection would apply. This can be addressed in a cover letter accompanying the application, stating which subsection would apply for the application, along with supporting evidence.

Fee exemptions do not apply to pre-submission meeting services and Independent Review services.

Table 1: Fee exemption categories as specified in the Regulations

Regulations reference	Fee exemption category	Full exemption category as per the Regulations
67(1)(a)	Temporary supply	A drug that is exempt from entry in the Australian Register of Therapeutic Goods because of an approval granted under section 19A of the *Therapeutic Goods Act 1989*
67(1)(b)	Public health events	If the Secretary considers that the supply of a drug, medicinal preparation or vaccine is necessary for the management of: (i) a public health event of national significance; or (ii) a biosecurity emergency that is declared to exist under subsection 443(1) of the *Biosecurity Act 2015*; or (iii) a human biosecurity emergency that is declared to exist under subsection 475(1) of the *Biosecurity Act 2015.*

Regulations reference	Fee exemption category	Full exemption category as per the Regulations
67(2)(a)	Price reductions	to offer a price reduction
67(2)(b)	Responsible person name change	to change the name of the responsible person for a brand of a pharmaceutical item
67(2)(c)	Vary a determination under ss9B(2)	to vary a determination under subsection 9B(2) of the Act so that a vaccine ceases to be a designated vaccine
67(2)(d)	Revoke a determination under ss9B(2)	to revoke a determination under subsection 9B(2) of the Act
67(2)(e)	Vary an arrangement under s100	to vary a special arrangement under subsection 100(2) of the Act so that a drug or medicinal preparation ceases to be a listed drug
67(2)(f)	Revoke an arrangement under ss100(2)	to revoke a special arrangement under subsection 100(2) of the Act
67(2)(g)	Vary a declaration under ss101(4AAA)	to vary a declaration under subsection 101(4AAA) of the Act so that a drug or medicinal preparation ceases to be a listed drug
67(2)(h)	Revoke a declaration under ss101(4AAA)	to revoke a declaration under subsection 101(4AAA) of the Act
67(2)(i)	Decrease a pack size with no price implications	to decrease the pack quantity (the existing pack quantity) of a listed brand of a pharmaceutical item if the amount that is to be the appropriate maximum price of the decreased pack quantity to be agreed under section 85AD of the Act will be calculated proportionally based on the approved ex-manufacturer price of the existing pack quantity on the day before the agreement under that section takes effect.
67(2)(j)	Increase a pack size with no price implications	to increase the pack quantity of a listed brand of a pharmaceutical item if the price for the increased pack quantity will be based on the proportional ex-manufacturer price worked out under section 85D of the Act
67(2)(k)	Vary a declaration, determination, arrangement, or other legislative instrument at the	to vary a declaration, determination, arrangement, or other legislative instrument made under Part VII or section 9B of the Act: (i) at the request of the Services Australia or the Therapeutic Goods Administration; or

Regulations reference	Fee exemption category	Full exemption category as per the Regulations
	request of SA, TGA or Government	(ii) that is a mandated change because of a Government initiative.
67(4),(5)&(6)	Orphan drug designation for first time submissions to PBAC only, within the first 12 months of being included on the Australian Register of Therapeutic Goods (ARTG)	*Exemption for submission services relating to designated orphan drugs* (4) No fee is payable under this instrument for submission services provided in response to a person's submission proposing a therapy involving the use of one or more drugs or medicinal preparations if: (a) on the day the submission is given to the Department, subsection (5) applies to each of those drugs or medicinal preparations; and (b) this subsection has not already applied to submission services provided in response to an earlier submission by the person proposing the same therapy involving the use of any of those drugs or medicinal preparations. (5) This subsection applies to a drug or medicinal preparation (the ***drug***) on a day if: (a) on that day, the drug is a designated orphan drug; or (b) both: (i) on that day, the Secretary is yet to decide whether to include the drug in the Australian Register of Therapeutic Goods in response to an application made by the person on or before that day; and (ii) were the drug to be so included, the registration fees for doing so would be waived under paragraph 45(12)(c) of the *Therapeutic Goods Regulations 1990* because the drug is a designated orphan drug; or (c) less than 12 months before that day, the drug was included in the Australian Register of

Regulations reference	Fee exemption category	Full exemption category as per the Regulations
		Therapeutic Goods and the registration fees for doing so had been waived under paragraph 45(12)(c) of the *Therapeutic Goods Regulations 1990* because the drug was a designated orphan drug. (6) For the purposes of paragraphs (5)(b) and (c) of this section, the registration fees are the fees described in paragraph 23B(2)(b) and subsection 24(1A) of the *Therapeutic Goods Act 1989*.

9.1.1 Orphan drugs

An 'orphan drug' is one that is designated by the TGA under Regulation 16J of the *Therapeutic Goods Regulations 1990*, as described on TGA's orphan drug eligibility criteria webpage.

An orphan drug fee exemption will be approved if one of the following criteria are met:

- Subsection 67(4)(a) & (b) – where an application has an active orphan drug designation status, and the therapy is being evaluated by the PBAC for the first time.
- Subsection 67(5)(b)(i) & (ii) - where an orphan drug designation lapsed, the PBAC submission has been submitted in parallel with an application for the orphan drug to be registered on the ARTG and the therapy is being evaluated by the PBAC for the first time.
- Subsection 67(5)(c) – where an orphan drug designation has lapsed, however the orphan drug was registered on the ARTG within the last 12 months and is being evaluated by the PBAC for the first time.

The applicant must provide the TGA letter showing a valid orphan drug designation for the same medicine and indication or provide supporting documentation to prove one of the above criteria.

9.2 Fee waivers

An applicant may apply to a delegate of the Secretary to waive the fee for ATAGI advice, submission services, pricing services or list management services if the application involves a public interest component and where payment of the fee would make proceeding with the application financially unviable.

In preparing a fee waiver request, the sponsor is required to provide sufficient evidence to allow a delegate to be satisfied that:

a) the submission involves the public interest; and

b) payment of fees would make the submission financially unviable.

Table 2 provides a summary of the supporting documentation that should be submitted with a fee waiver request. It is recommended the applicant includes all relevant information and supporting evidence for the Department to consider the facts and circumstances of their individual application. This can be addressed in a cover letter accompanying the application.

Table 2: Supporting documentation for a fee waiver requests

To address the public interest criterion:	**To address the financial unviability criterion:**
How the application involves the public interest, which may include but are not limited to applications where the drug or vaccine: • represents a suitable therapy for a patient population that is not large enough to make the application financially viable; or • is to be used for palliative care, as a paediatric medicine, or for medical treatment of Aboriginal and/or Torres Strait Islander peoples. **What the medicine, vaccine or other product seeks to do and its benefit, for example:** • If the PBAC or one of the Department's health working groups has encouraged the applicant to seek PBS/NIP listing of a medicine, vaccine or other product, the supporting documentation should include this information. • Provide sufficient justification to satisfy the delegate of how the product offers a benefit over other items listed on the PBS/NIP. **The target population including estimated utilisation, for example:** • Include a summary on population type, prevalence patient splits etc.	**A brief outline of the anticipated financial viability of the application:** • The applicant should provide evidence of how payment of the fee would make the application financially unviable. • It is recommended that details of the company's profit and loss for the product over a period of five to six years or over the lifecycle of the product be included. • The extent to which the fee that has been requested to be waived would be returned through expected revenue from future PBS/NIP listing. • Costs directly attributable to the product should be included, and while other costs not included in the production of the product may be included, this would need to be made clear and detailed. • If other costs are included (i.e., overhead costs), this must be able to be justified with additional supporting documentation, such as through a further breakdown to show the category split such as head office costs, storage and transportation costs or sales costs. An example of how financial unviability could be presented is shown in Table 3 below.

Table 3: Example of how financial unviability could be presented

	Year 1 $	Year 2 $	Year 3 $	Year 4 $	Year 5 $	Year 6 $
Revenue for the product (Price x est. sales volume)						
Less Cost of goods sold						
Less Overhead costs*						
= Net profit						

**While not required, if included, overhead costs would need to be justified, and a further breakdown showing the split between categories required.*

Review of fee waiver decisions

If no evidence is supplied, or a fee waiver is not approved, a notice will be issued to the applicant within 15 business days of receiving the application and the usual fees and payment terms will apply.

The applicant may lodge a request for internal review within 10 business days of being notified of this decision, and may provide additional supporting documentation, in order to have the fee waived or for any monies paid to be refunded (refer to Section 11 for details of the internal review process).

10 Request for Independent Review of a PBAC listing decision

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 or where the PBAC has declined to recommend an extension of the listing of an already listed drug. Further information is available at the Independent Review (PBS) website.

The Convener of the Independent Review (PBS) manages the independent review process, separate from the Department, industry, and other stakeholders. The Convener selects and contracts reviewers to perform the 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 the 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.

10.1 Fee for Independent Review

The fee for an Independent Review is specified in Part 8 of the Regulations and is outlined on the PBS cost recovery webpage.

11 Reviewable services

An applicant may apply for merits review of regarding:

- a decision that an ATAGI application is not in a simple category;
- a decision that the provision of ATAGI advice, submission or pricing services is required to address an urgent public health need;
- the determination of the evaluation category of a submission, and hence the evaluation fee payable;
- the determination of the pricing category of an application, and hence the pricing fee payable;
- a decision not to waive a fee that is payable;
- a decision that a fee is not refundable or remittable; and
- internal reviews initiated by the Department.

The first two reviews will be conducted internally by the Department (Section 11.1) and, if necessary, and external review can be conducted by the Administrative Appeals Tribunal (Section 11.2).

For further information on reviewable decisions please refer to Part 8 of the Regulations.

11.1 Internal review

A request for internal review must be made, in writing, within 10 business days (or a period longer if the delegate allows) of the applicant's receiving a notice of the Department's decision. The applicant must set out the reasons on which they are relying. In these instances, the Secretary or delegate may affirm, vary, or revoke the decision and, if the decision is revoked, make any other decision they consider to be appropriate.

An authorised person under the Regulations must review the decision and give written notice to the applicant of the review decision within 10 business days of receipt of the request for an internal review.

Further internal review

The applicant may, within 10 business days of receiving notice of this decision, apply in writing to the Secretary or a delegate for a further review of this decision. This further review must be conducted by an authorised officer that was not involved in either the original decision or the first review decision. That further reviewer must review the decision and give written notice to the applicant of the review decision within 10 business days of receipt of the request for the review. The Secretary or a delegate may, at any time, initiate a review of a reviewable decision. In these instances, the Department must give written notice to the applicant within 5 business days after a decision by the Secretary or delegate is made. If there is an overpayment of a fee as a result of a decision made during the internal review process, the Department must refund the overpayment amount within 28 calendar days of making the decision.

The Department may suspend the processing of the relevant submission until the internal review process has been completed.

11.2 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 suspend the processing of the relevant submission until the external review process has been completed.

12 Contacts

Questions or comments regarding PBS cost recovery fees and administrative processes should be directed to the Cost Recovery Unit, HTA Improvement and Cost Recovery Section, Office of Health Technology Assessment Policy Branch, Department of Health and Aged Care, by email at: PBScostrecovery@health.gov.au.

The Cost Recovery Unit will acknowledge receipt of email enquiries at the earliest opportunity and will endeavour to resolve enquiries within 10 business days, taking into consideration the complexity of the issue raised.

Questions relating to the application process, approved forms and/or timing for various application types should be directed to the relevant area within the Department of Health and Aged Care (refer to Appendix A of the Procedure Guidance).